

# Suicidality A Roadmap for Assessment and Treatment

## Suicidality A Roadmap for Assessment and Treatment

David V. Sheehan MD, MBA Jennifer M. Giddens





The book furthers the mission of Harm Research Institute and its publishing arm, Harm Research Press by disseminating knowledge in the pursuit of education, learning, and research in suicidality, homicidality, suinocerality, and hominocerality.

Unless otherwise noted © 2015 DV Sheehan and JM Giddens. All rights reserved.

Scales, interviews, assessment tools, images, case studies, and appendices are copyrighted by their respective authors. All rights reserved.

This publication is in copyright. Subject to statutory exception and to the provisions of relevant collective licensing agreements, no reproduction of any part may take place without the written permission of Harm Research Press, DV Sheehan, and JM Giddens.

This publication is available at http://HarmResearch.org

ISBN 978-0-9969729-0-1

Library of Congress Control Number: 2015919948

Harm Research Press has no responsibility for the persistence or accuracy of URLs for external or third-party internet websites referred to in this publication, and does not guarantee that any content on such websites is, or will remain, accurate or appropriate.

Every effort has been made in preparing this book to provide accurate and up to date information, in accord with accepted standards and practice at the time of publication. Although case histories are drawn from actual cases, every effort has been made to disguise the identities of the individuals involved. Nevertheless, the authors, editors, and publishers can make no warranties that the information contained herein is totally free from error, as clinical standards are constantly changing through research and regulation. The authors, editors, and publishers therefore disclaim all liability for direct or consequential damages resulting from the use of material contained in this book. Readers are strongly advised to pay careful attention to information provided by the manufacturer of any drugs or equipment that they plan to use.

### Dedication

### From David

To Kathy, without whose unending love and support, accommodation and guidance, this book would not have been written

and

To my pride and joy - my children Sascha and Tara, and my grandsons, Dashiell, Thapelo and Hamish, in the hope that they will inherit a world less victim to suicide.

### From Jennifer

To my parents - Ben and Linda; my brother - Matt; my aunt - Joan; Vic and Annie; Mark and Kara; Tim; and T. for their continued encouragement and support

and

To all who have struggled, are struggling, and will struggle with suicidality, hopefully new treatments will be available soon.

### Acknowledgements

### From David

A special thanks to my wife Kathy Harnett Sheehan PhD for her assistance, her valuable feedback on the book chapters and content, and her guidance on data analysis that led to many interesting findings; to Michael Sheehan MD for his assistance with the vector graphics designs in the book and for his clinical insights on suicidality; to Ivan Sascha Sheehan PhD for his insights on the role of homicidality and suicidality in suicide terrorism and international relations and his work on the homicidality tracking scale; to Christopher Gray BA for his many years of dedicated work in the computerization of the suicidality tracking scale and the Mini International Neuropsychiatric Interview; to Darlene Amado MPH and Darlene Beamon BSE MA for their valuable insights and collaboration on a novel methodology used in the linguistic validation in the pediatric versions of the suicidality tracking scale; to my friend Larry Alphs MD PhD with whom I have enjoyed many hours of fruitful and enjoyable collaboration on our work on suicidality; to Mark Opler PhD and Sofija Jovic PhD for taking a leadership role in developing superior modules and videos for the proper training on the suicidality tracking scales and related structured interviews; to Yves Lecrubier MD for his insights and collaboration in the early development of the Mini International Neuropsychiatric Interview and in his stressing the importance of the inclusion of a suicidality module for all patients being screened using structured interviews; to Vlad Coric MD who was the first to adopt the use of the suicidality tracking scale in a clinical trial and in investigating its use in geriatric patients and the lead author of the first publication on the suicidality tracking scale; to my close clinical colleagues at the University of South Florida Juris Janavs MD and Rosario Hidalgo MD with whom I enjoyed countless hours of discussion on scale and structured interview development and implementation; to Phil Chappell MD, Michelle Stewart PhD, Leonardo Tondo MD, Antonio Preti PhD, Paola Salvatore MD, Roger Meyer MD, Amir Kalali MD, Elizabeth Klumpp BA, Cheryl McCullumsmith MD, Eric Youngstrom PhD, Ahmad Hameed MD, Emily Bruer MEd, David Williamson PhD, John Greist MD, Jim Mundt PhD, and JP Lindenmayer MD for the many discussions and insights I enjoyed with them over years of collaboration on research and publications on suicidality issues; and most important to all our patients who communicated their long struggles, their fears and invaluable insights into the experience of suicidality. Patient insights have been very central in the development of the material for this book. None of these friends and colleagues should be held responsible for any of the errors, oversights, or excesses in this book. Some will disagree with some of the content. However I valued the debates with them on many of the points we raised and I look forward to future discussions and collaboration on the many unresolved issues as we all collaborate together in improving the lives of our patients.

### From Jennifer

A special thanks to Tim Henderson AS for his helpful feedback and technical assistance in web design; Kathy Harnett Sheehan PhD for her valuable assistance and feedback on many chapters; to Michael Sheehan MD for his assistance in creating several graphics and his feedback and clinical insight; to Mark Opler PhD for his feedback and clinical insights into the development of training modules for the suicidality tracking scales; to Elizabeth Klumpp BA for all of her detailed assistance on our prior publications on suicidality; to Elizabeth Ruegg LCSW for all of her clinical insight that showed me the need for the book and for leading to my introduction to David; and to all the suicidal subjects who have risked so much by freely sharing their experiences of suicidality. Without their honesty and willingness to share their experiences, this book would not be possible. None of the people should be held responsible for any of the content of the book.

And a special thanks to my co-author, David V. Sheehan MD, MBA, for all of his clinical insight, dedication, personal sacrifice, foresight, and never ending commitment to and composure while completing what sometimes seemed a monumental task. I have thoroughly enjoyed and acquired much in these years working with you and I look forward to our future collaborations.

### From David and Jennifer

A special thanks to the staff of Barnes & Noble Café, especially Val, who accommodated us so often during the years we were writing the book.

### Contents

### Preface

- 1 Assessing and Treating Suicidality: (A Roadmap for Developing Anti-Suicidality Medications)
  - 1.1 Addressing Myths About Suicidality
- 2 A New Non-Linear, Dynamic Model to Facilitate the Understanding of Suicidality
- 3 Introduction to the *Classification* of Suicidality
- 4 Classification of Suicidality Phenomena
  - 4.1 Suicidal Phenomena Definitions
  - 4.2 Distinction Between Suicide Method and Suicide Means
  - 4.3 Relationship Between Perceived Risk of Suicide Method and Level of Intent
- 5 Classification of Suicidality Events
  - 5.1 Suicidal Events (T-CASA)
  - 5.2 Structured Interview for T-CASA
  - 5.3 T-CASA Tracking Logs
- 6 Classification of Suicidality Disorders and Episodes
  - 6.1 Suicidality Disorders Criteria
  - 6.2 Impulse Attack Suicidality Disorder
- 7 Domains of Suicidality Disorders
- 8 Stages of Suicidality Disorders
- 9 Treatment
  - 9.1 *Medications* in the Treatment of Suicidality
  - 9.2 *Psychotherapy* for Suicidality
- 10 Putting Suicidality Assessment and Tracking into Practice
  - 10.1 Assessing and Tracking Suicidality in Clinical Practice
  - 10.2 Assessing and Tracking Suicidality in Research Settings

### 11 Stages of *Recovery*

- 12 Case Studies Observations Based on Data Mining
  - 12.1 Is the Suicide Event Count Important?
  - Does citalopram increase the frequency of up-switches of impulsive suicidality in a subject with Impulse Attack Suicidality Disorder? A case study
  - 12.3 Study of Magnesium in the Treatment of Impulse Attack Suicidality Disorder
  - 12.4 Analysis of A Dataset Collected Using the Tampa Classification Algorithm for Suicidality Assessment (T-CASA): A Case Study
  - 12.5 Do suicidal phenomena have a linear or a non-linear relationship with one another?
  - 12.6 What is a Patient Rated Scale Really?
- 13 One Hypothesis to Guide the Development of Specific Anti-Suicidality Medications
- 14 Appendices of Scales and Related Documents
  - 14.1 S-STS (Sheehan Suicidality Tracking Scale)
  - 14.2 S-STS CMCM (Sheehan Suicidality Tracking Scale Clinically Meaningful Change Measure version)
  - 14.3 Pediatric S-STS (Pediatric Sheehan Suicidality Tracking Scale)
  - 14.4. S-STS Related Documents
  - 14.5 S-STS Validation and Reliability
  - 14.6 SPTS (Suicide Plan Tracking Scale)
  - 14.7 SPTS Related Documents
  - 14.8 SMS (Suicidality Modifiers Scale)
  - 14.9 SIAS (Suicidal Impulse Attack Scale)
  - 14.10 Visit Face Sheet
  - 14.11 MINI 7.0.1 for Suicidality Disorders Studies (Mini International Neuropsychiatric Interview) and MINI 7.0.1 for Psychotic and Suicidality Disorders Studies
- 15 Appendices on Other Topics
  - 15.1 Safety / No Harm / No Suicide / (Insert Phrase Here) Contracts: A patient's perspective
  - 15.2 Response to United States Preventive Screening Task Force (USPSTF) Recommendation Against Screening for Suicide Risk in Primary Care
- 16 List of Acronyms

### Preface

It is our hope that the ideas, suggestions, and assessments in this book will provide a roadmap for the safe and effective conduct of clinical treatment studies for suicidality disorders. Our expectation is that this will become a major focus of research over the next several decades. Researchers will find several classes of effective and specific anti-suicidality medication treatments. Researchers will find more precise genetic and other biomarkers of suicidality. Researchers will better understand the pathophysiology of suicidality disorders. The medications so discovered will become future multi-billion dollar drugs and a major source of revenue for pharmaceutical companies. Clinicians will be able to lower death rates from suicide. Effecting these changes will have significant social, domestic, economic, religious, philosophical, and political consequences. More important, they will save the lives of many people and improve the quality of life of those who suffer from suicidality disorders.

1

### Assessing and Treating Suicidality: (A Roadmap for Developing Anti-Suicidality Medications)

"If I see an ending, I can work backwards."
- Arthur Miller

### Introduction

Our goal is to find specific anti-suicidality medications. But the map available to guide us is old and misleading.

The aim of this book is to offer a new guide to this destination.

Psychiatry has historically focused on reducing suffering, improving function and improving the quality of life. Medical psychiatry needs to focus even more directly on saving lives - from suicide. The field is on the threshold of realizing this goal.

How? Neuroscience will soon develop medicines that specifically treat suicidality, directly and quickly. This could become a major industry. These discoveries and a better understanding of the neurobiology of suicidality will alter how suicidality will be viewed, not only scientifically and medically, but also sociologically, religiously, and philosophically.

Yet medical science has historically hesitated to pursue suicidality directly as a target of treatment. Medical research often considered suicidal subjects as unpredictable, impulsive, irresponsible, unreliable, manipulative, frightening to deal with, medico-legally hazardous to treat, and as having symptoms that were difficult to control. It was considered unethical and medico-legally risky to include patients who were suicidal into

double blind, placebo controlled studies. This precluded the opportunity to study the suicidal patient in more depth and to be in a better position to identify specific antisuicidal treatments. It denied the field a better understanding of the phenomenology of suicidality. Such exclusions robbed many suicidal people of the hope of discovering treatments that might directly relieve their suffering.

### What is needed to move the field of suicidality treatment forward?

The agenda should include:

- 1. a dimensional phenomenologically-based rating scale, sensitive in detecting an efficacy signal for suicidality
- 2. a dimensional scale capable of showing whether the magnitude of efficacy is clinically meaningful
- 3. a classification of phenotypes of suicidality disorders, with specific diagnostic criteria
- 4. standards for research study protocols designed to investigate anti-suicidality medications
- 5. models to understand the mechanism of action of anti-suicidality medications
- 6. animal models of suicidality
- 7. candidate anti-suicidality medications
- 8. genetic and other biomarkers (state and trait) of suicidality

Drawing on a wealth of carefully analyzed patient data, this book attempts to address the above needs by offering:

- 1. a phenomenologically-based classification of suicidality phenomena
- 2. a classification of suicidality events and a way to capture this information
- 3. a classification of suicidality disorders phenotypes with associated criteria for each phenotype, and a structured interview to guide clinicians to correctly allocating patients to each phenotype
- 4. rating scales specifically designed to detect an anti-suicidality efficacy signal, a way to assess whether the signal is clinically meaningful, and scales to detect and monitor treatment emergent suicidality safety signals
- 5. a set of standards and ideas to consider in designing research protocols when investigating anti-suicidality medications
- 6. a new pharmacological treatment that may help some patients with suicidality disorders
- 7. a provisional pathophysiological model for some suicidality disorders to guide initial drug development
- 8. an alternative non-linear dynamic model to conceptually and clinically understand suicidality and to more accurately reflect the suicidality experience. This model challenges many myths about suicidality.
- 9. guidelines for a new type of psychotherapy specifically for suicidality

We also challenge many long accepted, but questionable assumptions about suicidality by addressing the following questions. Ask yourself. If you do not consider the responses offered below as possible or at least as an option, you may want to read this book.

#	Question	Response
1	Is there always a motive for suicide?	No
2	Is there always an external social event that precipitates suicide?	No
3	Is suicidal ideation always willful?	No
4	Do suicidal patients try to resist / fight against their own suicidality?	Yes
5	Does the progression of suicidality follow a predictable ordered, linear sequence, from passive to active ideation, to method, plan, intent, preparatory behavior, to attempt, to death by suicide?	No
6	Should we stop thinking about suicidality exclusively as a complication of depression?	Yes
7	Can suicidality be predicted reliably at an individual level?	No
8	Do those who make impulsive suicide attempts have impulsive personalities?	No
9	Are impulsive personalities more likely to make impulsive suicide attempts?	No
10	Can someone have a suicidal behavior and no suicidal ideation within a timeframe?	Yes
11	Is there more than one class of suicidality disorder?	Yes
12	Is there a classification of suicidality disorders?	Yes
13	Are suicidality disorders independent Axis 1 disorders?	Yes
14	Are there genetic vulnerabilities to suicidality disorders independent of the genetic vulnerabilities to mood disorders?	Yes
15	Do we need a different type of psychotherapy specifically for suicidality?	Yes
16	Can antidepressants worsen suicidality?	Yes
17	Can antidepressants improve suicidality?	Yes
18	Can some medications worsen suicidality?	Yes
19	Can some medications improve suicidality?	Yes
20	Do no harm contracts work?	No
21	Should healthcare systems screen for suicidality in addition to screening for depression?	Yes
22	Does talking to patients about suicidality increase their distress level?	No
23	In mental health settings, is the clinician interviewing the subject or is the subject interviewing the clinician?	Yes to both
24	Are clinicians uncomfortable, anxious and fearful when speaking to patients about suicide or suicidality?	Yes
25	Is there any neuroscience mechanism of action model, which might serve as a starting point, to guide the development of specific anti-suicidal medications?	Yes

Some day research will provide a more precise understanding of the pathophysiology, the biological basis for, and the clinical nature of the several primary suicidality disorders and the relationship between the suicidality phenomena themselves. There will also be a

confluence between the proposed phenotypes, and genetic and other biomarkers of suicidality.

We hope that this book will serve as a beginning to this process. We hope and expect that many of the ideas we propose, will be revised and improved in accuracy with the accumulation of scientific data.

In the meantime we need to listen to and investigate the patients' experiences of suicidality more attentively. We must involve suicidal patients and their families / loved ones in studies in the search for effective anti-suicidality medications. Involving patients gives them hope that we are actively engaged in finding better solutions for suicidality.

But we must not procrastinate in dealing with this serious healthcare challenge. With every minute, lives are lost.

### 1.1

### Addressing Myths About Suicidality

### Introduction

The purpose of this chapter is to address commonly accepted assumptions, myths, and questions relating to suicidality. The responses address a series of themes that recur throughout the book. They describe a perspective and the approach we have taken to outline a way forward in the future investigation of suicidality.

### **Suicidality Questions**

### Countertransference

Are suicidal patients aware that clinicians fear listening to patients talk about suicidality and fear discussing suicidality with patients? Are clinicians freaked out by suicidality? A patient stated, "You think you are interviewing us, but we are interviewing you. As the discussion of suicide deepens we can see the fear and anxiety in your eyes and face. You have tuned us out, you are no longer listening, and you do not want to hear any more."

### Willfulness

Is suicidal ideation always willful?

No. While it is commonly assumed that all suicidality is willful, sometimes it is not. (See chapter 6.2 on Impulse Attack Suicidality Disorder for more information.)

Do any suicidal patients try to resist their suicidal experiences?

Yes. While it is assumed that suicidal patients are not trying to help themselves get better, many of them are desperately struggling to keep themselves safe and alive. Contrary to popular belief, some patients with chronic suicidality have strong self-preservation instincts concurrent with their suicidality. It is a myth that patients will not meet internal resistance within themselves when they attempt suicide, even if they have

already planned the attempt. (See chapter 6.2 on Impulse Attack Suicidality Disorder for more information.)

Are all chronically suicidal people being willfully suicidal (possibly to seek attention)? No. Just because a patient's suicidality does not respond to a treatment, you cannot assume the patient is willfully suicidal. Many chronically suicidal people do not have access to effective anti-suicidality treatments. Until effective and specific anti-suicidality treatments are available to patients, it is premature to assume the patient is being willfully suicidal.

Most suicidal patients are deemed to be depressed and are treated with an antidepressant or a mood stabilizer. These treatments are not approved for the treatment of suicidality and, indeed, have boxed warnings about their increased risk of inducing suicidality, especially in those under 25 years. When many suicidal patients do not respond to these treatments and, especially when these treatments make their suicidality worse, they may give up hope. This hopelessness contributes to the worsening of their suicidality. They fear that their clinicians blame them for failing to respond to these ineffective treatments and that clinicians attribute their chronic suicidality to ongoing willfulness. This is a particular problem when their depression improves, but their suicidality does not.

Patients who experience suicidality should be seeking attention. If a patient is experiencing suicidality they are likely to be very distressed. These patients should be afforded the same opportunity to seek attention and care for their distress as a patient suffering from any other disabling condition or illness.

Do all suicidal people attempt suicide in order to hurt or to punish those around them? No. Many people who attempt suicide are drowning in their own pain and are unable to focus on the pain of those around them. They experience such despair that their mindset shifts and they feel they are a burden to those around them. They may feel that loved ones would be better off without them. Many of these people believe they will limit the suffering of their loved ones, by halting the ongoing frustration, worry, and distress that their loved ones would experience for many years, if they continue to live. They believe that killing themselves will free their loved ones from having to "put up with" them. They believe this is like quickly ripping off the Band-Aid so their loved ones can move on with their lives.

While it is common for the relatives and friends of suicidal people to feel hurt and suffer greatly in the aftermath of a suicide attempt, it does not mean that the person who made a suicide attempt (including those who died) intended this pain.

### Causes

Is there always an external social event that precipitates suicide?

No. Contrary to popular belief, some people are suicidal for reasons other than external social events. Not everyone who attempted suicide did so in response to a psychosocial event or because they were depressed. There are multiple other precipitants for suicide. Some patients experience suicidal impulse attacks (in some way similar to panic attacks in Panic Disorder) which causes them to feel a sudden need to make a suicide attempt often for no obvious reason to them. (See chapter 6.1 for Impulse Attack Suicidality Episode and Disorder criteria or chapter 6.2 for more details about these impulse attacks.) Others experience suicidality due to medical illnesses or neurological conditions. (See chapter 6.1 for Medical Illness / Neurological Condition Induced Suicidality Disorder criteria.)

### Is there always an obvious motive for suicide?

No. Although we would like to believe there is always a motive for suicide, this is not always true. Some people experience overwhelming or engulfing impulses to make a suicide attempt which last for hours. Many of these people may be unable to manage these suicidal impulses on their own and lose the struggle against these impulses. (See chapter 6.1 for Impulse Attack Suicidality Episode and Disorder criteria or chapter 6.2 for more details about these impulse attacks.) Others may attempt suicide in response to a suicidal command hallucination or to stop the command hallucination even though they themselves do not want to die. (See chapter 6.1for Psychotic Suicidality Episode and Disorder criteria.)

### Does suicidality progress in a predictable ordered sequence?

No. While this is a common belief, suicidality does not progress in a predictable ordered sequence. The belief that suicidality starts as passive suicidal ideation, moves into active suicidal ideation, which then leads to suicidal intent and on to suicidal planning, that turns into suicidal preparatory behaviors, and is followed by suicide attempts is a flawed model of suicidality. It seems like a very neat, orderly, logical sequence. Unfortunately, it does not reflect reality most of the time. (See chapter 2 for a descriptive phenomenological model of suicidality with flaws in Guttman Scaling model). Clinicians often gauged the severity of suicidality by how far the patient had progressed on this spectrum. This sequence also dictated the design of some suicidality scales and classification systems for events of suicidality. This model of suicidality provides clinicians with a false understanding of the patient's experience and can misguide the clinician in their judgment of suicide risk.

For example, a patient with Schizophrenia experiences command hallucinations ordering them to kill themself. When these command hallucinations relentlessly persist the patient may make a suicide attempt in response, but only because they want the auditory commands to stop and not because they want to kill themself. This patient may not engage in any other suicidal ideation, intent, planning, or preparatory behaviors.

Are there genetic vulnerabilities to suicidality independent of the suicidality vulnerability to mood disorders?

Yes. Some alleles, genetic mutations, and epigenetic changes are associated with a significantly increased rate of suicidal ideation and behaviors<sup>1 2 3 4 5 6</sup>. Many of these genetic biomarkers are not known to be associated with a predisposition to mood disorders<sup>7 8</sup>.

Are people with impulsive personality disorders more likely to make impulsive suicide attempts? Do those who make impulsive suicide attempts have impulsive personalities? Not necessarily. Nearly all clinicians have seen patients who have made impulsive suicide attempts. They assume that the person making the impulsive suicide attempt has an impulsive personality disorder. Studies using several different scales that measure impulsive personality traits have consistently found low correlations between scores on these scales and suicide attempts. This has always been a puzzle for clinicians. It appears that some patients who make impulsive suicide attempts have a unique Impulse Attack Suicidality Disorder (IASD). These subjects are not necessarily impulsive personalities in any way in the rest of their lives. Indeed they are often very cautious, even compulsively careful in their decision making, withdrawn, isolated, not sociable or outgoing, nor given to rash decisions in other areas of their life. The impulsive behavior in their case is strictly confined to the attacks of impulsive suicidality. (See chapter 6.2 on Impulse Attack Suicidality Disorder.)

<sup>&</sup>lt;sup>1</sup> Labonte B, Turecki G. Epigenetics. Chapter 32 (pages 288-306) in in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>2</sup> Bailey CR, Greene AM, Neumeister A. The use of neuroimaging to investigate the pathophysiology of suicide. Chapter 33 (pages 307-316) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>3</sup> Anango V, Bach H. Brain serotonin in suicides with psychological autopsy. Chapter 34 (pages 317-324) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>4</sup> Chandley MJ, Ordway GA. The noradrenergic system in depression and suicide. Chapter 35 (pages 325-335) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>5</sup> Pandey GN. Brain corticotropin releasing factor and the hypothalamic-pituitary-adrenal axis in suicide. Chapter 36 (pages 336-342) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>6</sup> Dwivedi Y. Receptor signaling in suicide. Chapter 37 (pages 343-356) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>7</sup> Niculescu, A. B., Levey, D. F., Phalen, P. L., Le-Niculescu, H., Dainton, H. D., Jain, N., ... & Salomon, D. R. (2015). Understanding and predicting suicidality using a combined genomic and clinical risk assessment approach. *Molecular psychiatry*, *20*(11), 1266-1285.

<sup>&</sup>lt;sup>8</sup> Kaminsky, Z., Wilcox, H. C., Eaton, W. W., Van Eck, K., Kilaru, V., Jovanovic, T., ... & Smith, A. K. (2015). Epigenetic and genetic variation at SKA2 predict suicidal behavior and post-traumatic stress disorder. *Translational psychiatry*, *5*(8), e627.

Bipolar Disorder may make some patients behave impulsively especially during manic / hypomanic episodes. Bipolar Disorder is itself associated with increased rates of suicidality. This does not mean every patient with Bipolar Disorder who acts impulsively during a manic episode has a primary impulsive personality disorder. Nor does it mean that everyone who makes an impulsive suicide attempt has Bipolar Disorder or an impulsive personality disorder. Missing the existence of a unique IASD in the past lead to this confusion and misunderstanding. (See chapter 6.1 for Impulse Attack Suicidality Episode and Disorder criteria or chapter 6.2 for more details about these impulse attacks.)

### Phenomena

Should we use the term 'suicidal ideation and behavior' or 'suicidality'?

We advise against using term 'suicidal ideation and behavior'. We prefer the term 'suicidality'. The reason is that the Unexpected Suicidal Impulse Attacks (USIA) start in a physical precognitive manner that antecedes suicidal ideation and behavior. Auditory command hallucinations start in an auditory form that antecedes suicidal ideation and behavior. Dreams are, strictly speaking, not generally considered as a form of suicidal ideation, but rather are memories of an antecedent event that contained images of suicidality phenomena. For these reasons and to cast the net widely enough to accommodate all these and other core phenomena experienced by those who are suicidal, while delimiting these from the phenomena of other neighboring classes, we prefer the broader term 'suicidality'. The following definition of suicidality accommodates those phenomena not currently captured within the bounds of usual 'suicidal ideation and behavior'.

suicidality [sui (of oneself) + cide (a killing) + ality (the state of being real or actual)] — all suicidal phenomena including ideation, behaviors, impulses, command hallucinations, dreams, delusions, and / or precognitive experiences related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame but did not appear as an ideation of behavior during that time frame. For example, a patient that previously made plans or intends to kill themself at a future date, but may not have thought about it during a particular time frame. (See definitions in chapter 6.1 on Suicidality Disorders for further clarification and examples.) This definition deliberately excludes theories or speculations about, predictions from or likelihood of a suicidal ideation or behavior. It also excludes experiences that may be comorbid with or correlated with core suicidal phenomena, but in and of themselves are not directly suicidal experiences (e.g. hopelessness, depression, anxiety, grief). The range of suicidality phenomena are identified and defined in chapter 4.1 on Suicidality Phenomena.

Should we stop thinking about suicidality exclusively as a complication of depression? Yes. Of the top 38 disorders in psychiatry, 34 have elevated standard mortality ratios (SMR) from suicide. Suicidality is associated with most of the disorders that psychiatrists

treat in clinical practice even in subjects who are not obviously depressed. The assumption that everyone who is suicidal must be depressed has lead to many unfortunate consequences. For example, it is commonly assumed that the way to screen people for suicidality is to ask them about depression. In reality, the best way to screen for suicidality is to ask about suicidality<sup>9</sup>. It has also lead to clinicians routinely trying to treat suicidality with antidepressants. While the use of antidepressants may be helpful for some patients with Major Depressive Disorder, it may also make other types of suicidality much worse. It has lead to research focusing its efforts on treating suicidality by using depression models in the search for such treatments and in the design and conduct of the clinical trials with anti-suicidality medications. It is likely to be more accurate to think about suicide disorders as a series of Axis 1 psychiatric disorders that can be comorbid with other psychiatric disorders, but could also exist independently of other psychiatric disorders. As long as we fail to disaggregate the suicidality disorder from other disorders it will be an impediment in searching for effective anti-suicidality medication treatments and in understanding the diverse pathophysiology associated with the different suicidality disorders.

While it may be true that many suicidal patients experience depression, there has been little if any research showing that the suicidality is *the result* of the depression. Some suicidal patients experience suicidality they cannot control and for which they have been unable to find effective treatments. These patients may become depressed due to the negative impact their suicidality has had upon their lives. Some of these patients may find that their suicidality leads to functional impairment in their work, their social life and relationships, and in their family life<sup>10</sup>. Researchers have assumed the depression is the cause of the suicidality, when the suicidality can actually be the cause of the depression. As one subject said, "all my psychiatrists assume that I am suicidal because I am depressed. Did it ever cross their minds that I might be depressed because I have a suicide disorder?"

Can someone have suicidal behavior and no suicidal ideation within a timeframe?

Yes. Although this is not common, it does occur. It seems to surprise clinicians when they see it for the first time. For example, when administering the suicidality module of the Mini International Neuropsychiatric Interview (MINI), a patient denied having any suicidal ideation in the past month. Towards the end of the suicidality module, when asked if he had made any suicide attempts in the past month, he admitted to having made a serious suicide attempt 5 days earlier. When asked to explain this apparent inconsistency, he described the events as follows: "I had been feeling very well for the last 3 months, without any suicidal ideation or behaviors. Then, in the past week, I

<sup>&</sup>lt;sup>9</sup> Preti, A., Sheehan, D. V., Coric, V., Distinto, M., Pitanti, M., Vacca, I., ... & Petretto, D. R. (2013). Sheehan suicidality tracking scale (S-STS): reliability, convergent and discriminative validity in young Italian adults. *Comprehensive psychiatry*, *54*(7), 842-849.

<sup>&</sup>lt;sup>10</sup> Giddens, J. M., & Sheehan, D. V. (2014). Is There Value in Asking the Question "Do you think you would be better off dead?" in Assessing Suicidality? A Case Study. *Innovations in clinical neuroscience*, *11*(9-10), 182. Available from: <a href="http://innovationscns.epubxp.com/i/425963/182">http://innovationscns.epubxp.com/i/425963/182</a>

noticed that I was getting increasingly manic and my wife started to irritate me more and more with her criticisms of my behavior. Five days ago, we got into a violent argument. I suddenly erupted into a volcanic rage and wanted to kill her, but I knew I shouldn't do that so I quickly tried to find some other way of punishing her. During this violent argument I saw a large bottle of her medications on a shelf, out of the corner of my eye. Without thinking, I suddenly ran over, opened the bottle, emptied the pills into my hand, and swallowed them, and when I had swallowed the whole bottle I said to her 'You see, what you are doing is going to kill me. You will have on your conscience for the rest of your life that you killed me and you will know that it was all your fault. I am going to leave in my car now and you will not be able to find me until I am dead.' I raced out of my house and went to a place in the woods where I knew they wouldn't be able to find me and shortly thereafter went into a coma and was found unconscious the next day. They brought me to the hospital where I recovered. All of this was done suddenly in a violent rage, without any thought that I was killing myself, but rather as a thought that I was punishing and harming her. So, no, I had no suicidal ideation in the past month, but I did make a suicide attempt." This is a reason why you cannot assume that if someone has no ideation that they had no suicidal intent, suicidal plans, or suicidal behaviors within a given timeframe.

### Can someone make a suicide plan and not have suicide intent?

Yes. When experiencing a suicidal impulse attack, some patients report they are able to more easily resist the suicidal impulse if they give into making a suicide plan. These patients report that making a suicide plan frequently causes the impulse attack symptoms to significantly reduce in severity. Patients may give into this urge to plan in order to more quickly reduce the severity of symptoms in an impulse attack, even if they have no intent to actually carry out this plan. Paradoxically, the generation of a suicide plan serves the role of warding off the need to immediately act on the suicidal impulse attack. We refer to this paradoxical strategy as the suicide plan *gambit* strategy. As in chess, a gambit is a strategy that makes a short-term sacrifice for a longer-term gain. (See chapter 6.1 for more details about this *gambit* in the Impulse Attack Suicidality Episode criteria or chapter 6.2 for more details about these impulse attacks.)

### Can someone have suicidal intent but no suicidal ideation within a timeframe?

Yes. Consider the patient who denied having any suicidal ideation in the past week. When asked if he had any suicidal intent he answered in the affirmative. When asked to explain this apparent discrepancy he clarified as follows. "Two years ago I was very depressed and suicidal and decided that I would kill myself. Then I realized that this would break my parents' hearts. They have been very good to me. I am their only son and I couldn't do this to them. However, I did decide that, because of my chronic suffering, that [sic] as soon as they died I would kill myself right away. I do not have any specific plan of how I would do this and postponed acting on it until after they died, but they are only in their 50s and they could live another 20 years (or more). However, if they were killed in a car accident next week, I would kill myself the following day. So, in the past week I have had no suicidal thoughts or plans, because this intent may be far off

in the future and there is no need for me to reflect on it. I made the decision 2 years ago, hence, in the past week, I have had no suicidal ideation, plans, or behavior, but the intent remains there from that past decision as a cloud, not in my overt consciousness, but ready to be implemented if the opportunity presents."

Do we need a new classification of suicidality events?

Yes. There are several current classifications of suicidal events. The most notable include the Columbia-Classification Algorithm of Suicide Assessment (C-CASA)<sup>11</sup>, the expanded USFDA classification categories in the 2012 draft guidance document (FDA-CASA 2012)<sup>12</sup>, and another proposed by O'Carroll et al 1996<sup>13</sup>. In general, these systems intermingle classifications of suicidal phenomena with suicidal events. Attempts to develop scales and classification categories / algorithms to capture information separating out individual suicidality events from each other have led to much confusion $^{14}$   $^{15}$ . The C-CASA and FDA-CASA 2012 are used in a manner that collapses all phenomena of suicidality experienced within a timeframe into one category, instead of capturing the phenomena experienced in each individual event of suicidality within a timeframe. It is not efficient and is too time consuming to complete a severity scale for suicidality phenomena on each event in a given timeframe, especially when there are many suicidality events. For example, consider a patient who has 10 suicidal events within a 24-hour period. If it takes 8 minutes for the average suicidal subject to complete the standard S-STS or C-SSRS, it would take 80 minutes to properly rate the phenomena across the day's events. The Tampa - Classification Algorithm for Suicidality Assessment (T-CASA) captures all necessary information on events in a fraction of this time for the 10 events. (See chapter 5.1 for T-CASA classification system.)

Using a suicidality scale to obtain the details of an event of suicidality requires rating the full spectrum of suicidal phenomena (including all of the suicidal phenomena not experienced and those experienced and to what extent). In contrast, the T-CASA only

<sup>&</sup>lt;sup>11</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, 164(7), 1035-1043.

<sup>&</sup>lt;sup>12</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm. Accessed November 6, 2015.

<sup>&</sup>lt;sup>13</sup> O'Carroll, P. W., Berman, A. L., Maris, R. W., Moscicki, E. K., Tanney, B. L., & Silverman, M. M. (1996). Beyond the Tower of Babel: a nomenclature for suicidology. *Suicide and Life-Threatening Behavior*, *26*(3), 237-252.

<sup>&</sup>lt;sup>14</sup> Giddens, J. M., Sheehan, K. H., & Sheehan, D. V. (2014). The Columbia-Suicide Severity Rating Scale (C–SSRS): Has the "Gold Standard" Become a Liability?. *Innovations in clinical neuroscience*, *11*(9-10), 66. Available from: <a href="http://innovationscns.epubxp.com/i/425963/66">http://innovationscns.epubxp.com/i/425963/66</a>

<sup>&</sup>lt;sup>15</sup> Sheehan, D. V., Giddens, J. M., & Sheehan, K. H. (2014). Current assessment and classification of suicidal phenomena using the FDA 2012 Draft Guidance document on suicide assessment: a critical review. *Innovations in clinical neuroscience*, *11*(9-10), 54. Available from: <a href="http://innovationscns.epubxp.com/i/425963/54">http://innovationscns.epubxp.com/i/425963/54</a>

requires the patients to indicate which phenomena they experienced from a list. (See chapter 5.1 for T-CASA classification system.)

In a recent single case report tracking 21,210 suicidality events over a 9-month period using the T-CASA the subject successfully captured all the necessary information on a daily basis in a very short period of time each day. If a standard suicidality severity rating scale, like the C-SSRS or the S-STS or the ISST-Plus or the SIBAT were used, it would have taken on average of 8 minutes $^{16}$  x 21,210 events = 169,680 minutes = 2,828 hours = 117.84 days without any sleep (or a total of 43% of the entire 9-month time frame [274 days] or 176 days or 65% of the waking hours during this time). Such a task would likely make anyone more suicidal.

There is no way for anyone using either the C-CASA or the FDA-CASA 2012 to know if an antidepressant is specifically increasing the severity or seriousness or frequency or time spent in nor the combinations of other suicidality phenomena associated with the USIAs within the event while on an antidepressant. (See chapter 12.2 for a case study illustrating this effect from an antidepressant.) Similarly, these two algorithms do not have a way to capture command hallucination events about suicidality if that occurs in response to a medication. These are major safety concerns and are not confined to only these examples.

To complicate matters further, when the FDA-CASA 2012 asks the rater to capture information on suicidality events, it focuses on capturing the event it deems the most serious using its Guttman Scaling procedure of ranking seriousness of events. However, as we have documented elsewhere<sup>17</sup> <sup>18</sup> <sup>19</sup> their Guttman Scale ranking of seriousness does not necessarily line up with the gravity of the events from the patient's perspective.

Do we need a classification of suicidality phenomena?

Yes. To our knowledge there is no strict classification of suicidality phenomena. However, there are classifications systems of suicidality events that include descriptions of many of the core suicidality phenomena within these suicidality event categories.

<sup>&</sup>lt;sup>16</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from: http://innovationscns.epubxp.com/i/425963/32

<sup>&</sup>lt;sup>17</sup> Giddens, J. M., Sheehan, K. H., & Sheehan, D. V. (2014). The Columbia-Suicide Severity Rating Scale (C–SSRS): Has the "Gold Standard" Become a Liability?. *Innovations in clinical neuroscience*, *11*(9-10), 66. Available from: http://innovationscns.epubxp.com/i/425963/66

<sup>&</sup>lt;sup>18</sup> Sheehan, D. V., Giddens, J. M., & Sheehan, K. H. (2014). Current assessment and classification of suicidal phenomena using the FDA 2012 Draft Guidance document on suicide assessment: a critical review. *Innovations in clinical neuroscience*, *11*(9-10), 54. Available from: http://innovationscns.epubxp.com/i/425963/54

<sup>&</sup>lt;sup>19</sup> Sheehan, D. V., Giddens, J. M., & Sheehan, I. S. (2014). Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Appendix F. *Innovations in clinical neuroscience*, *11*(9-10), 93. Available from: <a href="http://innovationscns.epubxp.com/i/425963/92">http://innovationscns.epubxp.com/i/425963/92</a>

Nonetheless, identifying the core suicidality phenomena in need of capture is a separate task from the capture of data on suicidality events. In general, all suicidality scales are designed to capture aggregate scores for a range of suicidality phenomena and their severity or seriousness within a given timeframe. For example, if a patient had multiple events of suicidal ideation or suicidal preparatory behaviors in the past month, the scales aggregate the severity / seriousness rating for the aggregate of these events over the past month. Some of these events may have been mild while others may have been severe. The aggregate rating might then be moderate. Hence, the system used to capture severity / seriousness ratings needs to be different from the data capture method used for individual suicidality events if it is to be done efficiently for each agenda. In the final analysis, to properly capture data about suicidality, one system is needed to directly capture information about the severity of the phenomena, a separate system is needed to capture suicidality event data, and a third classification system is needed to capture information about suicidality disorders. In this way the characteristics, attributes, and qualities associated with the phenomena, the events, and the disorders are captured in a way that is highly specific to the core features while delimiting them from their immediate neighbors.

### Classification

*Is there more than one suicide disorder?* 

Yes. There are at least several different suicidality disorders. For example, the experience and phenomena associated with an Impulse Attack Suicidality Disorder are quite different from the experience and phenomena associated with a Life Event Induced Suicidality Disorder. The response to treatment and the natural history of these disorders appear to be different. (See chapter 6.1 for Suicidality Disorder criteria or chapter 6.2 for more details about Impulse Attack Suicidality Disorder.)

*Is there a classification of suicidality disorders?* 

Yes. See chapter 6.1 for a phenotypic classification of Suicidality Disorders.

Are suicidality disorders independent "Axis I disorders"?

Yes. Currently suicidality is seen as a cluster of symptoms secondary to other 'Axis I' psychiatric disorders. It is assumed that when the Axis I psychiatric disorders are treated the suicidality will respond automatically in its wake. One only has to study the response of suicidality to antidepressants to see that this is often not the case. With antidepressants approved by the USFDA for the treatment of Major Depressive Disorder in those under 25 years the suicidality increases with decreasing age even when the medication is improving the depression. Between the ages of 25 and 65 the response to the suicidality is no different from placebo even when the drug is better than placebo in

treating the MDD. Only in those over the age of 65 is the antidepressant superior to placebo in treating the suicidality while it is also effective in treating the MDD<sup>20</sup>.

Sometimes, in treating a patient with Bipolar Depression, with lithium alone the suicidality resolves while the patient continues to be just as depressed as ever. Conversely, in some other patients with Impulse Attack Suicidality Disorder, treating the suicidality with magnesium can resolve the suicidality. The depression secondary to the suicidality subsequently resolves in its wake even though the magnesium has no direct antidepressant effect. This suggests that suicidality disorders and mood disorders may have a different pathophysiology and response to treatment. (See chapter 6.1 for Impulse Attack Suicidality Episode and Disorder criteria, chapter 9.1 for more details about how to use magnesium to treat these impulse attacks, and chapter 12.3 for a case study showing magnesium resolving one subject's suicidality.)

### Do we need a new classification of suicidality disorders?

Yes. If we find an effective and specific anti-suicidality treatment and use it in a clinical trial that includes an enriched sample of suicidal patients the trial is highly likely to fail. If we used an SSRI or an SNRI in a clinical trial that included an enriched sample of all patients who walked into the clinic declaring that they were very depressed, the SSRI and SNRI would fail to separate out from placebo in a double blind study. The reason is that such a depression study would have some patients with Major Depressive Disorder, some patients with Bipolar Disorder, some patients with Schizoaffective Disorder, some patients with cocaine or amphetamine withdrawal, etc. The benefit of the SSRI in the Major Depressive Disorder group would be offset by the failure of the other disorders to respond. Because of the heterogeneous nature of the different suicidality disorders, the anti-suicidality effect of the medication in one of the suicidality disorders may be offset by the failure to provide benefit in the other suicidality disorders. Hence, in conducting trials with anti-suicidality medications we need to investigate these disorder phenotypes one at a time in order not to miss when an anti-suicidality treatment is effective and when it is not. (See chapter 6.1 for Suicidality Disorder criteria.)

### Psychological Treatments

Do we need a new different type of suicide psychotherapy specifically for suicidality?

Yes. Listening to patients speaking about their suicidality makes many clinicians apprehensive. This anxiety interferes with their ability to learn, understand, and help patients cope with their suicidality. A new psychotherapy is needed to help clinicians better interact with suicidal patients so that the clinician can be more comfortable and the patient feels better understood and is not offended or alarmed by the clinicians reactions. (See chapter 9.1 for suggestions for a new psychotherapy for suicidality.)

<sup>2</sup> 

<sup>&</sup>lt;sup>20</sup> Stone, M., Laughren, T., Jones, M. L., Levenson, M., Holland, P. C., Hughes, A., ... & Rochester, G. (2009). Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. *Bmj*, 339.

Does talking to patients about suicidality make suicide attempts more likely? Sometimes yes, sometimes no. The evidence on this point remains unclear. Some data suggest that it is possible that talking to patients about suicidality may not increase their distress<sup>21</sup> <sup>22</sup>. However it probably depends how this is done, the relationship with the clinician, and the clinician's ability to tolerate such discussions without overreacting.

### **Medication Treatments**

Can some meds make suicidality worse?

Yes. ADs<sup>23</sup>, SSRIs<sup>24</sup>, SNRIs<sup>25</sup>, TCAs<sup>26</sup>, antipsychotics<sup>27</sup>, anticonvulsants<sup>28</sup>, varenicline<sup>30</sup>, oseltamivir<sup>31</sup>, corticosteroids<sup>33</sup>, have all been associated with a worsening of suicidality in some patients.

### Can ADs worsen suicidality?

Yes. Antidepressants can increase suicidality in those under 25 years compared to placebo. The younger the age, the greater the increased risk of suicidality<sup>35</sup>.

<sup>&</sup>lt;sup>21</sup> Gould, M. S., Marrocco, F. A., Kleinman, M., Thomas, J. G., Mostkoff, K., Cote, J., & Davies, M. (2005). Evaluating iatrogenic risk of youth suicide screening programs: a randomized controlled trial. *Jama*, *293*(13), 1635-1643.

<sup>&</sup>lt;sup>22</sup> Linehan, M. M., Korslund, K. E., Harned, M. S., Gallop, R. J., Lungu, A., Neacsiu, A. D., ... & Murray-Gregory, A. M. (2015). Dialectical Behavior Therapy for High Suicide Risk in Individuals With Borderline Personality Disorder: A Randomized Clinical Trial and Component Analysis. *JAMA psychiatry*, *72*(5), 475-482

<sup>&</sup>lt;sup>23</sup> Stone, M., Laughren, T., Jones, M. L., Levenson, M., Holland, P. C., Hughes, A., ... & Rochester, G. (2009). Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. *Bmj*, 339.

<sup>&</sup>lt;sup>24</sup> Ibid.

<sup>&</sup>lt;sup>25</sup> Ibid.

<sup>&</sup>lt;sup>26</sup> Perroud, N., Uher, R., Marusic, A., Rietschel, M., Mors, O., Henigsberg, N., ... & Aitchison, K. J. (2009). Suicidal ideation during treatment of depression with escitalopram and nortriptyline in genome-based therapeutic drugs for depression (GENDEP): a clinical trial. *BMC medicine*, *7*(1), 60.

<sup>&</sup>lt;sup>27</sup> Healy, D., Harris, M., Tranter, R., Gutting, P., Austin, R., Jones-Edwards, G., & Roberts, A. P. (2006). Lifetime suicide rates in treated schizophrenia: 1875–1924 and 1994–1998 cohorts compared. *The British Journal of Psychiatry*, 188(3), 223-228.

<sup>&</sup>lt;sup>28</sup> Arana, A., Wentworth, C. E., Ayuso-Mateos, J. L., & Arellano, F. M. (2010). Suicide-related events in patients treated with antiepileptic drugs. *New England Journal of Medicine*, *363*(6), 542-551.

<sup>&</sup>lt;sup>29</sup> Patorno, E., Bohn, R. L., Wahl, P. M., Avorn, J., Patrick, A. R., Liu, J., & Schneeweiss, S. (2010). Anticonvulsant medications and the risk of suicide, attempted suicide, or violent death. *Jama*, *303*(14), 1401-1409.

<sup>&</sup>lt;sup>30</sup> Kuehn, B. M. (2008). FDA warns of adverse events linked to smoking cessation drug and antiepileptics. *Jama*, *299*(10), 1121-1122.

<sup>&</sup>lt;sup>31</sup> Jeon, S. W., & Han, C. (2015). Psychiatric Symptoms in a Patient with Influenza A (H1N1) Treated with Oseltamivir (Tamiflu): A Case Report. *Clinical Psychopharmacology and Neuroscience*, 13(2), 209.

<sup>&</sup>lt;sup>32</sup> Kim, H. G., Kim, H. J., & Cho, Y. S. (2010). A Case of Auditory Hallucination after Intake of Oseltamivir for H1N1 Treatment. *Journal of the Korean Society of Emergency Medicine*, *21*(3), 402-404.

<sup>&</sup>lt;sup>33</sup> Lewis, DA and Smith, RE. Steroid-induced psychiatric syndromes: a report of 14 cases and a review of the literature. J Affect Disord. 1983; 5: 319–332.

<sup>&</sup>lt;sup>34</sup> Bräunig, P, Bleistein, J, and Rao, ML. Suicidality and corticosteroid-induced psychosis [letter]. Biol Psychiatry. 1989; 26: 209–210.

### Can ADs improve suicidality?

Yes. Antidepressants can decrease suicidality in those over 65 years compared to placebo. The older the age the more the antidepressant is superior to placebo in reducing suicidality<sup>36</sup>.

### Are there OTC medications that worsen suicidality?

Yes. For example, calcium supplements may worsen suicidality in those with magnesium sensitive Impulse Attack Suicidality Disorder (IASD) (perhaps by interfering with the absorption and effect of magnesium). Withdrawal from opiates and NMDA receptor antagonists like magnesium can worsen suicidality in some IASD subjects. (See chapter 12.3 for a case study on the treatment of IASD with a high magnesium / low calcium dietary intake.)

### Can some meds improve suicidality?

Yes. For example, magnesium may improve suicidality in those with IASD. (See chapter 6.2 for details on how to use magnesium to treat IASD and chapter 12.3 for a case study on the use of magnesium to treat IASD.) Another example, lithium decreases suicidality ideations and behaviors in a significant number of patients with both Bipolar Disorder and Major Depressive Disorder<sup>37</sup>. Clozapine has been approved by the USFDA for reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder<sup>38</sup> <sup>39</sup>.

Is it appropriate to exclude persons from clinical trials specifically designed for the treatment of suicidality because they are 'too suicidal'?

No. Excluding patients from clinical trials for suicidality due to the severity of suicidality is not appropriate. If a patient is able to provide informed consent to be in a study, they should be allowed to be in a study, regardless of their severity of suicidality. Not doing so borders on discrimination and is a violation of the Americans with Disabilities Act. (See chapter 10.2 on assessing and tracking suicidality in research settings.) If an individual patient is excluded from a clinical trial for a suicidality treatment because they are too suicidal, their exclusion from the study may actually cause them to feel more hopeless and more depressed which may actually end up contributing to their suicidality.

<sup>37</sup> Tondo, L., & Baldessarini, R. (2011, February 10). Can Suicide Be Prevented? Retrieved November 9, 2015, from http://www.psychiatrictimes.com/bipolar-disorder/can-suicide-be-prevented

https://www.pharma.us.novartis.com/product/pi/pdf/Clozaril.pdf Accessed May 1, 2015.

<sup>&</sup>lt;sup>35</sup> Stone, M., Laughren, T., Jones, M. L., Levenson, M., Holland, P. C., Hughes, A., ... & Rochester, G. (2009). Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. *Bmj*, *339*.

<sup>36</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> Novartis Pharmaceuticals Corporation. (2014). HIGHLIGHTS OF PRESCRIBING INFORMATION: CLOZARIL® (clozapine) tablets, for oral use. East Hanover, NJ. Retrieved from

<sup>&</sup>lt;sup>39</sup> Meltzer, H. Y., Alphs, L., Green, A. I., Altamura, A. C., Anand, R., Bertoldi, A., ... & Potkin, S. (2003). Clozapine treatment for suicidality in schizophrenia: international suicide prevention trial (InterSePT). *Archives of general psychiatry*, 60(1), 82-91.

Should we avoid conducting double-blind placebo controlled clinical trials to investigate medications for the treatment of suicidality?

No. We should conduct placebo-controlled trials with suicidal patients in investigating anti-suicidality treatments.

Failure to have a placebo arm in such studies can provide very misleading results and failure to control for the natural history of chronic suicidality. Such investigations would require exposing many more patients to risk to get an accurate answer to the questions compared to doing a non-inferiority trial design. On ethical grounds it is safer to aim for the greatest accuracy in getting an answer while exposing the fewest number of patients to potential risk compared to any of the alternative methodologies. For example, if a potential anti-suicidality treatment was investigated in a non-inferiority design while using an antidepressant as the active control comparator, the result could show a statistically significant difference in favor of the anti-suicidality treatment compared to the antidepressant. However, the antidepressant in such a trial might itself be increasing the risk of suicidality while the anti-suicidality medication was in fact behaving in a way that was no better than a placebo. Without the presence of a placebo arm in such a trial it would not be possible to make this assessment. Furthermore, it could lead to an antisuicidality treatment being deemed effective when in fact it was not. That itself could be a dangerous and inaccurate conclusion. In the meantime patients would have been exposed to danger in the generation of an inaccurate conclusion. This is hardly an ethical approach. The same standard as applied to all other serious and potentially lethal illnesses needs to be applied to suicidality research as well. Patients with suicidality are capable of giving informed consent and should have the option of giving that informed consent to participate.

Obviously, data safety monitoring boards should be an inherent part of the conduct of such trials and wisdom ought to prevail including all of the necessary safety precautions to ensure that patients are protected in an optimal way. The world needs to find specific anti-suicidality medication treatments. To do this in the most efficient and safe manner while providing scientific confidence in the results will require using double-blind placebo controlled designs.

### Do no-harm contracts work?

No. No-harm contracts do not prevent patients from attempting to kill themselves nor do they provide medico-legal protection for the clinician. Some research has even shown the use of no-harm contracts results in patients being less communicative about their suicidality<sup>40</sup>. (See chapter 15.1 for a patient's perspective of the use of no-harm contracts and a suggestion on how they might be used.)

<sup>&</sup>lt;sup>40</sup> Miller, MC. Contracting for safety. Chapter 40 (pages 372-377) in A Concise Guide to Understanding Suicide: Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

### Prediction

Can suicide attempts and deaths be predicted at an individual level?

No. The evidence suggests that suicide attempts and deaths can be correlated with some predictive factors at a group level. However, the ability to do this at the individual level is so fraught with false-positives and false-negatives that we have little confidence in such individual risk predictions  $^{41}$   $^{42}$   $^{43}$ .

Should efforts be focused on predicting suicidal behaviors?

It would be more productive to allocate resources to understand the phenomenology, genetic and other biomarkers of suicidality, and to find effective and specific antisuicidality treatments. Studies investigating predictive factors for suicidal behaviors at the individual level have found that it is not possible to reliably do so with our current methods<sup>44</sup> <sup>45</sup> <sup>46</sup>.

Has prediction of suicide risk helped lower suicide rates? This has been a holy grail of suicide research and has not been particularly fruitful.

Current research about suicide risk has been based upon lumping all suicidal subjects into the same suicidality class and attempting to find patterns. This is similar to lumping everyone with a heart problem into the same class and attempting to find mortality risk factors for their 'heart problem'. By subdividing 'heart problems' into separate disorders, researchers were better able to investigate individual cardiac disorders and to find appropriate treatments for each specific cardiac disorder. Using this approach, cardiologists were successful in lowering mortality rates from these 'heart problems'. Studying suicidality one phenotype (and some day, one genotype) at a time is likely to be a more productive approach to lowering suicide rates. (See chapter 6.1 for a classification system of Suicidality Disorders.)

### Conclusion

The abbreviated answers to the above questions provide an overview of the content covered in this book and where to find additional information on the related content. The answers show how the component pieces of this book fit together to describe the roadmap we are trying to outline for the future investigation of suicidality. It may serve

<sup>&</sup>lt;sup>41</sup> Jenkins GR, Hale R, Papanastassiou M, Crawford MJ, Tyrer P. Suicide rate 22 years after parasuicide: cohort study. BMJ. 2002;325:1155.

<sup>&</sup>lt;sup>42</sup> Pokorny, Alex D. "Prediction of suicide in psychiatric patients: report of a prospective study." Archives of general psychiatry 40.3 (1983): 249-257.

<sup>&</sup>lt;sup>43</sup> Pokorny, Alex D. "Suicide prediction revisited." Suicide and life-threatening behavior 23.1 (1993): 1-10.

<sup>&</sup>lt;sup>44</sup> Jenkins GR, Hale R, Papanastassiou M, Crawford MJ, Tyrer P. Suicide rate 22 years after parasuicide: cohort study. BMJ. 2002;325:1155.

<sup>&</sup>lt;sup>45</sup> Pokorny, Alex D. "Prediction of suicide in psychiatric patients: report of a prospective study." Archives of general psychiatry 40.3 (1983): 249-257.

<sup>&</sup>lt;sup>46</sup> Pokorny, Alex D. "Suicide prediction revisited." Suicide and life-threatening behavior 23.1 (1993): 1-10.

as a model to use in seeking more effective anti-suicidality treatments and in finding genetic and other biomarkers for suicidality phenomena and suicidality disorders.

### A New *Non-Linear, Dynamic Model* to Facilitate the Understanding of Suicidality

### The Problem

There is a problem with existing models used to understand suicidality. They do not accurately reflect clinical reality from the perspective of many suicidal patients. Such models and their associated assumptions are often not explicitly spelled out, but are implicitly understood. The assumptions within these models inform and are used in everyday clinical decision-making and in clinical trials. They are implicit in the hierarchy model of suicidal ideation and behavior used by the FDA in its 2012 draft guidance document on suicidal ideation and behavior¹ (FDA-CASA 2012) and by the Columbia group in the Columbia - Classification Algorithm of Suicide Assessment² (C-CASA) and in the Columbia - Suicide Severity Rating Scale³ (C-SSRS). In that hierarchy, the existence of any assumed "higher" level or "staircase step" of suicidality trumps the importance of the gravity of the assumed "lower" level or "staircase step" in the hierarchy. For example, in the hierarchy they use, agreement with the presence of a suicide plan assumes agreement with the presence of some intent and trumps it in importance. Active

<sup>&</sup>lt;sup>1</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration*. *Available at*:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm Accessed October, 5, 2012.

<sup>&</sup>lt;sup>2</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, 164(7), 1035-1043.

<sup>&</sup>lt;sup>3</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

ideation trumps passive ideation. These assumptions guide detection of suicidality in clinical trials.

Why did they design it this way? It has simplicity and apparent brevity. But this simplicity is at the expense of accuracy and comprehensiveness. Simplicity can contribute to type I errors. Failure to be comprehensive leads to type II errors. In the case of the FDA-CASA 2012 and the C-SSRS, they  $do^4$  5.

### The Fallacy of the Staircase Model

There is an inherent assumption in these models that patients progress from passive ideation, to active ideation, to method, then to intent and finally to plan, preparatory behaviors and attempts, as if progressively going higher on a staircase or climbing a ladder. Arriving on any stair assumes that the subject has stepped on the prior stairs and is on a higher plane.

There is an additional assumption that gravity and severity of suicidality is accurately reflected in a staircase manner with the progressive stepping higher through these stairs along a cumulative, unidimensional, linear path. While these models and assumptions of suicidal ideation may apply to some cases of suicidality, they are not generalizable to all cases. They are not comprehensive as a model of the dynamic, non-linear movement and interplay of suicidal phenomena over time. They do not necessarily reflect the gravity or seriousness of any one of these phenomena compared to others during any timeframe.

Scales or classification algorithms that assume such a cumulative, unidimensional, linear, staircase model typically use a Guttman scaling structure design. A Guttman scale is a cumulative scale. It is designed to measure progressively higher levels of a single unidimensional trait, attribute, concept, or phenomenon. It normally uses a dichotomous yes / no response format. The C-SSRS uses Guttman scaling to investigate the degree to which a subject has a higher level of suicidal ideation. It assumes that suicidal ideation has a cumulative, unidimensional structure along the dimension outlined on the scale. Agreement with item 2 assumes agreement with item 1, but not necessarily with items 3, 4, or 5. Agreement with item 5 assumes agreement with items 1, 2, 3, and

<sup>&</sup>lt;sup>4</sup> Sheehan DV, Giddens JM, Sheehan KH. Current assessment and classification of suicidal phenomena using the FDA 2012 Draft Guidance document on suicide assessment: a critical review. Innov Clin Neurosci. 2014;11(9–10):54–65 Available from <a href="http://innovationscns.epubxp.com/i/425963/54">http://innovationscns.epubxp.com/i/425963/54</a>
<sup>5</sup> Giddens JM, Sheehan KH, Sheehan DV. The Columbia–Suicide Severity Rating Scale (C-SSRS): Has the

<sup>&</sup>quot;Gold Standard" become a liability? Innov Clin Neurosci. 2014;11(9–10):66–80. Available from <a href="http://innovationscns.epubxp.com/i/425963/66">http://innovationscns.epubxp.com/i/425963/66</a>

4. This gives an overly optimistic impression of the reproducibility, the generalizability and the comprehensiveness of the hierarchy of categories and of the associated scale<sup>6</sup>.

The five chosen suicidal ideation categories in C-SSRS and FDA-CASA 2012 fall below an acceptable coefficient of reproducibility in their ability to correspond with Guttman cumulativeness. This is reflected in an analysis of 21,210 suicidality events in a single subject, 20% of all the events were of combinations not captured by the 5 FDA-CASA 2012 or the 5 C-SSRS suicidal ideation combination categories and this constituted almost 60% of the time spent in suicidality<sup>7</sup>.

What is required is a model and assessment measures that do not use such a Guttman scaling structure or Guttman assumptions of cumulativeness along a single dimension of suicidal ideation, and can capture all possible combinations that occur. Freedom from Guttman scaling assumptions permits a scale design to be more comprehensive and generalizable. Yet it can still be simple and brief.

### Linear Model of Suicidality

A further caricature of the linear model of suicidality is that on Monday a subject has passive suicidal ideation, on Tuesday they have active suicidal ideation, on Wednesday they think of a suicide method and / or means. On Thursday they formulate a suicide plan (e.g. when and where). On Friday they engage in preparatory suicidal behaviors (e.g. write a suicide note, buy a large collection of pills to take an overdose). On Saturday they take an overdose. On Sunday they die by suicide. But with rare exceptions, suicidality is not linear like this. Most clinicians have already learned this by listening to and observing their suicidal patients over time. So they already know that the model frequently does not match reality.

### The Reality of Suicidality

Typically patients who are suicidal over a period of time and those who are chronically or recurrently suicidal describe a different pattern. On any given day they may experience any one of the core suicidality phenomena in combination with any one or a number of other suicidality phenomena in the same suicidality event. For example, they may experience active suicidal ideation, followed by passive suicidal ideation, followed by scribbling notes for a final suicide note. Then this suicidality event dissipates. A day or several days later they may start thinking about methods of suicide. This event also ends. Days later the experience a feeling that they would be better off dead and later more

<sup>&</sup>lt;sup>6</sup> Sheehan DV, Giddens JM, Sheehan IS. Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Innov Clin Neurosci. 2014;11(9–10):93–140. Appendix H. pp139-140. Available from <a href="http://innovationscns.epubxp.com/i/425963/92">http://innovationscns.epubxp.com/i/425963/92</a>

<sup>&</sup>lt;sup>7</sup> Giddens JM, Sheehan DV. Do the five combinations of suicidal ideation in the FDA 2012 Draft Guidance document and the C–SSRS adequately cover all suicidal ideation combinations in practice? Innov Clin Neurosci. 2014;11(9–10):172–178. Available from <a href="http://innovationscns.epubxp.com/i/425963/172">http://innovationscns.epubxp.com/i/425963/172</a>

passive suicidal ideation. The following day they experience a sudden unexpected, unprovoked impulse to drive their car into oncoming traffic at high speed, which terrifies them and they pull over and call a friend asking to be rescued. A week later exhausted by this repetitive suicidality, they make a decision to kill themselves by the end of the year if this suicidality continues for another few months. And so on. Various suicidal phenomena come and go, weave in and weave out; loop back and either reinforce or detract from the gravity of earlier suicidality. New suicidal ideation may interact with a fragment of suicidality as remembered, or with new plans or varying degrees of intent or shifting deadlines to attempt suicide. This dynamic interweaving of various phenomena over time with varying intensities and degrees of urgency, feedback looping, interaction of earlier fragments with each other in varying combinations is more the norm than the exception. As one suicidal subject put it "if I can't predict my own suicide, or in what way I may be suicidal tomorrow, how can you?"

Suicidality is non-linear, as experienced by a suicidal individual over time. It is dynamic, involving a complex interaction of core suicidal experiences ("phenomena") over time, often unique within each class of suicidality disorder, and within each individual. The better the model the better it should be to model all scenarios. It is not linear, not unidimensional, not necessarily cumulative, and not necessarily like a staircase. An alternate model accommodating such non-linear, dynamic interplay, feedback looping, sudden impulses to act, then recoil and temporary horror at the danger, may help clinicians better understand the complexity of suicidality in their individual patients as it changes over time.

### Choice of Alternative Models

Thomas Kuhn noted in his seminal book "The Structure of Scientific Revolutions", that even when scientists know that their existing paradigms are flawed, they continue to hold on to the old paradigm past their insight into its flaws, until the current flawed paradigm is replaced by a new paradigm that better explains the observed phenomena and by general consensus provides a more heuristic way forward for the field. Without a replacement paradigm for the existing linear staircase model of suicidality, we are left with a flawed paradigm.

Our purpose in this chapter is to provide an alternative more heuristic paradigm to better model and understand suicidality.

### Other Metaphors for Suicidality

Looking at the apparently chaotic ups and down and dynamic interplay of phenomena over time has some similarities to planets orbiting in a solar system or a listening to a piece of chamber music or jazz, more than it has to a staircase.

<sup>&</sup>lt;sup>8</sup> Kuhn, T. S. (2012). *The structure of scientific revolutions*. University of Chicago press.

### The solar system metaphor

The various suicidal phenomena may resemble planets orbiting around each other, interacting as if pulled into each other's gravitational fields and as they align and get closer the danger appears to escalate. But the reality of most cases of chronic suicidality is that the suicidal phenomena do not have nice elliptical or regular orbits like planets and at times appear to follow no predictable pattern. Each individual case is its own solar system. But this model is not close enough and not heuristic in guiding new research or understanding.

### The music metaphor

Listening to a piece of chamber music or jazz offers another metaphor that reflects the non-linear interactive dynamics and interplay of music. A piece of music may start with the playing of a theme. Variations on the theme follow. Then fragments of the theme feedback and interact with the main first theme. Different instruments toss the theme around and influence it. Then a second theme enters. Then we hear more variations on the second theme. More fragments of the second interact with the main theme. Then both themes interact with each other and fragments of both themes interact with and alter the main themes. It is a dynamic interplay. It is non-linear. It is often unpredictable, sometimes wild and chaotic and turbulent, sometimes predictable orderly and patterned. It rarely repeats exactly.

Table 2.0.1: Music Metaphor for Suicidality

Suicidality	Music Equivalent	
Phenomenon	Notes	
Event	Themes	
Stages of the disorder	The key the melody or theme is played in	
Suicidality Disorder	Piece structure	
Impulsivity	Tempo	
Episode duration	Length of piece	
Treatment	Volume	
Time since age of onset	Time since first heard piece	
Social stigma	Concert venue	
Genetic / epigenetic biomarker	Composer	
Other biomarkers	Instrument	
Subject	Person listening	
Comorbidity	Genre of music	

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

For each patient there are standard event clusters that repeat like unique music themes.

The stage of the disorder that you are in, like the key in a piece of music, determines how you experience the notes, the themes, (the music) around you.

Volume relates to the treatment because the treatment can turn the suicidality up or turn it down.

Social stigma relates to the perspective the people in your social group have to suicidality. This influences the way you experience the suicidality / music in a way similar to how the acoustic of the venue influences how the music is perceived.

Each suicidality disorder has its own structure like the structure or form of a piece of music (sonata, canon, chaconne, fugue, passacaglia, prelude). Each disorder plays true to form.

One subject described the non-linear dynamic parallels with music as follows:

The more exhausted / overwhelmed / hopeless / anhedonic you become the more the planning and preparatory behavior "themes" came on. It was only when the planning was willful that the preparatory behaviors occurred (92% of the time when the planning was willful it did not result in preparatory behaviors). When the planning was not willful (during the impulse attacks) the preparatory behaviors were less likely to occur.

Passive [suicidal] ideation, active [suicidal] ideation, intent were random in relation to each other. [Six of the possible combinations consistently occurred for this subject]. 8 combinations are theoretically possible.

Exhaustion came mainly from impulse attacks more than from the routine phenomena. However, several days of phenomena and events could themselves become so exhausting that they eventually led to exhaustion / overwhelmed / hopeless / anhedonic feeling and then [suicidal] planning. It usually took several experiences of such exhaustion and planning before preparatory behaviors emerged. The frequency of exhaustion experiences were much more important than intensity of exhaustion experiences in the emergence of the preparatory behaviors. The previously described pattern repeated several times in succession over years (sometimes months) as the major driver of the suicide attempts. In early stages of the disorder (different keys) this progression was more likely to take months, while it was more likely to take years in later stages of the disorder (as I developed coping strategies for and experience with the impulse attacks).

As effective treatment increases, the volume decreases. The increase of calcium in the diet served to increase the volume and decrease the effective treatment.

A life event can distort the sound of the suicidality in a way that makes it entirely different from the usual, prior suicidality (e.g. sound mixing - some microphones warp some voices and not others). Life events distort the relative sound balance between phenomena, so that some parts of the suicidality are relatively louder/ distorted in relation to other parts

even though the overall volume is the same. Similar to raising one microphone input when a solo is performed. The life events raise one, two, or several of the phenomena in relation to the other phenomena.

In early stages (when younger) most of the non-impulse attack phenomena was autonomous. In the later stages (when older) most of the non-impulse attack was also autonomous. The difference is that in the earlier stages the active or passive [suicidal] ideations were more likely to snowball into other suicidal phenomena and suicidal planning. In the later stages I learned to use cognitive techniques to break up this progression of phenomena. The percentages of the non-impulse attack phenomena being autonomous in both of these stage areas are likely very similar, if not the same. The difference is that in the later stages the use of the cognitive techniques to break up the progression or to stop the phenomena actually resulted in increasing their frequency so that paradoxically in the later phases the net end result in terms of percentage is the same. The percentage of the time that the phenomena occurred willfully versus autonomously was 2.5% versus 97.5%. experiences of other suicidal subjects I interact with online are similar to this, with maybe an additional 15 - 20 % or so (this likely depends on the bias of the observer).

#### Limitations of the music model

Although the music metaphor captures the non-linearity and dynamic interplay of suicidality phenomena and events, it is not scientific enough and is too variable and too complex to be useful as a scientific model for suicidality. But as a teaching metaphor it has some utility and brings us far beyond the over simplistic linearity and hierarchical structure of the staircase model.

The non-linear dynamic systems model (or Turbulence Theory or Chaos model<sup>9</sup> <sup>10</sup> <sup>11</sup>) What is needed is a model with a basis in scientific method, in mathematical patterning, yet accommodates the non-linear, dynamic interplay in the patient's clinical descriptions and in the time series observations of large databases of suicidal phenomena experienced by suicidal individuals.

We embarked on such a quest by collecting data on and then regularly mining the data on suicidality phenomena and events using the scales and data collection systems described in chapters 5.1 and 14.1. This resulted in the collection of daily data on 43,690 suicidality events over 2.99 years. It became clear early on in this process that suicidality

<sup>&</sup>lt;sup>9</sup> Edward N Lorenz. The Essence of Chaos. University of Washington Press. Seattle 1993.

<sup>&</sup>lt;sup>10</sup> James Gleik. Chaos: Making a New Science. Penguin Books. New York, New York. 2008.

<sup>&</sup>lt;sup>11</sup> Stewart I. Does God Play Dice?: The New Mathematics of Chaos. 2<sup>nd</sup> Edition. 1997. Blackwell Publishing. Malden, Massachusetts, USA.

was indeed non-linear, dynamic, sometimes patterned, frequently apparently chaotic, and unpredictable with wild unexpected swings. The attempts to understand and find pattern in this data over time led to the transitions through the planetary solar system metaphor and the music metaphor described above. Over and over the relationships between any of the suicidality phenomena were never linear. There was often close to a polynomial relationship of the 4<sup>th</sup> order between many of the phenomena. While we attempted to find equations that could model the relationships over time, it became increasingly clear that the data was trying to reveal a different narrative.

While searching for equations to model the data we stumbled across the non-linear, aperiodic systems differential equations formulated by Massachusetts Institute of Technology (MIT) mathematician Edward N Lorenz<sup>12</sup>. Lorenz was a mathematician and meteorologist who studied mathematical models for predicting weather and extending the predictions horizon for what appeared to be the chaotic turbulent behavior seen in weather systems. He was able to show that he could pattern in a computer model the "chaotic", turbulent behavior of weather with a longer-term horizon with only 3 nonlinear differential equations. Although this pattern based on a computer model of 3 differential equations ought to have been reproducibly predictable, he found that the same 3 equations yielded different patterns each time he ran them on the computer based on tiny deviations in initial conditions. In other words the results of each run were highly sensitive to initial conditions and deviated from each other to a far greater extent than anyone expected. The patterns modeled quite well the turbulent dynamic interactive behavior of weather patterns. The patterns appeared at times chaotic, but the apparent chaos had it own non-linear pattern. Yet it was a pattern that never exactly repeated itself. Differential equations can model the way systems change continuously over time. This showed that very small changes initially and along the way could result in substantial qualitative changes beyond anyone's expectations and beyond anything predicted by linear modeling.

Others like Smale at University of California at Berkeley later showed that these dynamic systems could be visualized graphically and topologically. This ability to combine topology and dynamic systems and mathematics was anticipated by the great mathematician Henri Poincare in the late 1800s. He was the first person to discover a chaotic deterministic system and anticipated the work in the 1960 and 1970s of "chaos theory". A dynamic system can have both stable and unstable patterns, turbulence and organized pattern within it at the same time. Islands of structure can appear within turbulent disorder. Oscillators - pendulums and electrical circuits can behave in nonlinear and chaotic ways. The firing of transmembrane protein 4 controlling the voltage gated calcium ions channels in the NMDA receptor complex could behave in this nonlinear, dynamic manner. This could lead to turbulence at times in this channel, when the firing mechanism behaves as if it were fibrillating and causing an arrhythmia in the voltage gated calcium channel.

. .

<sup>&</sup>lt;sup>12</sup> Lorenz E N. Deterministic Nonperiodic Flow. Journal of the Atmospheric Sciences 20 (1963), pp 130-141.

While physicists and mathematicians can examine a system, understand how it works and from first principles choose the correct equations, biological scientists cannot yet deduce the correct equations to model the biological behavior.

To investigate whether there was order in the apparent non-linear chaos of suicidality we explored a number of methods that would allow us to graphically portray any pattern in the time series data of 43,690 suicidality events over 2.99 years in our dataset. Similarly, we wished to investigate any patterns between the suicidality scores as captured by the S-STS from one week to the next in another database of 169 weeks of data in a subject who was suicidal on a daily basis for over 20 years prior to any data collection. These datasets appeared to us to display a non-linear, dynamic chaos. We wanted to see if there was a pattern or an order in this apparent chaos. If the data were linear it would graphically align along a straight line. On the other hand, if the data were a form of random chaos, that is truly random, the data points would be scattered all over the graph. There would be no relationship shown between one interval and the next, but if the data was organized in a partly structured and partly chaotic manner, it might organize itself around an attractor hidden within the data. We hoped that this attractor could be used to display a pattern in the apparent chaos.

We found a method that was used by Robert Stetson Shaw, a physicist at the University of California at Santa Cruz, to graphically display the oscillations in water droplets from a dripping faucet. He needed to find a way of using raw data from an experiment to find an equation that described the data. Initially he graphed these values in 2-dimensional (2D) space with "the x axis represent[ing] the time interval between a pair of drops and y axis represent[ing] the next time interval" between drops <sup>13</sup>. In other words, he looked at the interval between drop 1 and drop 2 and the interval between drop 2 and drop 3. However, he found many of the data points overlapped one another on the 2D plot. He needed another method to display the data, but in 3-dimensional (3D) space. He realized he could illustrate the data graphically by using the first interval as the x axis, the second interval as the y axis, and the third interval as the z axis (interval between drop 1 and drop 2, interval between drop 2 and drop 3, interval between drop 3 and drop 4) (x, y, z), so that all three intervals were plotted as one point in this 3D space.

Using this methodology we used the total time spent in suicidality on the first day as the x axis, the total time spent in suicidality on the second day as the y axis, and the total time spent in suicidality on the third day as the z axis (time spent on day 1, time spent on day 2, time spent on day 3) (x, y, z). This was repeated using the data for days 2, 3, and 4; days 3, 4, and 5; and so on through the entire dataset through its end at days 1063, 1064, and 1065. This methodology had the ability to graphically display a pattern that could be ingrained in "chaos". The 3D data display can be rotated to display any inherent patterns. We used the above methodology to also display the data in 2D space. This 2D display lends itself more easily to display in a book.

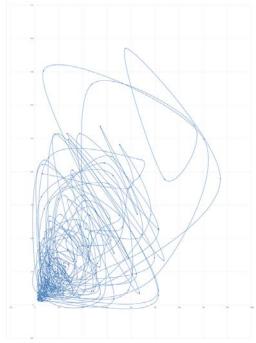
<sup>&</sup>lt;sup>13</sup> James Gleik. Chaos: Making a New Science. Penguin Books. New York, New York. 2008, pp 264 - 267.

This applied mathematical approach allowed us to reconstruct in phase space a previously unseen attractor for suicidality. It reflected our belief that order is so deeply engrained in the apparent disorder of impulsive suicidality that it would find a way of expressing itself even though we did not know what physical variables to measure and were unable to measure such variables directly. Physicist J. Doyne Farmer explained, "When you think about a variable, the evolution of it must be influenced by whatever other variables it is interacting with. Their values must somehow be contained in the history of that thing. Somehow their mark must be there." as cited in James Gleik, 2008<sup>14</sup>.

During this timeframe we discovered a new treatment for this subject's chronic daily suicidality (Impulse Attack Suicidality Disorder). We divided the total dataset into two timeframes; before the subject began taking high magnesium oxide / low calcium dietary intake regimen and the timeframe on this treatment regimen. These displays show the attractor / accelerator / aggregator of the pure, untreated suicidality compared to the pattern seen after starting this effective treatment.

Figure 2.0.1 graphically displays the pattern in the data comparing one day with the next day (day 2) before the subject began to take the treatment. Figure 2.0.2: graphically displays the pattern in the data comparing one day with the next day (day 2) after the subject began to take the treatment.

Figure 2.0.1: Graphic Display of Attractor Pattern in Time Spent Data Comparing Day 1 and Day 2 Before Treatment



<sup>&</sup>lt;sup>14</sup> James Gleik. Chaos: Making a New Science. Penguin Books. New York, New York. 2008, page 266.

Figure 2.0.2: Graphic Display of Attractor Pattern in Time Spent Data Comparing Day 1 and Day 2 After Treatment

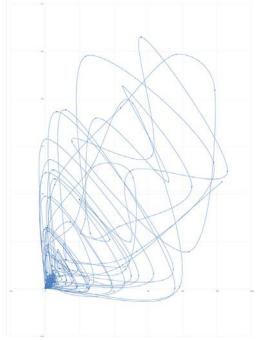
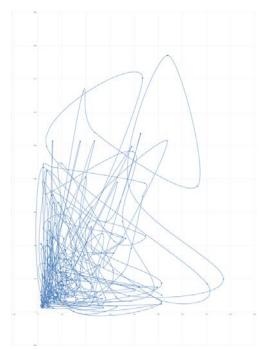


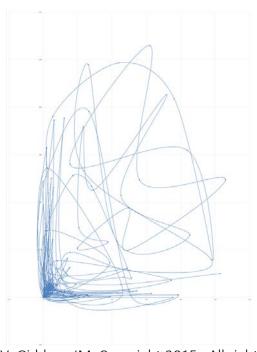
Figure 2.0.3 graphically displays the pattern in the data comparing one day with the third day (day 3) before the subject began to take the treatment. Figure 2.0.4 graphically displays the pattern in the data comparing one day with the third day (day 3) after the subject began to take the treatment.

Figure 2.0.3: Graphic Display of Attractor Pattern in Time Spent Data Comparing Day 1 and Day 3 Before Treatment



Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 2.0.4: Graphic Display of Attractor Pattern in Time Spent Data Comparing Day 1 and Day 3 After Treatment



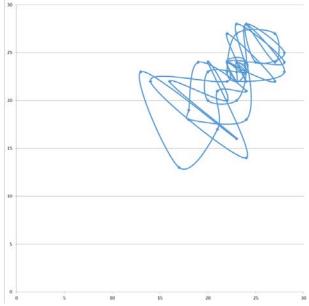
When you examine the Figures 2.0.1 - 2.0.4 you see small circular data points reflecting the movement of the data along sequential days as it orbits through the time series in the dataset. If the data were linear in Figures 2.0.1 - 2.0.4 they would graphically align along a straight line. On the other hand, if the data were a form of random chaos, that is truly random, the data points would be scattered randomly all over the graphs. There would be no relationship shown between one interval and the next. But the data is organized in a partly structured and partly chaotic manner, organizing itself around an attractor / accelerator hidden within the data. This attractor / accelerator displays a pattern in the apparent chaos. Consider the data as tracing the point of a pendulum as it oscillates in a non-linear dynamic fashion and traces a loop moving endlessly around and around, never quite repeating itself exactly as before. The oscillations never return to a state of stability or equilibrium, but keep looping or orbiting on their own. It is not possible to predict if adjacent points will end up close together or far apart in the days that follow. The pattern shows sensitive dependence on initial conditions and exposes the futility of long term accurate prediction of suicidality at the individual level - just as Lorenz learned about long term weather forecasting. This pattern is clearly non-linear, dynamic, and displays episodic turbulence / chaos / unpredictability. All of this is consistent with non-linear dynamics theory / turbulence theory / chaos science.

When you compare Figures 2.0.1 and 2.0.2 it appears that the effective treatment is restoring a more organized equilibrium and stability to the prior turbulence / chaos and the behavior from one day to the next has become more predictable in contrast to the prior greater level of unpredictability. When you examine Figures 2.0.3 and 2.0.4 you see that the effective treatment is restoring the equilibrium and stability to an even greater extent than seen in the contrast between Figures 2.0.1 and 2.0.2. It reflects the progressive improvement over the days of a relatively quick acting treatment. This methodology could be used as an outcome measure in a clinical trial.

A similar methodology was used to explore the weekly Sheehan - Suicidality Tracking Scale (S-STS) total score data. The total S-STS score for week 1 was used as the x axis, the total S-STS score for week 2 was used as the y axis, and the total score for week 3 was used for the z axis. This was then repeated using the data for weeks 2, 3, and 4; weeks 3, 4, and 5; and so on through the entire dataset through its end at weeks 167, 168, and 169. We used the above methodology to also display the data in 2D space. This 2D display lends itself more easily to display in a book like this and so we offer those 2D displays below as Figures 2.0.5 - 2.0.8.

Figure 2.0.5 graphically displays the pattern in the data comparing one week with the next week (week 2) before the subject began to take the treatment. Figure 2.0.6 graphically displays the pattern in the data comparing one week with the next week (week 2) after the subject began to take the treatment.

Figure 2.0.5: Graphic Display of Attractor Pattern in S-STS Data Comparing Week 1 and Week 2 Before Treatment



Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 2.0.6: Graphic Display of Attractor Pattern in S-STS Data Comparing Week 1 and Week 2 After Treatment

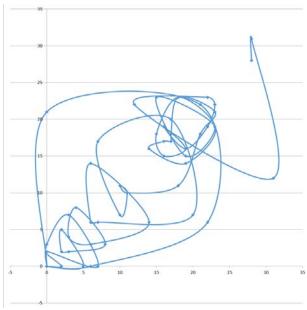
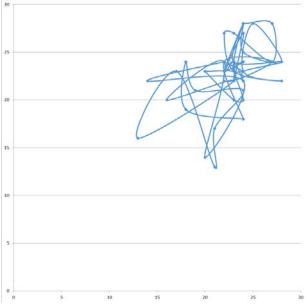


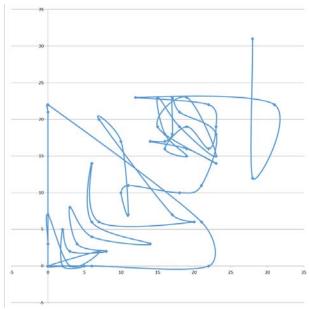
Figure 2.0.7 graphically displays the pattern in the data comparing one week with the third week (week 3) before the subject began to take the treatment. Figure 2.0.8 graphically displays the pattern in the data comparing one week with the third week (week 3) after the subject began to take the treatment.

Figure 2.0.7: Graphic Display of Attractor Pattern in S-STS Data Comparing Week 1 and Week 3 Before Treatment



Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 2.0.8: Graphic Display of Attractor Pattern in S-STS Data Comparing Week 1 and Week 3 After Treatment



Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

These figures reflect the weekly total scores on the S-STS, which dimensionally aggregate seriousness ratings across suicidality phenomena. They display the relationship in these total scores as the suicidality orbits from week to week over the course of the data collection period. As with the daily time spent Figures 2.0.1 - 2.0.4, Figures 2.0.5 - 2.0.8 demonstrate that the data is organized in a partly structured and partly chaotic manner,

organizing itself around an attractor / accelerator / aggregator hidden within the data. This attractor / accelerator displays a pattern in the apparent chaos. As with the time spent data the pattern is clearly non-linear, dynamic, and displays episodic turbulence / chaos / unpredictability. This is consistent with non-linear dynamics theory / turbulence theory / chaos science.

When you compare Figures 2.0.5 and 2.0.6 it appears that the effective treatment is restoring a more organized equilibrium and stability to the prior turbulence / chaos and that the behavior from one day to the next has become more predictable in contrast to the prior greater level of unpredictability. When you examine Figures 2.0.7 and 2.0.8 you see that the effective treatment is restoring the equilibrium and stability to an even greater extent than seen in the contrast between Figures 2.0.5 and 2.0.6. This reflects the progressive improvement over the days of a relatively quick acting treatment.

How might this non-linear dynamic systems (or turbulence theory) model benefit clinicians and researchers and make some predictions? It suggests that:

- 1. there is much more dynamism, turbulence, richness and unpredictability in each individual's experience of suicidality over time than previously thought
- 2. it enriches clinical understanding of chronic suicidality as it progresses over time
- 3. it may enhance the clinician's ability to connect with the patient by being open to the non-linear dynamism, richness, and unpredictability of each patient's suicidality experience. This allows the patient to feel better understood in their struggle with suicidality and thereby gives the patient hope.
- 4. suicidality phenomena move in a non-linear way over time
- 5. suicidality phenomena interplay with each other in a dynamic way over time
- 6. suicidality phenomena do not live in nor are they constrained by a hierarchy
- 7. suicidality phenomena are dimensional rather than categorical
- 8. suicidality phenomena may emerge in a cumulative fashion, or in a non-cumulative manner
- 9. two identical sets of suicidality phenomena can have a different dynamic and a different outcome depending on the order of emergence of the phenomena within each set (sensitive dependence on initial conditions)
- 10. it opens up the possibility of greater richness, more flexibility and dynamism than the staircase model
- 11. it provides a way to capture images of the restoration of equilibrium and a more organized pattern to the unpredictable chaos in chronic suicidality in response to effective anti-suicidal treatments
- 12. it provides a way to capture the images of the induction of rapid cycling upswings and increased unpredictability in suicidality in response to antidepressants in some vulnerable patients, especially those with impulse attack suicidality disorder (IASD) by displaying an organization in the pattern of the upswings that were not there prior to the antidepressant

- 13. researchers need to be more skeptical of the value and accuracy of using linear approaches to capturing and analyzing data on suicidality or in trying to predict suicidality at the individual level
- 14. insensitive instruments are not capable of detecting these patterns
- 15. different suicidality phenotypes and genotypes may display their own unique attractor pattern
- 16. the speed of onset of action of anti-suicidality medications may be captured with precision in attractor graphic displays of data and may differ across different treatments
- 17. the model reflects that suicidality is more predictable and organized at the milder, less serious levels and it more chaotic and unpredictable at higher levels of seriousness
- 18. that time spent in suicidality is a very sensitive outcome measure and is sensitive early (within days) in detecting the suicidality oscillator signal and in reflecting the progressive improvement over time
- 19. that a dimensional scale reflecting the full spectrum of suicidal phenomena is capable of reflecting in an attractor both the chaos and turbulence of the phenomena over time in the untreated state, the worsening of this chaos in response to antidepressants in some vulnerable patients, and the improved organization and predictability in response to effective anti-suicidality medications
- 20. The failure of deterministic systems to accurately predict suicidality at the individual level is now easier to understand. As Nobel Prize winner Niels Bohr said, "Prediction is very difficult, especially about the future" <sup>15</sup>.
- 21. It reflects the observation that suicidality is an oscillator with both an orderly impulse and a disorderly impulse together and at times they decouple

The non-linear dynamic relationships between phenomena of suicidality may be best modeled using non-linear modeling techniques like those used in non-linear dynamics, non-linear systems theory, turbulence theory, aperiodicity, sometimes referred to as Chaos Science or simply as "Chaos". These approaches are sophisticated, scientifically and based in applied mathematics and lend themselves to being able to model complex, dynamic functions.

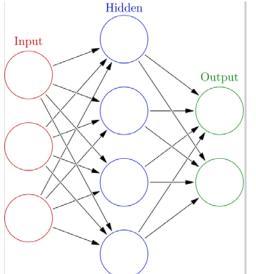
#### Neural networks

Another approach is to try to model suicidality over time using artificial neural network machine learning principles. These techniques can model very complex phenomena in a dynamic system. Neural networks are a collection of models that starting with no knowledge, "learn" with greater precision over time from acquired data, the relationships between non-linear dynamic inputs and dynamic outputs. They store these learned functions in a hidden layer of adaptive functions or weights, which they apply to future

<sup>&</sup>lt;sup>15</sup> Stewart I. Does God Play Dice?: The New Mathematics of Chaos. 2<sup>nd</sup> Edition. 1997. Blackwell Publishing. Malden, Massachusetts, USA.

inputs to predict future outputs. (See Figure 2.0.9 below). These principles are applied in improving classification, prediction and control in many areas of investigation, where such relationships are not well understood.

Figure 2.0.9: Graphic Representation of Neural Networks



"Colored neural network.svg" by Glosser.ca, CC BY-SA 3.0

See <a href="https://en.wikipedia.org/wiki/Predictive">https://en.wikipedia.org/wiki/Predictive</a> analytics

Also see <a href="https://en.wikipedia.org/wiki/Artificial neural network">https://en.wikipedia.org/wiki/Artificial neural network</a>

#### Conclusion

The relationships between the phenomena of suicidality as they move through time are non-linear and dynamic. They are best understood in the context of non-linear dynamics theory / non-linear systems theory / turbulence theory / chaos science. These models provide a more realistic and accurate reflection of the progression of suicidality which can be reflected graphically in unique time series attractors.

# Introduction to Classification of Suicidality

We subscribe to the principles on classification outlined in the UN Guidelines on Classification<sup>1</sup>. Those guidelines are based on the seminal work of Sneath & Sokal<sup>2</sup>. In essence these guidelines recommend that "essential components" of all good classifications should:

- 1. contain categories that are mutually exclusive
- 2. contain categories that are exhaustive
- 3. contain *definitions that are clear and unambiguous* and which define the content of each category
- 4. be robust enough to last for a period of time
- 5. meet user needs
- 6. provide comparability over time and between collections
- 7. make the assumptions that guide the text be as explicit as possible
- 8. provide an economy of memory
- 9. "carve nature at the joints"

Classifications are developed to serve a specific goal (or goals). Our goal is to have classifications of suicidality that serve the goal of providing a roadmap for the development of anti-suicidality medications and treatments. For this we need an outcome measure (or measures) that is highly sensitive in detecting an anti-suicidality efficacy signal and concurrently a safety signal (of treatment emergent suicidality).

<sup>&</sup>lt;sup>1</sup> United Nations. *Best Practice Guidelines for Developing International Statistical Classifications*. UN Department of Economic and Social Affairs Statistics Division. Report from Expert Group Meeting on International Statistical Classifications. New York, NY: May 13–15, 2013.

<sup>&</sup>lt;sup>2</sup> Sneath, P. H., & Sokal, R. R. (1973). *Numerical taxonomy. The principles and practice of numerical classification*.

Towards these ends, we elected to develop 3 classifications.

- 1. a classification of core suicidality *phenomena* (suicidal symptoms and signs)
- 2. a classification of suicidality *events*
- 3. a classification of suicidality disorders (phenotypes)

The structure of each of these 3 classifications is different.

A classification can be either categorical or dimensional. It can be either flat or hierarchical.

A categorical classification has categories – e.g. something is present or not (2 categories Yes and No).

A dimensional classification allows for continuous, numerical, variable data (or ordinal scale data treated as a continuous variable, if there is interval constancy). An example of a dimensional classification is the assessment and tracking on a continuous dimension of severity, or frequency, of the symptoms and signs of Major Depressive Disorder (MDD).

In a hierarchical classification, one class may trump (or be deemed more important or serious) than another class (or classes). An example of a hierarchical classification is that proposed by the Columbia-Classification Algorithm of Suicidal Assessment (C-CASA<sup>3</sup>) or by the FDA-CASA 2012 (based on categories in the C-SSRS<sup>4</sup>), as outlined in the 2012 FDA draft guidance document on assessment of suicidal ideation and behavior<sup>5</sup>. In both of these classification systems some categories trump or are deemed more serious than others and only "the most serious" category is recorded (based on a-priori assumptions about seriousness of group suicide risk).

In a flat classification, each item or item class is considered on a par with all the others. An example of a flat classification is the classification of items used to assess and track depression on a depression rating scale. It makes few if any assumptions. All are given equal weight and all are deemed of equal importance in the rating.

<sup>&</sup>lt;sup>3</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, 164(7), 1035-1043.

<sup>&</sup>lt;sup>4</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

<sup>&</sup>lt;sup>5</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156. htm. Accessed October, 5, 2012.

Figure 3.0.1: Four Possible Combinations of Classification Types

	Categorical	Dimensional
Flat	# 1	# 3
Hierarchical	# 2	# 4

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

In such a classification of classifications, we have 4 possible groupings:

- 1. Categorical + flat
- 2. Categorical + hierarchical
- 3. Dimensional + flat
- 4. Dimensional + hierarchical

Our classification of core suicidality *phenomena* (suicidality symptoms and signs) is a *flat* classification (See chapter 4.1 for a classification of suicidality phenomena). It is a listing of essential core suicidality *phenomena* (suicidality symptoms and signs) that need to be measured and tracked over time. The items it contains need to be clear and unambiguous, mutually exclusive, exhaustive, yet brief enough to meet user needs without being overwhelming or too time consuming, and to make as few assumptions as possible. The method outlining how these phenomena are to be elicited needs to be operationally explicit. We collect the data on this classification in a *dimensional* way (#3) using dimensional rating scales e.g. the Sheehan - Suicidality Tracking Scale (S-STS) or the S-STS Clinically Meaningful Change Measure version (CMCM) (See chapters 14.1 and 14.2, respectively). The precise wording of the S-STS questions provides an operational guide on how to optimally elicit the required information. Interviewers are not limited to these questions and should follow up as clinically necessary. However the interviewer should exercise caution in not straying too far from the spirit and wording of each question. Good training is needed to ensure good inter-rater reliability.

A suicidality *event* classification should provide a system that makes it relatively easy for a subject to precisely and accurately capture and classify in a time efficient manner every suicidality event and its associated phenomena. Yet it also needs to have event categories that are unambiguous, mutually exclusive and exhaustive, and to make as few assumptions as possible. Our Tampa - Classification Algorithm for Suicidality Assessment (T-CASA) classification of suicidality *events* is a *categorical and hierarchical* classification (#2) (See chapter 5.1 on the T-CASA).

Other classification systems of suicidality events collect data *only* in a hierarchical classification. Unlike these classifications, our hierarchical event classification accommodates the collection of *that* data in a manner that does not make them mutually exclusive. See the T-CASA in the Chapter 5.1 for details, where columns 1 through 4 are hierarchical and mutually exclusive, while columns 5 & 6 are flat and not mutually exclusive. For example, our classification system requires suicidal planning, suicidal preparatory behavior, and suicide attempt data to be captured for the same event. Other classifications make the items within this event mutually exclusive, and only code

the event as a suicide attempt, because they assume this to be the "most serious" category. The rationale for the unique design of T-CASA is described in chapter 5.

Our classification of suicidality disorders is a categorical and hierarchical classification (#2). It is a phenotypic classification, in contrast to a genotypic classification. It is a classification based on currently available composites of the clinically observable symptoms, signs, behaviors, development, family history, course of illness, and response to treatment. Each suicidality disorder class / phenotype should be a predictive cluster, like the disorders in DSM-5<sup>6</sup>, with specific diagnostic criteria for each, with a structured diagnostic interview that can guide the clinician in assigning subjects to each diagnostic class. Such clusters are sometimes derived in psychiatric treatment research by what Donald Klein referred to as "pharmacological dissection". In other words, you find a cluster of symptoms and signs that responds to a specific treatment in some unexpected way. You then carve out this cluster as a distinct disorder class. When you identify this disorder in the future you predict that it will respond to a specific treatment. Using an array of different medication treatments, you could make a classification based on differential treatment response. Until such time as we have better genetic and other biomarkers that allow us to classify based on genotyping, biomarkers and etiology, it is likely that this "working backwards from the answer" method is likely the provide the best interim solution to identifying different classes of suicidality disorders. Over time some of the genetic and other biomarkers may to some degree align with the proposed phenotypic classification and bring about a combined phenotype / genotype / biomarker classification that provides better predictive clustering of treatment response, disease natural history, family history and likely complications.

There is no need to restrict our understanding of suicidality to either a categorical or the dimensional classification, as others have done<sup>8</sup> <sup>9</sup>. They are complementary, and need not necessarily be competing approaches or be used in a mutually exclusive manner. Each has its advantages and its disadvantages. Categorical approaches do not lend themselves to the sensitive measurement of variation in symptoms and signs over time and across individuals. But they may provide an economy of memory in clinical settings, if a few categories with good predictive value provide a good guide to a successful choice of treatment. However, when there are too many categories, e.g. in circumstances

<sup>&</sup>lt;sup>6</sup> American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC.

<sup>&</sup>lt;sup>7</sup> Klein, D. F. (1989). The pharmacological validation of psychiatric diagnosis. *Validity of Psychiatric Diagnosis. Raven: New York*, 203-216.

<sup>&</sup>lt;sup>8</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, 164(7), 1035-1043.

<sup>&</sup>lt;sup>9</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at: h ttp://www.fda.* 

gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156. htm. Accessed October, 5, 2012.

where it is necessary to have an exhaustive classification, this "economy of memory" advantage is defeated. Categorical classifications provide much less sensitivity and less statistical power. Dimensional measures can be numerical, and have more sensitivity and more statistical power. Categorical systems usually require very large datasets and meta-analyses to detect signals. In contrast, dimensional measurement usually needs smaller sample sizes. Hence the signal can be detected more rapidly and at less cost.

Symptoms are dimensional in nature, while events and disorders are categorical in nature. Dimensional assessments lend added precision to tracking results from treatment decisions based on categorical classifications. Mangling all these systems into one system does not make sense to us. Given the complexity of suicidality phenomena, we have the opportunity to have the best of all approaches, if we use both categorical and dimensional approaches together, to maximize the advantages of each in achieving our goal.

We recommend using a dimensional scale to track symptom severity, a categorical approach to classify and assess disorders, and a combined categorical and dimensional approach to assess and track events (e.g. panic disorder). This is the approach that has been the standard method used to investigate treatment outcomes for all other psychiatric disorders. We do not see a compelling reason why suicidality treatment studies should be approached in a different way.

Our approach in developing these classifications was phenomenological. We aimed to directly observe and describe the phenomena of suicidality, as they were "consciously experienced, without theories about their causal explanation and as free as possible from unexamined preconceptions and presuppositions"<sup>10</sup>.

43

<sup>&</sup>lt;sup>10</sup> Spiegelberg, H. (2015, June 11). Phenomenology. Retrieved October 24, 2015, from http://www.britannica.com/topic/phenomenology

## 4.1

# Classification of Suicidality Phenomena

### Definitions of Suicidality Phenomena

Suicidality - [sui (of oneself) + cide (a killing) + ality (the state of being real or actual)] - all suicidal phenomena including ideation, behaviors, impulses, command hallucinations, dreams, delusions, and / or precognitive experiences related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame, but did not appear as an ideation or behavior during that time frame. For example, a patient who previously made plans or intends to kill herself at a future date, but may not have thought about it during a particular time frame. (See event of suicidal intent, event of suicidality, episode of suicidality, and unexpected suicidal impulse attack for further clarification and examples.) This definition deliberately excludes theories or speculations about, predictions from or likelihood of a suicidal ideation or behavior. It also excludes experiences that may be comorbid with or correlated with core suicidal phenomena, but in and of themselves are not directly suicidal experiences (e.g. hopelessness, depression, anxiety, grief).

USIA (Unexpected Suicidal Impulse Attack) Physical and Ideation Subtype - any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way that is associated with enough symptoms to meet the criteria for a USIA Physical and Ideation Subtype. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. See USIA Physical and Ideation Subtype criteria in the Suicidality Disorders Criteria.

USIA (Unexpected Suicidal Impulse Attack) Ideation Only Subtype - any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way that is *not associated with enough physical symptoms* to meet the criteria for a USIA Physical and Ideation Subtype. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. See USIA Ideation Only criteria in the Suicidality Disorders Criteria.

Non-Suicidal Self-Harm Impulse Attack, containing Transient Suicidal Ideation - any event of physical symptoms associated with self-harm ideation or an urge to self-harm that after its onset contains transient suicidal ideation. This event may occur as a precursor of or as the devolution of a suicidality disorder. In the event this occurs in isolation and not part of one of the specified suicidality disorders, consider it to be a part of the Suicidality Disorder, Not Elsewhere Specified.

**Hallucination with Suicidal Content** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of an auditory or visual hallucination

**Delusion with Suicidal Content** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of a delusion (i.e. mistaken belief)

**Dream of Suicidality** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of a dream

**Suicidal Obsession** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of any classic obsession typically seen in Obsessive Compulsive Disorder

**Suicidal Compulsion** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of any compulsive behavior typically seen in Obsessive Compulsive Disorder

**Suicidality Related to PTSD** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of a Post-Traumatic Stress Disorder (PTSD)

Suicidality Related to a Substance or Substances - any event of suicidality following the ingestion of or exposure to a substance that occurred while under the influence of or withdrawal from the substance

**Suicidality Related to Any Medical Illness(es)** - any event of suicidality restricted exclusively to or best explained by the direct effect of any general non psychiatric medical condition

**Suicidality Related to Any Psychiatric Disorder(s)** - any event of suicidality experienced exclusively as the direct and / or immediate consequence of any psychiatric disorder other than Impulse Attack Suicidality Disorder, any psychotic disorder, Substance Abuse or Dependence, or Obsessive Compulsive Disorder

Suicidality Related to Any Life Event(s) - any event of suicidality experienced as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be obvious to any third party outside the clinician and the patient involved in the assessment.

Suicidal Ideation - a desire or wish or need or preference to be dead <u>or</u> a thought about being dead in relation to another experience of suicidality <u>or</u> a thought to hurt, harm, or injure oneself with the intent or awareness that one could die as a result <u>or</u> any strategizing for or accounting of or thought(s) of future action(s) for a suicide attempt (including thoughts to make a plan). The ideation may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

Suicidal Ideation and / or Urge - a desire or wish or need or preference to be dead <u>or</u> thought about being dead in relation to another experience of suicidality <u>or</u> a thought to hurt, harm, or injure oneself with the intent or awareness that one could die as a result <u>or</u> an urge to attempt suicide or urge to plan for a suicide attempt

**Suicidal Urgent Need** - any event of suicidality experienced as a sudden urgent need to plan or to act in any suicidal way

Passive (Suicidal) Ideation - any thought of wishing or wanting or needing to be dead <u>or</u> of wishing or wanting or needing to not be alive anymore <u>or</u> the thought of being better off dead <u>or</u> the desire to go to sleep <u>and never wake up or</u> the thought of not wanting to be alive anymore. The phrase "passive ideation" refers to ideas of dying that <u>do not require a change in usual behavior</u> on the part of the patient to die.

Active (Suicidal) Ideation - any thought of killing oneself. The phrase "active ideation" refers to ideas of dying that requires a change in usual behavior on the part of the patient to die.

**Suicidal Planning** - any strategizing for or accounting of or thought(s) of future action(s) for a suicide attempt (including thoughts to make a plan). This planning may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

Suicide Plan - any strategy for or account of or thought(s) for future action(s) of a suicide attempt (including thoughts to make a plan). This plan may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

**Suicide Method** - any thought of a way any person could attempt to kill themself. This includes, but is not limited to a specific method (e.g. gunshot wound to the head), a general method (e.g. exsanguination), an active method (e.g. an overdose of insulin), or a passive method (e.g. an insulin dependent diabetic failing to take their insulin).

Suicide Means - any thought of tool(s) any person could use to attempt to kill themself. Examples include a rope to hang themself or a gun to shoot themself. This includes, but is not limited to a specific means (e.g. their mother's sleeping medication) or a general means (e.g. some type of pills).

**Suicide Location** - any thought of a location any person could use to attempt to kill themself. Examples include their car in a closed garage to die via carbon monoxide poisoning or the Golden

Gate Bridge where they could jump to their death. This includes, but is not limited to a specific location (e.g. the Sea of Trees in Japan) or a general location (e.g. the forest).

Suicide Date - any thought of a date any person could use to attempt to kill themself or any thought of a time frame within which they would like to die. This includes, but is not limited to a specific date (e.g. January 1st, 2016), a specific time frame (e.g. before next year), or a general date or time frame (e.g. soon).

Work On or Completion of Unfinished Tasks - any time spent actively engaged in a task that a patient would like to complete prior to a suicide attempt. This includes, but is not limited to tasks the patient works on or completes with the mind-set that they will be closer to making a suicide attempt when the task is completed. This includes, but is not limited to tasks the patient works on or completes that they previously thought were important for them to complete prior to making a suicide attempt.

Suicidal Intent\* - any intent\* > 0 to make a plan to kill oneself <u>or</u> to take action to kill oneself <u>or</u> to die as the result of a suicide attempt at any point in time. This includes, but is not limited to: the intent\* to consider the method, means, location, date, time frame, unfinished tasks, or involvement of others to be used in the suicide plan; active and passive suicide attempts (see suicide method for examples of active and passive methods); persons that actually make an attempt and those that did not make an attempt, but did have some intent\* > 0 to attempt to kill oneself; and persons that actually make an attempt, and those that did not make an attempt, but did have some intent\* > 0 to attempt to kill oneself.

Intent\* to Plan in the Future - any intent\* > 0 to make a plan to kill themself at some point in the future. This includes, but is not limited to the intent\* to consider the method, means, location, date, time frame, unfinished tasks, or involvement of others to be used in the suicide plan.

Intent\* to Act in the Future - any intent\* > 0 to take action to kill themself at some point in the future

Intent\* to Die in the Future - any intent\* > 0 to die as the result of a suicide attempt at some point in the future. This includes, but is not limited to both active and passive suicide attempts. (See suicide method for examples of active and passive methods.)

Intent\* to Plan at Time of Event of Suicidality - any intent\* > 0 to make a plan to kill themself during the event of suicidality being coded. This includes, but is not limited to the intent\* to consider the method, means, location, date, time frame, unfinished tasks, or involvement of others to be used in the suicide plan.

Intent\* to Act at Time of Event of Suicidality - any intent\* > 0 to take action to kill themself during the event of suicidality being coded. This includes, but is not limited to persons that actually make an attempt and those that did not make an attempt, but did have some intent\* > 0 to attempt to kill themself.

Intent\* to Die at Time of Event of Suicidality - any intent\* > 0 to die as the result of a suicide attempt during the event of suicidality being coded. This includes, but is not limited to both active and passive suicide attempts. (See suicide method for examples of active and passive methods.)

Suicidal Behavior - any (set of) behavior(s), either incomplete or completed, that are either 1) not viewed by the patient to be potentially lethal and stop short of taking action on a suicide attempt, but assist the patient in preparing to take action on a suicide attempt  $\underline{or}$  2) perceived by the patient to be potentially lethal, connected with any level of intent\* ( > 0 ) to die, that does not result in a fatality  $\underline{or}$  3) a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless or negligent behavior that is connected with any level of intent\* to die as a result of said self-injurious or purposely reckless behavior. (See the definitions for suicidal preparatory behavior, suicide attempt halted, suicide attempt not halted, and died by suicide for more details and information.)

**Aborted Action** - any action that is stopped by the subject on their own initiative, without interruption by an external intervention

**Interrupted Action** - any action perceived by the patient to intervene to the extent of stopping the action from proceeding

Suicidal Preparatory Behavior - any behavior(s) that are not viewed by the patient to be potentially lethal and stop short of taking action on a suicide attempt, but assist the patient in preparing to take action on a suicide attempt. These preparatory behavior(s) may concern, but are not limited to, the method, the means, the location, the date, and / or any unfinished tasks. We deliberately did not try to make subtypes of these behaviors or try to classify them in a hierarchal array as in FDA-CASA 2012 because there is no way to correctly generalize any such hierarchy to any individual case based on the gravity of the preparations. We judge the gravity of the preparatory behaviors based upon the patient's perception of the gravity rather than relying on the details. Here, as elsewhere, the focus of seriousness / gravity / danger is patient centric rather than circumstance or clinician centric. The patient's perspective on potential lethality can be inferred by a reasonable group of experts, if the patient is not available or refuses to provide it themselves, but should not always be assumed, unless the evidence is compelling.

Suicide Attempt - any (set of) behavior(s), either incomplete or completed, perceived by the patient to be potentially lethal, connected with any level of intent\* ( > 0 ) to die, that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The (set of) behavior(s) may or may not be incomplete due to an interruption by events outside the patient's body or existence, or may be incomplete due to the patient aborting\*\* the already started, perceived lethal behavior(s) before it (they) are fully executed. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt. \*\*The patient's desire to abort the already started, perceived lethal behaviors can be self-imposed, or imposed by another.

Suicide Attempt Halted - any incomplete (set of) behavior(s) perceived by the patient to be potentially lethal connected with any level of intent\* ( > 0 ) to die that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The (set of) behavior(s) may be incomplete due to an interruption by events outside the patient's body or existence, or may be incomplete due to the patient aborting the already started, perceived lethal behavior(s) before it (they) are fully executed. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.

Suicide Attempt Not Halted - any completed (set of) behavior(s) perceived by the patient to be potentially lethal that is connected with any level of intent\* ( > 0 ) to die that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The behavior does not have to be potentially injurious. Only the patient's perception that it is self-injurious is necessary. (See Examples 1 and 2 below.) The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.

Example 1: consider a cinnamon challenge competition for young adults. The goal in this challenge was to attempt to swallow a heaping tablespoon full of cinnamon within 60 seconds without drinking any water. To dissuade her child from participating in the challenge one mother warned the child that it would kill them. The belief that the cinnamon challenge was potentially lethal spread among teens. With this understanding a teen decides to make a suicide attempt by trying to swallow a heaping tablespoon of cinnamon. This counts as a suicide attempt, because the teen thought this would kill them.

Example 2: a child just finished watching the movie Snow White. In an attempt to harass the young child an older sibling offers the child an apple, which they tell their younger sibling, comes from the same tree as the one in the movie. With the assumption it would make them sleep forever, the child eats the apple. Because the child thought eating the apple would kill them, just as it put Snow White into the 'Sleeping Death', this event counts as a suicide attempt.

Substitute Variant - the deliberate substitution of any method, means, location, date or behavior that is used for the purpose of substantially diminishing the risk of a lethal outcome. An example would include the patient that feels the strong urge to kill themself using an overdose of their medication. To deal with and lessen this urge they deliberately take several handfuls of M&Ms while pretending to themself that these are real tablets even though deep down they know this is very unlikely to be lethal. Such a tactic is used by some patients as a coping strategy.

Died by Suicide / Death by Suicide / Completed Suicide - a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless behavior that is connected with any level of intent\* ( > 0 ) to die as a result of said self-injurious or purposely reckless or negligent behavior. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury resulting

in death is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.

**Suicidal Experience Not Classified Above** - suicidal presentation of symptoms of the event of suicidality that does not fit the definition of any other category in either the Hierarchy of Experiences column or the Action Event column

#### Additional Related Definitions

Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die - any event where a subject has increased interest in the suicidal content in a medium like a movie, a book, music, or the news which is accompanied by a desire for the suicidal subject in the medium to die.

**Non-Suicidal Physical Symptom Attack (NSPSA)** - any event of physical symptoms usually experienced in an USIA that is *not associated with suicidal ideation*. See NSPSA criteria in the Suicidality Disorders Criteria.

Non-Suicidal Self-Injurious Behavior / Non-Suicidal Self-Injury - any (set of) behavior(s), either incomplete or completed, that are either 1) not viewed by the patient to be potentially lethal and stop short of taking action on a self-injury attempt, but assist the patient in preparing to take action on a self-injury attempt  $\underline{or}$  2) perceived by the patient to not be potentially lethal, connected with no level of intent\* ( = 0 ) to die, that does not result in a fatality  $\underline{or}$  3) a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless behavior that is connected with no level of intent\* to die ( = 0 ) as a result of this self-injurious or purposely reckless or negligent behavior. We do *not* consider non-suicidal self-injurious behavior to be suicidal behavior. However, as with the suicidal behaviors there may be interrupted, aborted, or neither interrupted nor aborted self-injurious behaviors.

Non-Suicidal Self-Injury Ideation - a desire or wish or need or preference to be injured  $\underline{or}$  thought about being injured  $\underline{or}$  a thought to hurt, harm, or injure oneself with NO intent ( = 0 ) to die as a result  $\underline{or}$  any strategizing for or accounting of or thought(s) of future action(s) for a self-injury attempt (including thoughts to make a plan). The ideation may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks."

<sup>\*</sup> Intent is defined as the state of a person's mind that directs them towards a specific action.

## 4.2

#### Distinction Between Suicide Method and Suicide Means

The terms 'means' and 'method' are sometimes interchangeably used when referring to the planning of a suicide. These terms are not only distinct, but they can occur individually.

The method is the way the suicidal individual could attempt to end their life. Examples of methods include, but are not limited to, overdose, suffocation, hanging, poisoning, hypothermia, and excessive blood loss.

The means are the tool(s) the suicidal individual could use to attempt to end their life. Examples of means include, but are not limited to, insulin and / or syringe, plastic bag and / or tape, rope and /or ladder, oleander tea, frozen pond, and scalpel.

Method	Means
overdose	insulin and syringe
suffocation	plastic bag and tape
hanging	rope and ladder
poisoning	oleander tea
hypothermia	frozen pond
blood loss	scalpel

There is a higher awareness of a suicidal individual selecting the method to kill themself with or without selecting the means and a lower awareness of a suicidal individual selecting the means to kill themself without selecting the method.

#### Example of a Method With Means

Alex is an outcast at school. He has very few friends and is sometimes bullied. He had hopes of joining the school's swim team and spent months of hard work training. Alex felt assured his hard work would pay off and ensure him a place on the team. He expected others to respect him when he makes the team. Today Alex learned he failed to make the team and is devastated by the news. He feels overwhelmed. Alex is unable to see past his disappointment and feels frustrated by his life. Alex remembers recently hearing about a student at a nearby school that hung herself. Alex knows his mother has rope in the garage and researches what it is like to die by hanging, even watching videos of hanging from movies, and how to make the hangman's knot. After some consideration, Alex decides to hang (method) himself with the rope (means) in the garage.

#### Example of a Method Without Means

Three years ago Ashley was driving her partner, Suzie, to work. While driving, Ashley felt an itch on her leg and reached down to scratch it. In the few moments Ashley was distracted, the car in the lane to the right of them abruptly swerved into their lane. Due to the distraction, Ashley did not react very quickly and the cars collided. The impact caused internal bleeding to Suzie, but her injury was not immediately noticed. Although doctors tried to save her, Suzie died as a result. Ashley blames herself for the death of her partner. She thinks the most fitting punishment for killing Suzie is to die in an accident, the way Suzie did, so that she could have the same experience Suzie did in her final moments. Ashley is so fixated on dying as the result an accident (method) that she has not yet given thought to what tools (lack of means) she would use to make that happen.

#### Example of a Means Without Method

Martin's father, Dennis, is an avid hunter, as was Martin's grandfather. Dennis has a rifle that was given to him by his father and, throughout all of Martin's life, Dennis has cherished this rifle because it reminds him of the quality time he spent hunting with his father. Martin and Dennis have never really been close. Martin's sister has always been Dennis' favorite. Martin recently told his family that he is involved in BDSM. Dennis feels his son's actions are not in accordance with the family's strong Protestant values so he has shunned Martin and refused to talk to him for the past several months. Martin feels frustrated by his father's response and by other issues going on in his life. He is considering killing himself with his father's prized rifle in hopes of sending a message to his father. Martin has not made any further plans (lack of method), but continues to think about killing himself with his father's rifle (means).

### 4.3

### Relationship Between Perceived Risk of Suicide Method and Level of Intent

Examples of suicide attempt spectrums include, but are not limited to, jumping from a 4ft porch, jumping from the roof of a 2 story building, and jumping from the top of a 13 story building; shallow cut to wrists, deep cut to wrists, deep cut to throat severing arteries; touching a candle flame, walking through a campfire, self-immolation; overdose - 5 vitamins, overdose - 100 aspirin, overdose - 3 vials of insulin; suffocating self with own hands, suffocating self with plastic bag, suffocating self with rope while intoxicated; and shooting self with paint ball gun, shooting self in arm with handgun, shooting self in heart with handgun. Please note the level of intent to die is not directly linked to the level of perceived risk of method.

or

Examples of suicide attempt spectrums include, but are not limited to:

- jumping from a 4ft porch
- shallow cut to wrists
- touching a candle flame
- overdose 5 vitamins
- suffocating self with own hands
- shooting self with paint ball gun

- 2 story building
- deep cut to wrists
- walking through a campfire •
- overdose 100 aspirin
- suffocating self with plastic
  - shooting self in arm with handgun

- jumping from the roof of a jumping from the top of a 20 story building
  - deep cut to throat severing arteries
  - self-immolation
  - overdose 3 vials of insulin
  - suffocating self with rope while intoxicated
  - shooting self in heart with handgun

Please note the level of intent to die is not directly linked to the level of perceived risk of method.

5

## Classification of Suicidality Events

#### Introduction

Suicidality phenomena, suicidality events, and suicidality disorders are not the same things and should not be confused with each other. Attempts to collect useful data on both the phenomena and the events with the same scale / instrument and algorithm / classification system have led to much confusion. Data on suicidality phenomena and events are best collected using different, yet parallel and consistent systems. It is the same problem that arises when a scale tries to capture information on both the severity and the frequency of each phenomenon at the same time. In the case of suicidality, this problem is further compounded by the potential that multiple phenomena can present during the same event in a vast number of combinations.

In searching for an efficient solution to capture data on the severity / seriousness of phenomena and on the event data, we found it best to disaggregate these two agendas and capture each using a different instrument. The S-STS / S-STS CMCM / SPTS / SIAS all capture data on the severity / seriousness of suicidality phenomena, and in a more limited way, they capture some information on frequency and time spent. The T-CASA, in contrast, is a classification algorithm designed specifically to capture suicidality event data in a time efficient, yet comprehensive manner.

For example, some patients taking antidepressants report an increase in the frequency of Unexpected Suicidal Impulse Attacks (USIA). The severity or seriousness of these USIAs may not have changed during a timeframe, but the frequency has dramatically changed and the time spent in experiencing this specific suicidal event has significantly increased within a timeframe. (See chapter 12.2 for a case study showing this effect from an antidepressant.) Item 11 on the S-STS will capture the seriousness of the USIA within a given timeframe, but does not capture the time spent experiencing USIAs nor the

frequency of the USIAs. It is very difficult to get a scale like the S-STS, the ISST-Plus<sup>1</sup>, the SIBAT<sup>2</sup>, or the C-SSRS<sup>3</sup> to capture the former data at the same time as it is collecting frequency and time spent data. The T-CASA, in contrast, captures the frequency and the time spent in each event and all of the important associated phenomena that occurred within the event. However, the T-CASA does not capture data on the severity / seriousness of the event. The reason is that capturing severity / seriousness data on each event when it occurred, in our experience, was not reliable. For example, in the case of USIAs a patient may need to minimize the severity / seriousness of the USIA in order to assist them in coping with the experience. If the patient is asked about this severity / seriousness in close proximity to the event, they may not be able to offer an accurate assessment of the severity / seriousness. Even when the patient was aware of this problem and attempted to compensate for it, it still yielded unreliable data.

There is no way for anyone using either the C-CASA<sup>4</sup> or the FDA-CASA 2012<sup>5</sup> to know if an antidepressant is specifically increasing the severity or seriousness or frequency or time spent in nor the combinations of other suicidality phenomena associated with the USIAs within the event while on an antidepressant. (See chapter 12.2 for a case study showing this effect from an antidepressant.) Similarly, these two algorithms do not have a way to capture command hallucination events about suicidality if that occurs in response to a medication. These are major safety concerns and are not confined to only these examples.

Using many different methods over several years across tens of thousands of suicidality events we evolved a system, by trial and error, which seemed to efficiently track suicidality events. This system is presented below as the Tampa - Classification Algorithm for Suicidality Assessment (T-CASA). On first inspection this system of event data capture seems difficult. In practice, subjects accommodated to it with repetition and found it quick and simple to record on a daily basis, using the associated tracking logs.

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156. htm. Accessed October, 5, 2012.

<sup>&</sup>lt;sup>1</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from: http://innovationscns.epubxp.com/i/425963/32

<sup>&</sup>lt;sup>2</sup> Alphs, L., Canuso, C., & Williamson, D. (2015). P. 1. k. 032 The Suicide Ideation and Behavior Assessment Tool: development of a novel measure of suicidal ideation and behavior and perceived risk of suicide. *European Neuropsychopharmacology*, *25*, S371.

<sup>&</sup>lt;sup>3</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

<sup>&</sup>lt;sup>4</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, 164(7), 1035-1043.

<sup>&</sup>lt;sup>5</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

5.1

Tampa - Classification Algorithm for Suicidality Assessment (T-CASA)

Tampa - Classification Algorithm for Suicidality Assessment (T-CASA)

Code one o	ption for each of the first 4	l categories <sup>1</sup> :		Code all that app	ply:
Hierarchy of Experiences <sup>2</sup>	<u>Ideation</u> <u>Type</u>	<u>Willfulness</u> <u>Level</u>	Emotion <u>Level</u>	Action Event <sup>3</sup> (1# - 11# occurred in reality, 1& - 6&, 10& occurred in dream, psychosis, or delirium <sup>1</sup> , 1% - 6%, 10% occurred in the medium entertained <sup>1</sup> )	Associated <u>With</u> <sup>4</sup>
<ul> <li>1A. USIA Physical &amp; Ideation Subtype</li> <li>1B. USIA Ideation Only Subtype</li> <li>1C. Non-Suicidal Physical Symptom Attack</li> <li>1D. Non-Suicidal Self-Harm Impulse Attack, containing Transient Suicidal Ideation</li> <li>2. Hallucination with Suicidal Content</li> <li>3. Delusion with Suicidal Content</li> <li>4. Dream of Suicidality</li> <li>5. Suicidal Obsession</li> <li>6. Suicidal Compulsion</li> <li>7. Suicidality Related to PTSD</li> <li>8. Suicidality Related to a Substance or Substances</li> <li>9. Suicidality Related to Any Medical Illness(es)</li> <li>10. Suicidality Related to Any Psychiatric Disorder(s)</li> <li>11. Suicidality Related to Any Life Event(s)</li> <li>12. Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die</li> <li>13. Suicidal Experience Not Classified Above</li> <li>14. Non Suicidal Event or Unknown</li> </ul>	<ol> <li>Pre Awareness</li> <li>Thought Only</li> <li>Thought Process</li> <li>In Background</li> <li>Not Classified         Above or         Unknown</li> </ol>	<ol> <li>Not At All</li> <li>A Little</li> <li>Moderately</li> <li>Mostly</li> <li>Completely</li> <li>Unknown</li> </ol>	<ol> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Unknown</li> </ol>	<ol> <li>Suicidal Ideation and / or Urge</li> <li>Suicidal Planning</li> <li>Suicidal Preparatory Behavior</li> <li>Suicide Attempt Halted</li> <li>Suicide Attempt Not Halted</li> <li>Died by Suicide / Death by Suicide / Completed Suicide</li> <li>Self-Injury, Unknown Intent</li> <li>Fatality, Not Enough Information</li> <li>Subject Alive, Not Enough Information</li> <li>Fatality, Not by Suicide</li> <li>Suicidal Experience Not Classified Above</li> <li>Not Classified Above or Unknown</li> </ol>	<ul> <li>A. Suicide Method</li> <li>B. Suicide Means</li> <li>C. Suicide Location</li> <li>D. Suicide Date</li> <li>E. Intent<sup>5</sup> to Plan in the Future</li> <li>F. Intent<sup>5</sup> to Act in the Future</li> <li>G. Intent<sup>5</sup> to Die in the Future</li> <li>H. Intent<sup>5</sup> to Plan at Time of Event of Suicidality</li> <li>Intent<sup>5</sup> to Act at Time of Event of Suicidality</li> <li>J. Intent<sup>5</sup> to Die at Time of Event of Suicidality</li> <li>K. Work On or Completion of Unfinished Tasks</li> <li>L. Aborted Action</li> <li>M. Interrupted Action</li> <li>N. Life Event Related</li> <li>O. Suicidal Urgent Need</li> <li>P. Provisional Information Needing Final Confirmation</li> <li>Q. Substance Related</li> <li>S. Substitute Variant</li> <li>T. Passive Ideation</li> <li>U. Active Ideation</li> </ul>

<sup>1</sup>See coding examples. <sup>2</sup>You must rule out each of the experiences listed in the hierarchy in the order in which they are listed before assigning an experience at the lower end of the list. <sup>3</sup>Code the event in this column within a parenthesis and include symbol. For example if the patient experienced 2,3, and 4 in reality, code as (2#-4#). See coding examples. <sup>4</sup>Maintain alphabetical order when coding the Associated With column. <sup>5</sup>Intent is defined as the state of a person's mind that directs them toward a specific action. Sheehan DV, Giddens JM, © 2012-2015. All rights reserved.

#### **Coding Examples:**

A patient experienced an event of suicidality as the direct result of a family member's death (suicidality related to a life event). During this event he engaged in a thought process which was mostly willful while experiencing moderate emotion. This event contained suicidal ideation and suicidal planning. The event resulted in a suicidal preparatory behavior. He reported thinking about the method and means of his attempt and that he had the intent\* to plan at the time of the event of suicidality. This is coded as 11.3.4.3.(1#-3#).ABH. or as 11.3.4.3.(1#-3#).ABHN. (The addition of the "N" for the suicidality related to a life event is optional as it was already coded by the 11 in the Hierarchy of Experiences column.)

A patient experienced a dream of suicidality where she went through a moderately willful thought process to plan her death (suicidal planning including method, means, location, and date). This was experienced with an extreme level of emotion and with the intent\* to plan, to act, and to die at the time of the event of suicidality. During the dream the patient planned and obtained the means (preparatory behavior) for her death. The patient then killed themself in the dream (completed suicide). This is coded as 4.3.3.5.(2&,3&,6&).ABCDHIJ.

A patient experienced an USIA Physical and Ideation Subtype with the thought only to kill herself that was not at all willful. This event was experienced with no emotion and resulted in suicidal ideation without planning only where she had the intent\* to act at the time of the event of suicidality. This is coded as 1A.2.1.1.(1#).I. or as 1A.2.1.1.(1#).IO. (The addition of the "O" for the suicidal urgent need is optional as it was already coded by the 1 in the Hierarchy of Experiences column.) Please note: the patient in this example indicated they experienced no emotion because she experienced depersonalization at the time of the attack. Also, the patient resisted the urge to plan and to act during this event, therefore no suicidal planning or behaviors occurred.

A patient with MDD was feeling extremely depressed (suicidality related to a psychiatric disorder) was on the Observation Deck (the 86th floor) of the Empire State Building (location and means) and, after a short thought process, decided to kill himself (intent\* to die at the time of the event). He jumped (method) from the Observation Deck (date and intent to act at the time of the event are implied). The patient experienced severe emotion at the time and reported the event was moderately willful. Instead of falling all the way to the ground, he landed on the 85th floor with a hurt ankle. Initially, the patient was disoriented from the pain of his ankle and focused exclusively on that for 1 minute. Then the patient looked over the ledge on the 85th floor (means and location) and debated jumping again (method). (The date is implied.) Soon building security arrived and the patient moved close enough to allow them to help him inside. Building security reported having pulled the patient to safety. The patient reported having weighed his options and decided to not make a second jump, even though he considered it and at one point took steps closer to the ledge (the intent\* to act and to die at the time of the event are implied). The patient also reports experiencing moderate emotion during his time on the 85th floor and that his thought process while there was a little willful. This would be coded as two separate events. The first event was the suicide attempt not halted that was made and ended once the

patient jumped from the Observation Deck. The first event did not contain any suicidal ideation, any suicidal planning, or any suicidal preparatory behaviors. This first event would be coded as 10.3.3.4.(5#).ABCDIJ. The second event of suicidality started shortly after the patient landed on the 85th floor and when he considered a second jump from the 85th floor (suicidal planning). This second event was a suicide attempt halted and aborted. It is coded as an aborted action and not a halted action because the patient reported it as an aborted event. The T-CASA is designed to be patient centric. This second event is coded as 10.3.2.3.(2#,4#).ABCDIJL.

A patient experienced a delusion with suicidal content, which was followed by a thought process where she experienced ideation, planning, and engaged in preparatory behaviors. She reported the thought process was a little willful and experienced with extreme emotion. This event resulted in a suicide attempt halted where the patient wanted to die immediately (date and intent\* to die at the time of the event). During the event she decided to overdose on aspirin (method), had obtained and began taking the aspirin (means), and had the intent\* to plan and to act at the time of the event of suicidality, but the patient ultimately aborted the attempt. This is coded as 3.3.2.5.(1#-4#).ABDHIJL.

A patient was watching a movie where a person became depressed because a loved one died (Life Event). This patient found themself rooting for the depressed person in the movie to make and die from a suicide attempt. The patient experienced an increased interest in suicidal content in the media, accompanied by a desire for the suicidal subject to die. The patient reported experiencing this as a thought that was a little willful with severe emotion. The subject in the movie ended up thinking about suicide, but did not experience any other related suicidality phenomena. This is coded as 12.2.2.4.(1%).N.

A patient experienced a suicidal experience not classified in the Hierarchy of Experiences column. He reported experiencing a thought process that was moderately willful with moderate emotion. This event resulted in a suicidal preparatory behavior where he purchased rope (means) and planned to hang himself (method and suicidal planning). This is coded as 13.3.3.3.(2#,3#).AB.

A patient that is **not available to provide information**, reportedly due to a suicide attempt that resulted in a coma. This is coded as **14.10.10.10.(5#).P**.

A patient that does not attend their scheduled appointment for unknown reasons. This is coded as 14.10.10.10.(12#).P.

\* Intent is defined as the state of a person's mind that directs them towards a specific action.

#### Hierarchy of Experiences Definitions

- 1A. USIA (Unexpected Suicidal Impulse Attack) Physical and Ideation Subtype any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way that is associated with enough symptoms to meet the criteria for a USIA Physical and Ideation Subtype. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. See USIA Physical and Ideation Subtype criteria in the Suicidality Disorders Criteria.
- **1B. USIA (Unexpected Suicidal Impulse Attack) Ideation Only Subtype** any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way that is *not associated with enough physical symptoms* to meet the criteria for a USIA Physical and Ideation Subtype. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. See USIA Ideation Only criteria in the Suicidality Disorders Criteria.
- **1C.** Non-Suicidal Physical Symptom Attack (NSPSA) any event of physical symptoms usually experienced in an USIA that is *not associated with suicidal ideation*. See NSPSA criteria in the Suicidality Disorders Criteria.
- **1D. Non-Suicidal Self-Harm Impulse Attack, containing Transient Suicidal Ideation** any event of physical symptoms associated with self-harm ideation or an urge to self-harm that after its onset contains transient suicidal ideation. This event may occur as a precursor of or as the devolution of a suicidality disorder. In the event this occurs in isolation and not part of one of the specified suicidality disorders, consider it to be a part of the Suicidality Disorder, Not Elsewhere Specified.
- **2.** Hallucination with Suicidal Content any event of suicidality experienced exclusively as the direct and / or immediate consequence of an auditory or visual hallucination
- 3. **Delusion with Suicidal Content** any event of suicidality experienced exclusively as the direct and / or immediate consequence of a delusion (i.e. mistaken belief)
- **4. Dream of Suicidality** any event of suicidality experienced exclusively as the direct and / or immediate consequence of a dream
- 5. Suicidal Obsession any event of suicidality experienced exclusively as the direct and / or immediate consequence of any classic obsession typically seen in Obsessive Compulsive Disorder
- **6. Suicidal Compulsion** any event of suicidality experienced exclusively as the direct and / or immediate consequence of any compulsive behavior typically seen in Obsessive Compulsive Disorder
- 7. Suicidality Related to PTSD any event of suicidality experienced exclusively as the direct and / or immediate consequence of a Post-Traumatic Stress Disorder (PTSD)

- **8.** Suicidality Related to a Substance or Substances any event of suicidality following the ingestion of or exposure to a substance that occurred while under the influence of or withdrawal from the substance
- 9. Suicidality Related to Any Medical Illness(es) any event of suicidality restricted exclusively to or best explained by the direct effect of any general non psychiatric medical condition
- **10. Suicidality Related to Any Psychiatric Disorder(s)** any event of suicidality experienced exclusively as the direct and / or immediate consequence of any psychiatric disorder other than Impulse Attack Suicidality Disorder, any psychotic disorder, Substance Abuse or Dependence, or Obsessive Compulsive Disorder
- 11. Suicidality Related to Any Life Event(s) any event of suicidality experienced as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be obvious to any third party outside the clinician and the patient involved in the assessment.
- 12. Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die any event where a subject has increased interest in the suicidal content in a medium like a movie, a book, music, or the news which is accompanied by a desire for the suicidal subject in the medium to die.
- **13. Suicidal Experience Not Classified Above** suicidal presentation of symptoms of the event of suicidality that does not fit the definition of any other category in the Hierarchy of Experiences column
- **14. Non Suicidal Event or Unknown** event not related to suicidality or no information about the event experience is unknown

#### **Ideation Type Definitions**

- 1. Pre Awareness a sensation or experience without any ideation that occurs before the subject is able to interpret the meaning of the sensation or experience
- 2. Thought Only an ideation or mental identification of a sensation or an experience or an idea
- 3. Thought Process a series of thoughts connected by a common concept
- 4. In Background a prior decision about method, means, location, date, or any intent to plan, or to act, but was not undone and was not consciously thought about during the interval under study (i.e. the past week)

Example: several months ago the patient made the decision to kill himself when his parents die. The patient feels a responsibility to not die before his parents because he does not want his parents to experience the pain of his death. Although the patient did not think about it since his last visit, the patient also did not decide to not kill himself when his parents die. This prior decision is clinically relevant because there is the potential of his parents dying in a car accident at any time which could then trigger the patient's suicide attempt.

**10. Unknown** - presentation of symptoms of the event of suicidality that does not fit the definition of any other category in the Ideation Type column

#### Willfulness of Suicidality Definitions

willfulness of suicidality - any amount (> 0) of deliberately thinking about or planning to kill oneself <u>or</u> any amount (> 0) of deliberately engaging in suicidal behaviors (preparatory or otherwise)

## **Examples of Ideation Types**

A pre awareness is an experience that has not been identified or labeled by the mind. The thought is a static ideation. Once the thought begins to evolve it turns into a thought process.

Pre Awareness	<u>Thought</u>	Thought Process	<u>In Background</u>
sensation of hunger	I feel hungry.	I feel hungry. ► I should eat something. ► I want a sandwich. ► I will make a sandwich.	previously made plans to meet a friend for dinner
sensation of pain in the head	I have a headache.	I have a headache. ► I need to make this headache go away. ► I can take some aspirin to make it go away. ► I will take some aspirin.	the knowledge that chocolate always gives them a headache
experience of exhaustion and emotional pain	I am tired of hurting.	I am tired of hurting. ►  The pain never ends. ►  I want the pain to end.  ► Killing myself will  make the pain end. ► I  should kill myself.	prior decision to kill themselves before the end of the year

Please note that multiple thoughts do not necessarily indicate a thought process:

"I feel hungry" followed by "A sandwich would taste good" is not a thought process unless these two thoughts are somehow tied by another thought such as "A sandwich would satisfy this feeling of hunger."

"I should buy a gun" followed by "I should kill myself" is not a thought process unless these two thoughts are somehow tied by another thought such as "I should kill myself with a gun."

#### **Action Event Definitions**

- 1. Suicidal Ideation and / or Urge a desire or wish or need or preference to be dead <u>or</u> thought about being dead in relation to another experience of suicidality <u>or</u> a thought to hurt, harm, or injure oneself with the intent or awareness that one could die as a result <u>or</u> an urge to attempt suicide or urge to plan for a suicide attempt
- 2. Suicidal Planning any strategizing for or accounting of or thought(s) of future action(s) for a suicide attempt (including thoughts to make a plan). This planning may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.
- 3. Suicidal Preparatory Behavior any behavior(s) that are not viewed by the patient to be potentially lethal and stop short of taking action on a suicide attempt, but assist the patient in preparing to take action on a suicide attempt. These preparatory behavior(s) may concern, but are not limited to, the method, the means, the location, the date, and / or any unfinished tasks. We deliberately did not try to make subtypes of these behaviors or try to classify them in a hierarchal array as in FDA-CASA 2012 because there is no way to correctly generalize any such hierarchy to any individual case based on the gravity of the preparations. We judge the gravity of the preparatory behaviors based upon the patient's perception of the gravity rather than relying on the details. Here, as elsewhere, the focus of seriousness / gravity / danger is patient centric rather than circumstance or clinician centric. The patient's perspective on potential lethality can be inferred by a reasonable group of experts, if the patient is not available or refuses to provide it themselves, but should not always be assumed, unless the evidence is compelling.
- **4. Suicide Attempt Halted** any incomplete (set of) behavior(s) perceived by the patient to be potentially lethal connected with any level of intent\* ( > 0 ) to die that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The (set of) behavior(s) may be incomplete due to an interruption by events outside the patient's body or existence, or may be incomplete due to the patient aborting the already started, perceived lethal behavior(s) before it (they) are fully executed. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.
- 5. Suicide Attempt Not Halted any completed (set of) behavior(s) perceived by the patient to be potentially lethal that is connected with any level of intent\* ( > 0 ) to die that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The behavior does not have to be potentially injurious. Only the patient's perception that it is self-injurious is necessary. (See Examples 1 and 2 below.) The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.

Example 1: consider a cinnamon challenge competition for young adults. The goal in this challenge was to attempt to swallow a heaping tablespoon full of cinnamon within 60 seconds without drinking any water. To dissuade her child from participating in the challenge one mother warned the child that it would kill them. The belief that the cinnamon challenge was potentially lethal spread among teens. With this understanding a teen decides to make a suicide attempt by trying to swallow a heaping tablespoon of cinnamon. This counts as a suicide attempt, because the teen thought this would kill them.

Example 2: a child just finished watching the movie Snow White. In an attempt to harass the young child an older sibling offers the child an apple, which they tell their younger sibling, comes from the same tree as the one in the movie. With the assumption it would make them sleep forever, the child eats the apple. Because the child thought eating the apple would kill them, just as it put Snow White into the 'Sleeping Death', this event counts as a suicide attempt.

- 6. Died by Suicide / Death by Suicide / Completed Suicide a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless behavior that is connected with any level of intent\* ( > 0 ) to die as a result of said self-injurious or purposely reckless or negligent behavior. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury resulting in death is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt.
- 7. Self-Injury, Unknown Intent any self-injury where the intent\* of the patient is not known
- **8.** Fatality, Not Enough Information a fatality without enough information to include or to exclude the possibility of a completed suicide
- **9. Subject Alive, Not Enough Information** subject alive, but not available for reasons other than suicide <u>or</u> for uncertain reasons <u>or</u> lost to follow up
- 10. Fatality, Not by Suicide known death from causes other than suicide
- **11. Suicidal Experience Not Classified Above** suicidal presentation of symptoms of the event of suicidality that does not fit the definition of any other category in the Action Event column
- **12. Not Classified Above or Unknown** events of suicidality or injury / physical harm that does not fit the definition of any other category in the Action Event column
- \* Intent is defined as the state of a person's mind that directs them towards a specific action.

#### **Associated With Explanations**

- A. Suicide Method any thought of a way any person could attempt to kill themself. This includes, but is not limited to a specific method (e.g. gunshot wound to the head), a general method (e.g. exsanguination), an active method (e.g. an overdose of insulin), or a passive method (e.g. an insulin dependent diabetic failing to take their insulin).
- **B.** Suicide Means any thought of tool(s) any person could use to attempt to kill themself. Examples include a rope to hang themself or a gun to shoot themself. This includes, but is not limited to a specific means (e.g. their mother's sleeping medication) or a general means (e.g. some type of pills).
- **C.** Suicide Location any thought of a location any person could use to attempt to kill themself. Examples include their car in a closed garage to die via carbon monoxide poisoning or the Golden Gate Bridge where they could jump to their death. This includes, but is not limited to a specific location (e.g. the Sea of Trees in Japan) or a general location (e.g. the forest).
- **D.** Suicide Date any thought of a date any person could use to attempt to kill themself or any thought of a time frame within which they would like to die. This includes, but is not limited to a specific date (e.g. January 1st, 2016), a specific time frame (e.g. before next year), or a general date or time frame (e.g. soon).
- E. Intent\* to Plan in the Future any intent\* > 0 to make a plan to kill themself at some point in the future. This includes, but is not limited to the intent\* to consider the method, means, location, date, time frame, unfinished tasks, or involvement of others to be used in the suicide plan.
- F. Intent\* to Act in the Future any intent\* > 0 to take action to kill themself at some point in the future
- **G.** Intent\* to Die in the Future any intent\* > 0 to die as the result of a suicide attempt at some point in the future. This includes, but is not limited to both active and passive suicide attempts. (See suicide method for examples of active and passive methods.)
- **H.** Intent\* to Plan at Time of Event of Suicidality any intent\* > 0 to make a plan to kill themself during the event of suicidality being coded. This includes, but is not limited to the intent\* to consider the method, means, location, date, time frame, unfinished tasks, or involvement of others to be used in the suicide plan.
- I. Intent\* to Act at Time of Event of Suicidality any intent\* > 0 to take action to kill themself during the event of suicidality being coded. This includes, but is not limited to persons that actually make an attempt and those that did not make an attempt, but did have some intent\* > 0 to attempt to kill themself.

- J. Intent\* to Die at Time of Event of Suicidality any intent\* > 0 to die as the result of a suicide attempt during the event of suicidality being coded. This includes, but is not limited to both active and passive suicide attempts. (See suicide method for examples of active and passive methods.)
- K. Work On or Completion of Unfinished Tasks any time spent actively engaged in a task that a patient would like to complete prior to a suicide attempt. This includes, but is not limited to tasks the patient works on or completes with the mind-set that they will be closer to making a suicide attempt when the task is completed. This includes, but is not limited to tasks the patient works on or completes that they previously thought were important for them to complete prior to making a suicide attempt.
- L. Aborted Action any action that is stopped by the subject on their own initiative, without interruption by an external intervention
- M. Interrupted Action any action perceived by the patient to intervene to the extent of stopping the action from proceeding
- **N.** Life Event Related any social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be obvious to any third party outside the clinician and the patient involved in the assessment.
- O. Suicidal Urgent Need any event of suicidality experienced as a sudden urgent need to plan or to act in any suicidal way
- P. Provisional Information Needing Final Confirmation some information is available, but it is not yet definitive enough to accurately classify the event
- **Q. Substance Related** any event of suicidality following the ingestion of or exposure to a substance that occurred while under the influence of or withdrawal from the substance
- **R.** Medical Illness Related any event of suicidality restricted exclusively to or best explained by the direct effect of a general non psychiatric medical condition
- S. Substitute Variant the deliberate substitution of any method, means, location, date or behavior that is used for the purpose of substantially diminishing the risk of a lethal outcome. An example would include the patient that feels the strong urge to kill themself using an overdose of their medication. To deal with and lessen this urge they deliberately take several handfuls of M&Ms while pretending to themself that these are real tablets even though deep down they know this is very unlikely to be lethal. Such a tactic is used by some patients as a coping strategy.
- T. Passive (Suicidal) Ideation any thought of wishing or wanting or needing to be dead <u>or</u> of wishing or wanting or needing to not be alive anymore <u>or</u> the thought of being better off dead <u>or</u>

the desire to go to sleep *and never wake up* <u>or</u> the thought of not wanting to be alive anymore. The phrase "passive ideation" refers to ideas of dying that *do not require a change in usual behavior* on the part of the patient to die.

**U.** Active (Suicidal) Ideation – any thought of killing oneself. The phrase "active ideation" refers to ideas of dying that *requires a change in usual behavior* on the part of the patient to die.

<sup>\*</sup> Intent is defined as the state of a person's mind that directs them towards a specific action.

#### Additional Definitions

Suicidality - [sui (of oneself) + cide (a killing) + ality (the state of being real or actual)] - all suicidal phenomena including ideation, behaviors, impulses, command hallucinations, dreams, delusions, and / or precognitive experiences related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame, but did not appear as an ideation or behavior during that time frame. For example, a patient who previously made plans or intends to kill herself at a future date, but may not have thought about it during a particular time frame. (See event of suicidal intent, event of suicidality, episode of suicidality, and unexpected suicidal impulse attack for further clarification and examples.) This definition deliberately excludes theories or speculations about, predictions from or likelihood of a suicidal ideation or behavior. It also excludes experiences that may be comorbid with or correlated with core suicidal phenomena, but in and of themselves are not directly suicidal experiences (e.g. hopelessness, depression, anxiety, grief).

Suicide Plan - any strategy for or account of or thought(s) for future action(s) of a suicide attempt (including thoughts to make a plan). This plan may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

Suicidal Behavior - any (set of) behavior(s), either incomplete or completed, that are either 1) not viewed by the patient to be potentially lethal and stop short of taking action on a suicide attempt, but assist the patient in preparing to take action on a suicide attempt <u>or</u> 2) perceived by the patient to be potentially lethal, connected with any level of intent\* ( > 0 ) to die, that does not result in a fatality <u>or</u> 3) a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless or negligent behavior that is connected with any level of intent\* to die as a result of said self-injurious or purposely reckless behavior. (See the definitions for suicidal preparatory behavior, suicide attempt halted, suicide attempt not halted, and died by suicide for more details and information.)

Suicide Attempt - any (set of) behavior(s), either incomplete or completed, perceived by the patient to be potentially lethal, connected with any level of intent\* ( > 0 ) to die, that does not result in a fatality. The behavior may or may not result in any actual harm to the patient. The (set of) behavior(s) may or may not be incomplete due to an interruption by events outside the patient's body or existence, or may be incomplete due to the patient aborting\*\* the already started, perceived lethal behavior(s) before it (they) are fully executed. The intent to die can be inferred by a reasonable group of experts, but should not always be assumed, unless the evidence is compelling. Not all self-injury is suicidal. This intent to die refers to the intent at the time of initiation of the suicide attempt. \*\*The patient's desire to abort the already started, perceived lethal behaviors can be self-imposed, or imposed by another.

Suicidal Ideation - a desire or wish or need or preference to be dead <u>or</u> a thought about being dead in relation to another experience of suicidality <u>or</u> a thought to hurt, harm, or injure oneself with the intent or awareness that one could die as a result <u>or</u> any strategizing for or accounting of or thought(s) of future action(s) for a suicide attempt (including thoughts to make a plan).

The ideation may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

Non-Suicidal Self-Injurious Behavior / Non-Suicidal Self-Injury - any (set of) behavior(s), either incomplete or completed, that are either 1) not viewed by the patient to be potentially lethal and stop short of taking action on a self-injury attempt, but assist the patient in preparing to take action on a self-injury attempt  $\underline{or}$  2) perceived by the patient to not be potentially lethal, connected with no level of intent\* ( = 0 ) to die, that does not result in a fatality  $\underline{or}$  3) a fatality clearly and confidently (evidence beyond a reasonable doubt) caused by self-injurious or purposely reckless behavior that is connected with no level of intent\* to die ( = 0 ) as a result of this self-injurious or purposely reckless or negligent behavior. We do *not* consider non-suicidal self-injurious behavior to be suicidal behavior. However, as with the suicidal behaviors there may be interrupted, aborted, or neither interrupted nor aborted self-injurious behaviors.

Non-Suicidal Self-Injury Ideation - a desire or wish or need or preference to be injured <u>or</u> thought about being injured <u>or</u> a thought to hurt, harm, or injure oneself with NO intent ( = 0 ) to die as a result <u>or</u> any strategizing for or accounting of or thought(s) of future action(s) for a self-injury attempt (including thoughts to make a plan). The ideation may concern, but is not limited to, the method, the means, the location, the date, and / or any unfinished tasks.

<sup>\*</sup> Intent is defined as the state of a person's mind that directs them towards a specific action.

The T-CASA was designed to capture the details about the events of suicidality. The order of columns from left to right was deliberately designed to lend itself to a fluid sequence of data capture from the patient's perspective. It gives the clinician insight into the patient's experience by asking the patient to document the ideation type, the level of willfulness, and the emotion level associated with the experience. This data is not captured by other classification systems, leading some patients to feel as though their experience is not heard or understood or validated. Patients believe it is important to capture this data to provide these clinicians, researchers, and regulatory agencies accurate insight into their experience of these events. One patient reported that using the T-CASA in place of the C-CASA<sup>6</sup> and the FDA-CASA 2012<sup>7</sup> resulted in "feeling as though someone better understood" their experience.

#### How to use the T-CASA

The T-CASA is rated daily on the T-CASA Tracking Logs using the T-CASA Structured Interview below. The relevant number(s) from each column in the T-CASA is recorded on the Tracking Logs as illustrated in the sample row on the Tracking Logs below. In the terminal columns record the time spent and the number of that event combination that occurred within the day. This structured interview usually only needs to be followed exactly the first several times this data is captured. With practice patients quickly grasp the flow of capturing the suicidality event data using T-CASA. Subsequently, the structured interview is available to them as a script to follow in the event they need to refresh their memories on the details of implementation. It serves as a guidance document.

The T-CASA, unlike prior attempts to classify events, is uniquely designed to capture data in a patient-centric rather than a clinician-centric manner. The columns are ordered according to the usual flow of perceived experiences in the event of suicidality. The columns are completed from left to right in order. The reason for this is that the concepts in each column (from left to right) mirror how many subjects with suicidality experience the events. For many patients, the starting point in the sequence of conceptualizing a suicidality event is connecting to the triggering stimulus or lack thereof. Many patients view the categories listed in the Action Event column as a later progression of the event.

<sup>&</sup>lt;sup>6</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, *164*(7), 1035-1043.

<sup>&</sup>lt;sup>7</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156. htm. Accessed October, 5, 2012.

5.2

Structured Interview for T-CASA

#### T-CASA Structured Interview

Instructions for Clinician: Directions for the clinician are in regular font. Statements for the clinician to make or questions for the clinician to ask the patient are *italicized*.

Hand patient page 1 of the T-CASA.

Here is a list of experiences relating to suicide you might have had in the past (timeframe).

Which of the experiences listed in column 1 (Hierarchy of Experiences) did you experience over the past (timeframe)? Take your time in answering. Ask me to clarify if anything is unclear in the choices available. You can select more than one experience.

Clinician: Take note of all the experiences the patient reports from the Hierarchy of Experiences column in the order they are mentioned.

Start with the first experience mentioned.

When (insert experience here) occurred, which of the ideation types in the second column occurred with it? You can select more than one type.

If only one "Ideation Type" occurs, ask about "Willfulness Level" (Column 3):

When (insert BOTH the experience type AND the ideation type here) occurred, which of the willfulness levels in the third column occurred with it? You can select more than one level.

Continue this process, recording the combination, until an entire combination is completed. After an entire combination is completed:

Over the past (timeframe) how many times did this specific type of event occur?

Over the past (timeframe) how long did this specific type of event typically last?

Rule: complete each column until reaching a split. If there are no splits complete the columns for combination until all 6 columns are completed.

After identifying each unique type of event combination, go back to the start of each split and complete the documentation on the next column from left to right, for that unique event, as above.

For example, consider a patient who identifies the following 3 event combination sequences:

1B.3.1.2.1#.ADIOTU

1B.3.2.

1B.4.

After completing the first of the above 3, the clinician takes the patient through the second event combination (1B.3.2.). Since these 2 events are similar in their first 2 columns (1B.3.) and only differ in the third column, the split between these 2 occurs at the third column. Starting with the second event combination sequence above (1B.3.2.) the clinician asks about the next column of data for this event combination. If this second event combination results in further splits, the clinician repeats this data acquisition process for each event combination, starting at each split point, as above. Complete each column until reaching a split. Then complete each example until reaching a new split. Continue this process until you complete a combination. Then go back to the most recent split and complete that combination until it splits. And again and again.

To extend the above example, consider that the 1B.3.2. combination above results in the following 2 further combinations.

1B.3.2.3.

1B.3.2.1.

These two combinations are identical in their first 3 columns, but split into two in their 4<sup>th</sup> column. The clinician next asks for the information about the next column (column 5 - Action Event) on the first of these (1B.3.2.3.). The clinician tries to identify which Action Event experiences occurred together in the same event, and which occurred in separate events. For example, if both 1 and 2 occurred, they may have both occurred within the same event, or in separate events. The clinician must document all the Action Event categories that occurred in each specific event. Next the clinician records if the Action Events occurred in reality (#) <u>or</u> occurred in dreams, psychosis or delirium (&) <u>or</u> in the medium entertained (%). It might become 1B.3.2.3.1# and 1B.3.2.3.1#-2#. These 2 examples are now split at the 5<sup>th</sup> column. Each example needs to be continued into the next column until a further split is identified. The clinician now completes the next column until another split occurs.

1B.3.2.3.1#.CDIOTU

1B.3.2.3.1#-2#.ACDIJOTU

Once these 1B.3.2.3. combinations are recorded, the clinician then goes back to the 1B.3.2.1. combination above and completes the next column(s) until they split. And again and again. Until

the clinician returns to and completes the combination strings 1B.4 listed above.

In contrast to the scoring of columns 1 through 4 where there is one choice per column for each event, in columns 5 and 6 you are expected to endorse all options that apply for each event.

After each event combination is completed, ask the patient about the number of times each specific type of event occurred and the length of time each specific type of event typically lasted.

Continue the process recording each specific type of event until all combinations are recorded.

If any of these specific type of events occur regularly, come up with some name for the combination that is easily identifiable to the patient. The name needs to be individualized to each patient (e.g. ask "If you were going to give a name or label to this specific experience, what would you name it?").

Record each combination on the suicidality events T-CASA Tracking Scoring Log.

The above steps / process could be automated in a computer program <u>or</u> transparencies could be used to lie over the T-CASA columns and each pattern recorded on the overlay transparency one pattern on one transparency at a time <u>or</u> a flip book with 6 columns and one page for each of the items in each column. If using transparencies label them with the name the patient gave for that combination.

When a patient is familiar with this data gathering system, this process can be simplified. Clinicians can show the named transparencies collected on earlier visit(s) to the patient. Take note of any of the prior event combinations are repeated exactly or in any new variants. If using the transparencies, create a new transparency with this new combination. Create a name for this new combination and record it on the T-CASA Tracking Scoring Log. Take note of the number of times and the typical length of time for each combination.

While the above process appears to be quite complex and is difficult to explain, in practice, it can be done very quickly. This system permits the rapid daily recording of any presentation of suicidality event. Patients quickly recognize the particular combinations they recurrently experience. For each patient this is usually a small number and often relatively unique for that patient. Alternative systems of capturing specific information about suicidality events may appear simpler to follow and understand initially. However, in practice, such systems (most of which we have already tried to use in practice) turn out to be much more cumbersome and difficult and time consuming and even prone to inaccuracies. The numbering system above also lends itself to a coding pattern that is easier to analyze in spreadsheets and in statistical packages. This system captures more specific information about individual events of suicidality and allows investigators to more rapidly identify very specific signals of treatment emergent adverse events and signals of efficacy within these events. This was the primary goal in organizing this suicidality event data acquisition system in the manner outlined above.

5.3

T-CASA Tracking Logs

# Tampa - Classification Algorithm for Suicidality Assessment (T-CASA) Event Tracking Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

# See T-CASA and T-CASA Structured Interview:

Name	Date		Associated With Column:  A B C D E F G H I J K L M N O P Q R S T U														:					,		Count of	Typical	Clinician				
		1			4	5	Α	В	С	D	Е	F	G	Н		١ .	JI	K	L	М	N	0	Р	Q	R	S			Duration	Initials
need to be dead	01/01/13	13	2	1	2	1#																					Т	15	1 min	JG

Data on 01/01/13 is an example.

# Tampa - Classification Algorithm for Suicidality Assessment (T-CASA) Event Tracking Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

# See T-CASA and T-CASA Structured Interview:

Name	Week Number /		C	Colun	nn Nu								Δ	ssoc	iate	d Wi	th Co	lum	n:								Count of	Typical	Clinician	
	Visit Number		2	3		5	Α	В	С	D	Е	F	G	Н	1	J	K	L	М	N	0	Р	Q	R	S	Т	U	Events	Duration	Initials
need to be dead	Week 1	13	2	1	2	1#																				Т	٠   .	15	1 min	JG

Data for Week 1 is an example.

#### Outputs and Analysis of T-CASA Data

Data collected using the T-CASA can be output in two principal ways. The first is a simplified output, which records changes over the duration of the study in column 1, column 3, column 5, and column 6 (A – M, T, and U). This output could be in both tabular and line graph format. The trendline in the line graph format allows rapid visualization of any changes. It is possible to then study any significant changes at a granular level from the output of the raw data in the aggregate sample. This would show which element(s) within the events are moving in a negative or a positive direction. (See chapter 12.4 for a case study which used this method to analyze T-CASA data.) The second output is of all the raw data for the aggregate sample in a format similar to the sample T-CASA Tracking Log above. In the future it will be possible to analyze the data from the T-CASA using neural networks and the applied mathematics of non-linear systems theory to identify and predict change patterns in a more detailed and accurate manner than is currently possible using current standard statistical analyses.

# Classification of Suicidality Disorders and Episodes

# Classification of Suicidality Disorders

#### Introduction

Suicidality has been seen primarily as a complication of depression and / or mood disorders. Of the top 44 disorders in psychiatry, 36 have elevated standard mortality ratios (SMR) from suicide<sup>1</sup>. Suicide can occur even in the absence of depression. Depression is neither necessary nor sufficient for suicide.

Accumulating evidence suggests the possibility that suicidality may be a cluster of independent Axis I psychiatric disorders that can be comorbid with many other psychiatric disorders, but can also occur independently. There is an implicit assumption that the way to treat suicidality is to use antidepressants or mood stabilizers. This has lead to our neglecting to seek specific anti-suicidality medication treatments.

However, if we are to find specific anti-suicidality treatments we need several things in place. First we need a suicidality tracking scale that is sensitive in detecting an antisuicidality efficacy signal between drug and placebo. Second we need a classification of suicidality disorders. If we find a specific anti-suicidality medication and test it in a heterogeneous group of suicidal subjects it is very likely that it will fail to separate from placebo. This would be akin to putting everyone who walks into a clinic who complains of feeling depressed on an SSRI and then finding that in the ensuing study the SSRI failed to separate from placebo. The reason is because patients with the presenting complaint of depression may be suffering from Major Depressive Disorder or Bipolar Disorder or Cocaine Withdrawal or Schizoaffective Disorder or Mood Disorder Due to a General

<sup>&</sup>lt;sup>1</sup> Harris, E. C., & Barraclough, B. (1997). Suicide as an outcome for mental disorders. A meta-analysis. *The British Journal of Psychiatry*, 170(3), 205-228.

Medical Condition. With the exception of Major Depressive Disorder, the other disorders are not antidepressant sensitive, and in the case of Bipolar Depression, may even get worse. The conflicting response in all of these disorders would likely cancel each other out to drown the efficacy signal of the SSRI.

Similarly, in suicidality it is likely that the anti-suicidality medication that works for one suicidality disorder may fail in another and may even worsen the other. A classic example of this currently is that known, approved, effective antidepressants, even when they are effective for depression, can make those under 25 years more suicidal, those over 65 less suicidal, and those between the ages of 25 and 65 no better off than placebo in controlling their suicidality<sup>2</sup>. In this scenario the antidepressants appear to be making one group of suicidal patients better, the other worse, while the third group remain unchanged. It is likely that the same scenario will pertain to suicidality disorders. Hence, we need a phenotypic classification of suicidality disorders.

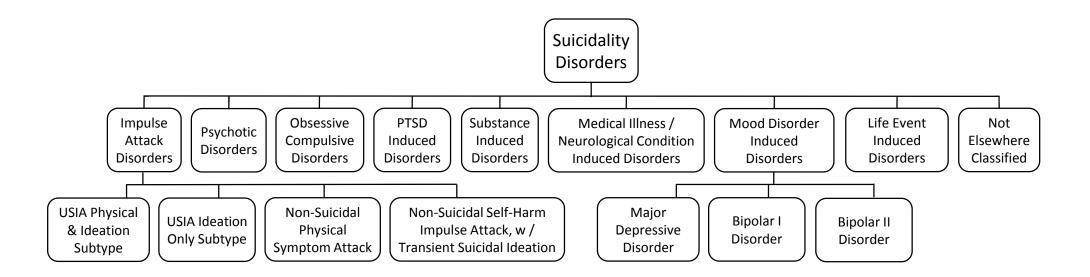
Someday, with better genotyping and biomarkers, phenotypic and genotypic / biomarker classifications will emerge to give us a more ideal classification of suicidality disorders. In the meantime it seems best to start with what appear to be clinical phenotypes in the interest of moving this agenda forward.

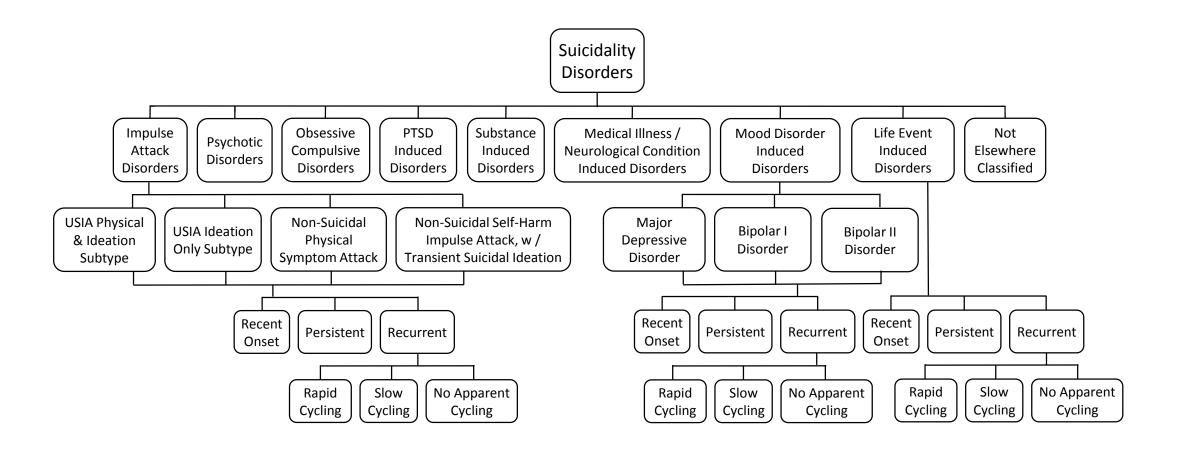
The classification presented below is based on phenomenological observations of suicidal patients and the mining of datasets of suicidal patients over time. It will inevitability be improved with better evidence and by trial and error.

We recommend that when planning studies with specific anti-suicidality treatments that the protocols be designed to sample each of these phenotypic classes of suicidality disorders one by one. In this way, we are more likely to have earlier success in isolating, which medications work for which of these suicidality disorders. This strategy may also help lead us to a better understanding of the pathophysiology of these disorders and to help us to identify classes of medications that may be uniquely effective for each suicidality disorder.

81

<sup>&</sup>lt;sup>2</sup> Stone, M., Laughren, T., Jones, M. L., Levenson, M., Holland, P. C., Hughes, A., ... & Rochester, G. (2009). Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. *Bmj*, 339.





# 6.1

# Suicidality Disorders Criteria

## Suicidality Disorders Definition of Terms

- life event in a Life Event Induced Suicidality Disorder social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
- **event** something that occurs during a particular interval of time and is followed by a noticeable change in the core phenomena of the event.
- **event of suicidal intent** intent to plan or to act in any suicidal way that spans over or occurs during any period of 24 hours.
  - Example 1: Subject is under immense levels of stress and reacts with suicidal intent for only 20 minutes.
  - Example 2: Subject previously made the decision to definitely commit suicide when their parents die and to not act upon it until then. Even though the intent is not thought about on an ideation level for periods of time it spans over this time frame while the subject never reverses this conditional decision.
- event of suicidality 1 event involving any singular suicidal phenomenon or combination of suicidal phenomena including ideation, behavior, impulse, command hallucination, dream,

delusion, and / or precognitive experience related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame even if it didn't appear as an ideation or behavior during that time frame. (See suicidality for an example of suicidal phenomena that arches across time.)

episode of suicidality - any period of at least 1 event of suicidality that is followed by at least 24 hours without an episode of suicidality of the same type. This 24 hours without suicidality must not be the result of any obvious distracting life event intruding to preclude the event(s) of suicidality.

Example 1: A <u>masculine subject</u> was suicidal every day for 2 weeks. Within that 2 weeks, his father experienced chest pain and was taken to the hospital for observation and tests. After 24 hours, the subject's father was deemed to be dehydrated. The stress from the uncertainty of his father's condition precluded the regularly occurring suicidality for those 24 hours his father was at the hospital. Although 24 hours passed without suicidality, the 2 weeks of suicidality are coded as 1 episode of suicidality, rather than 2, because the 24 hours without suicidality was due to this distracting life event.

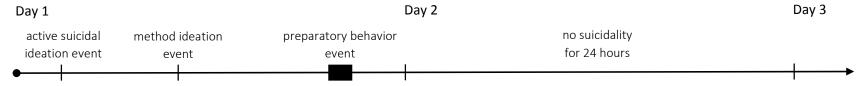
Example 2: A <u>feminine subject</u> experienced one auditory command hallucination in the morning telling her to kill herself and another similar hallucination in afternoon on the same day. She did not experience any suicidal hallucinations in the following 24 hours. This would be coded as 1 Psychotic Suicidality Episode. (Depending upon the number of Psychotic Suicidality Episodes in the subject's lifetime, the subject may also meet the criteria for Psychotic Suicidality Disorder.)

Example 3: A gender neutral subject experienced zes first ever auditory command hallucination in the morning telling zem to kill zemself. Later that evening, ze experienced zes first ever Unexpected Suicidal Impulse Attack (USIA). Ze did not experience any suicidality for over 24 hours following the USIA. This would be coded as 1 Psychotic Suicidality Episode comorbid with Impulse Attack Suicidality Disorder, Fresh Onset. Choosing an appropriate pronoun (words) that are equivalent to he / she or to himself / herself or to his / her is still an open debate. We have chosen here to use the terms "ze", "zes", "zem", and "zemself" as the gender neutral pronouns equivalent respectively to "he", "his", "him", and "himself". Our best guidance at this juncture is to ask, out of respect for each subject, what is their pronoun and to use that pronoun for that subject. Then follow this preference throughout the interview. This issue is of special importance in the LGBTQIAA+ community that currently have higher rates of suicidality than the general population.

episode of suicidal normalcy - a period of time with 100% freedom from any event of suicidality for at least 1 day that is not the result of any obvious distracting life event intruding to preclude the event(s) of suicidality. (See Example 1 under episode of suicidality for clarification.)

## Distinction Between Event and Episode and Disorder

We use the terms *Event* of Suicidality, *Episode* of Suicidality and Suicidality *Disorder* in several chapters throughout the book. These terms are distinct from each other. The distinction between an event of suicidality and an episode of suicidality and a suicidality disorder is shown graphically in the following diagram.



Each one of 3 (active suicidal ideation, method ideation, and preparatory behavior) is one event.

Day one is one episode because the 3 events span a 24-hour period and it is followed by 24 hours of no suicidality.

For some disorders this 1 episode is only an episode.

For other disorders this 1 episode can be a disorder (e.g. episode of mania  $\rightarrow$  bipolar disorder).

Phenomenon - something that can be observed.

**Event** - something notable that happens.

Episode - an event that is distinctive and separate although part of a larger series.

- You can track events as they happen (and the related phenomena).
- After the fact, you can retroactively look-back to identify separate episodes. If 24 hours have passed since the last episode of suicidality and you are now experiencing an event of suicidality then you are in a new episode.

**Disorder** - a condition that is not normal or healthy; an ailment that affects the function of mind or body; a disruption of normal physical or mental functions.

**intent** - the state of a person's mind that directs them towards an action.

non-suicidal physical symptoms attack (NSPSA) - the physical symptoms that accompany a physical and ideation subtype unexpected suicidal impulse attack, but this subtype does not present with the suicidal ideation or behaviors specified in the physical and ideation subtype criteria. In order to meet the criteria for this episode the patient must have experienced one full USIA (see definition and later criteria below) in their lifetime. This type of episode may be the last to go when symptoms subside, or the first one to appear when the condition begins to recur (see NSPSA criteria).

suicidality [sui (of oneself) + cide (a killing) + ality (the state of being real or actual)] - all suicidal phenomena including ideation, behaviors, impulses, command hallucinations, dreams, delusions, and / or precognitive experiences related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame, but did not appear as an ideation or behavior during that time frame. For example, a patient who previously made plans or intends to kill herself at a future date, but may not have thought about it during a particular time frame. (See event of suicidal intent, event of suicidality, episode of suicidality, and unexpected suicidal impulse attack for further clarification and examples.) This definition deliberately excludes theories or speculations about, predictions from or likelihood of a suicidal ideation or behavior. It also excludes experiences that may be comorbid with or correlated with core suicidal phenomena, but in and of themselves are not directly suicidal experiences (e.g. hopelessness, depression, anxiety, grief).

unexpected suicidal impulse attack (USIA) - any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. These events can occur either with or without the physical symptoms described in the USIA Physical and Ideation Subtype. See USIA Physical and Ideation Subtype criteria below. If the presentation of symptoms is not associated with enough physical symptoms to meet the criteria for a USIA Physical and Ideation Subtype, then this is a USIA Ideation Only Subtype. See USIA Ideation Only criteria below.

# Prior Disorder Classification vs. Suicidality Disorder Classification

The experience of suicidality must be looked at in the absence of any diagnosis of other disorders or medical conditions. The presence of a prior diagnosis does not necessarily mean the suicidality is related to the prior diagnosis.

Not all patients that have a history of psychosis will experience suicidality related to a psychosis. If a person with schizophrenia is now suicidal as a result of being raped or after being abused by their mother, this suicidality would be classified as a Life Event Induced Suicidality. Because this event of suicidality was not experienced as a direct and / or immediate consequence of an auditory command hallucination or a delusion, this is not counted as an event of suicidal psychosis. This event of suicidality emerged a direct and / or immediate consequence of the rape or abuse (which are life events). This example is clearly different from a patient with schizophrenia that is experiencing a command hallucination to kill themself. This latter patient would be classified as having experienced an event of Psychotic Suicidality.

A patient with a history of a major depressive disorder may find that taking a smoking cessation medication causes them to become suicidal. This patient's experience of suicidality is due to the medication and is not a direct and / or immediate result of a primary mood disorder. This event of suicidality would be classified as a Substance Induced Suicidality. This is clearly different from a patient with Major Depressive Disorder starting to think about suicide as an alternative to the crippling depression they are experiencing. This latter patient would be classified as having experienced an event of Mood Disorder Induced Suicidality.

A patient with a history of Obsessive Compulsive Disorder finds that they have been diagnosed with amyotrophic lateral sclerosis (ALS). As this patient learns more about ALS, they worry about dying from the disease and start to think about killing themself before the ALS slowly suffocates them. This patient's suicidality was not a direct and / or immediate consequence of an obsession or a compulsion, but was a result of the diagnosis of the medical illness. This patient's suicidality would be classified as Medical Illness Induced Suicidality. This is in contrast with a patient that experiences an obsessive thought to kill themself. This latter patient would be classified as having experienced an event of Obsessive Compulsive Suicidality.

Suicidality Disorders Criteria

# Unexpected Suicidal Impulse Attack (USIA) Episode

Any of the following subtypes:

## Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype

(B + D + E + F + G) are mandatory),  $A \pm H \pm I$  are usual, but not mandatory to diagnose such episodes if the evaluation is done within the first 3 days after the episode.

- A. **Prodromal Aura**: An unexpected, unprovoked onset of a unique aural prodromal perceptual distortion with an impending awareness of a partial or a complete loss of control. It may last up to 5 minutes, but typically lasts between 30 seconds and 3 minutes.
- B. **Physical Symptoms**: A sudden onset of 2 or more of the following, experienced within a 10 minute time frame:
  - 1. sensation of external pressure on the upper central forehead
  - 2. depersonalization experienced over all or most of the body or derealization or amnesia for blocks of time ranging from minutes to hours with a sudden onset and offset (i.e. "feeling outside of or detached from part or all of the body" or "feeling that things around you are strange, detached, or unfamiliar" or "cannot recall what happened for a block of time even though there was no other loss of consciousness")
  - 3. pain surrounding the thoracic spine
  - 4. increased heart rate or awareness of heart racing in the neck arteries
  - 5. difficulty or more effort in breathing or interrupted breathing or slow, shallow breathing
  - 6. an unexplained sensation of an interruption in swallowing or an unexplained increased frequency in swallowing or each swallowing event is prolonged without explanation or an unexplained repetitive swallowing
  - 7. chest pain or pressure or discomfort
  - 8. frontal headache

Note: When the symptoms in criterion B occur, they are often sequenced in the above order.

- C. Pre Awareness Need to be Dead Sensation: A sensation occurs that the subject often later associates with a need to be dead. This sensation is pre awareness. It may be immediately followed by a cognitive awareness of the need to be dead or the suicidal impulse (criterion D). This sensation at times can occur without any awareness of the need to be dead. This sensation is less likely to occur if there is full depersonalization or amnesia. This sensation may last less than 1 second or as long as 10 seconds, but usually lasts 5 seconds. (This is usual in an USIA, but is not mandatory.)
  - Note 1: Typically this sensation occurs at each peak of symptoms (e.g. in Figure 6.2.1 in chapter 6.2 on Impulse Attack Suicidality Disorder, it occurred at 9 minutes and 30 seconds; at 30 minutes and 20 seconds; at 80 minutes and 30 seconds; and at 2 hours, 8 minutes, 30 seconds at the peak of each symptom surge).

Note 2: Subjects may find it difficult to put this experience into words.

Note 3: This sensation can occur on its own outside the context of an unexpected suicidal impulse attack.

- D. **Suicidal Impulse**: 1 or more of the following, experienced within a 20 minute time frame either before, during, or after the symptoms in criterion B, but it is usually within the same 10 minute time frame as criterion B:
  - 1. the unexpected, intrusive or overwhelming or engulfing need (with varying degrees of urgency) to attempt suicide
  - 2. the unexpected, intrusive or overwhelming or engulfing need (with varying degrees of urgency) to plan for a suicide attempt
  - Note 1: The urge in either D1 or D2 always reduces and usually displaces any positive influence memories or external events have in reducing suicidal symptoms.
  - Note 2: D1 or D2 may be associated with a sense that resisting the urge is wrong or that they are "not allowed" to resist the urge.
  - <u>Note 3</u>: This urge may be experienced like two shifts in gear in the intensity escalation curve of its profile. There may be 2 very brief reductions during the course of escalation before the escalation continues.
- E. **Sensory**: One of the following are present in conjunction with criterion D:
  - 1. all sensations are muffled or muted (visual, auditory, tactile)
  - 2. instinctive detection and awareness in the immediate vicinity of means that could be used to attempt suicide
  - 3. time becomes distorted (slows down)
- F. Gambit: Either 1 or 2 and either 3 or 4 in conjunction with criterion D:
  - 1. resisting the urge to plan may evolve into an urge to act within 20 to 60 minutes
  - 2. resisting either the urge to plan or the urge to act <u>or</u> both the urge to plan and the urge to act results in an increase in the intensity and duration of suicidal and physical symptoms
  - 3. giving into the urge to plan, even if it has evolved into the urge to act, results in a reduction of suicidal and physical symptoms
  - 4. giving into the urge to act results in a reduction of suicidal and physical symptoms

Note: A Gambit is any maneuver that seeks to gain an advantage by making a sacrifice.

- G. **Hours After**: 1 or more of the following, within 24 hours after the first symptom in criterion B:
  - 1. exhaustion
  - 2. severe sleepiness
  - 3. aches in parts of the body associated with depersonalization
  - 4. diarrhea
- H. Days After: 1 or both of the following:
  - 1. within 3 days of the onset of criterion A, but usually not within the first 24 hours, an increase in the intensity of depression or an increase in the intensity and duration of willful suicidal ideation and / or behavior
  - 2. craving for fatty (calcium-rich) foods about a week after the onset of criterion A

I. **Minimization**: At multiple points in the above process (criterion A through H), there is a <u>need to minimize</u> the symptoms to self (because this makes it easier to cope) and to others (because they may overreact and may not understand). There may also be a fear others will interpret the above symptoms as attention seeking.

#### Additional Associated Phenomena

Note 1: A situational panic / anxiety attack may occur at any time during the above process after criterion A and before criterion G. This typically occurs with 10 - 50% of the USIAs. When such a situational panic / anxiety attack occurs it results in a temporary pause in the USIA process. The USIA process will subsequently resume only when the situational panic / anxiety attack subsides. In the early natural history of USIAs these situational panic / anxiety attacks occur more frequently. Later in the natural history these situational panic / anxiety attacks become less frequent with the evolution of coping skills.

<u>Note 2</u>: Most people experiencing an USIA are so focused on trying to live through the attack that they may not be able to identify or be fully aware of all of the component features associated with the attack.

<u>Note3:</u> These attacks may be associated with varying degrees of emotions from no emotional reaction at all to high alarm or distress.

# Unexpected Suicidal Impulse Attack Episode Ideation Only Subtype (Without Physical Symptoms)

(A + B are mandatory)

- A. Subject has 1 or more of the following:
  - 1. the unexpected, intrusive or overwhelming or engulfing need (with varying degrees of urgency) to attempt suicide
  - 2. the unexpected, intrusive or overwhelming or engulfing need (with varying degrees of urgency) to plan for a suicide attempt
- B. Subject fails to meet criteria A, or B, or E, or G for an Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype
- C. Subject may or may not meet criteria C, or F, or H, or I for an Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype

These attacks may be associated with varying degrees of emotions from no emotional reaction at all to high alarm or distress.

# Non-Suicidal Physical Symptoms Attack (NSPSA) Episode

(A + B are mandatory)

- A. Subject meets criteria B, and E, and G for an Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype
- B. Subject fails to meet criteria C, or D, or F for an Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype
- C. Subject may or may not meet criteria A or H or I for an Unexpected Suicidal Impulse Attack Episode Physical and Ideation Subtype

These attacks may be associated with varying degrees of emotions from no emotional reaction at all to high alarm or distress.

# SC1. Impulse Attack Suicidality Disorder

(A is mandatory)

- A. One or both of the following:
  - 1. at least 1 unexpected suicidal impulse attack *physical and ideation subtype* in patient's lifetime.
  - 2. at least 1 unexpected suicidal impulse attack ideation only subtype in patient's lifetime.
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.

#### **Specifiers**

Characteristic most recent episode, symptom pattern, timeframes, age of onset, and current level of symptoms in Impulse Attack Suicidality Disorder may be further clarified using the following specifiers:

#### 01 Most Recent Episode

- 01 **USIA Physical and Ideation Subtype Episode** This specifier should be used if the most recent episode is an unexpected suicidal impulse attack physical and ideation subtype. See prior criteria.
- 02 **USIA Ideation Only Subtype Episode** This specifier should be used if the most recent episode is an unexpected suicidal impulse attack ideation only subtype. See prior criteria.
- 03 **Expected Suicidal Impulse Attack Episode** This specifier should be used if the most recent episode meets most criteria of either subtype of unexpected suicidal impulse attack except the patient expected the impulse attack to occur as a direct and immediate consequence of a stressor. This is similar to the expected / situational type of panic attacks.
- 04 Non-Suicidal Physical Symptom Attack Episode This specifier should be used if the most recent episode is a non-suicidal physical symptom attack subtype. See prior criteria. This

type of episode may be the last to go when symptoms subside, or the first one to appear when the condition begins to recur.

#### 02. Symptom Pattern

- 01 Fresh Onset This specifier should be used if all of the following criteria (1 + 2 + 3) are met:
  - 1. at least 1 event of suicidality within a 3 month period.
  - 2. if more than 1 event of suicidality within a 3 month period, the events cannot continue on a daily basis for longer than 3 months.
  - 3. if history of previous episode(s) of suicidality followed by episode(s) of suicidal normalcy, no more than 2 total episodes of suicidality in patient's lifetime, one of which must be an unexpected suicidal impulse attack.
- 02 **Persistent** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4) are met:
  - 1. at least 12 events of suicidality within a 3 month period (not all 12 of these events of suicidality need to be USIA episodes; some of them can be made of other events of suicidality).
  - 2. events of suicidality occur on a daily basis for more than 3 months with the exception of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 3. events of suicidality cannot be absent for more than 3 days in succession and their absence cannot adhere to any clear cycle.
  - 4. criteria 1 through 3 are present for at least 3 months in patient's lifetime.
- 03 **Recurrent, Rapid Cycling** This specifier should be used if all of the following criteria (1+2+3+4+5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime, one of which must be an unexpected suicidal impulse attack.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for 1 day to 3 months and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.
- 04 **Recurrent, Slow Cycling** This specifier should be used if all of the following criteria (1+2+3+4+5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime, one of which must be an unexpected suicidal impulse attack.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the  $3^{rd}$  episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for more than 3 months and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.

- 05 **Recurrent, No Apparent Cycling** This specifier should be used if all of the following criteria (1+2+3+4+5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime, one of which must be an unexpected suicidal impulse attack.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy do not adhere to any clear pattern and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the unexpected suicidal impulse attack symptoms have occurred within the past 2 weeks.
- **02 Recent Past** This specifier should be used if the timeframe for the unexpected suicidal impulse attack symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the unexpected suicidal impulse attack symptoms occurred more than 1.5 years ago.

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs from the age of 6 through the age of 11.
- **O3** Adolescence Onset This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs from the age of 18 through the age of 24.
- **05 Mid Adulthood Onset** This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs from the age of 25 through the age of 64.
- **06** Late Adulthood Onset This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the unexpected suicidal impulse attack symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of unexpected suicidal impulse attack, which has *not yet responded positively* (< 50% response).
- **O2 Still Symptomatic Response but Not Yet Remission** This specifier should be used if the patient still has symptoms of unexpected suicidal impulse attack, which is *somewhat* controlled, but has *not yet become under complete control* (≥ 50% response, but < 70% response).

**O3 Still Symptomatic – Remission but Not Yet Recovered** - This specifier should be used if the patient still has symptoms of unexpected suicidal impulse attack, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).

**O4 Recovered / Under Complete Control** - This specifier should be used if the patient is no longer having any unexpected suicidal impulse attack symptoms and is not on any active medications  $\underline{or}$  is under complete control on medication  $\underline{or}$  is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Psychotic Suicidality Episode

#### (A + B are mandatory)

- A. at least 1 event of suicidality experienced exclusively as the direct and / or immediate consequence of an auditory command hallucination or a delusion.
- B. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- C. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- D. before assigning the description of Psychotic Suicidality Episode to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder in a patient with psychotic disorder.
- E. please note: if a patient has more than 2 episodes of Psychotic Suicidality in their lifetime, their symptoms may also meet the criteria for Psychotic Suicidality Disorder.

# SC2. Psychotic Suicidality Disorders

#### (A is mandatory)

- A. at least 3 events of suicidality experienced exclusively as the direct and / or immediate consequence of an auditory command hallucination or a delusion.
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- C. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Psychotic Suicidality Disorder.

#### Specifiers

Characteristic timeframes, specific mood disorder with psychotic features or psychotic disorder involved, age of onset, and current level of symptoms in Psychotic Suicidality Disorder may be further clarified using the following specifiers:

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the psychotic suicidality symptoms have occurred within the past 2 weeks.
- **02 Recent Past** This specifier should be used if the timeframe for the psychotic suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the psychotic suicidality symptoms occurred more than 1.5 years ago.

#### 04 Disorder Involved

Specify the specific mood disorder with psychotic features or psychotic disorder involved:

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the psychotic suicidality symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the psychotic suicidality symptoms occurs from the age of 6 through the age of 11.
- **03** Adolescence Onset This specifier should be used if the first onset of the psychotic suicidality symptoms occurs from the age of 12 through the age of 17.
- **O4 Early Adulthood Onset** This specifier should be used if the first onset of the psychotic suicidality symptoms occurs from the age of 18 through the age of 24.
- **O5 Mid Adulthood Onset** This specifier should be used if the first onset of the psychotic suicidality symptoms occurs from the age of 25 through the age of 64.
- **06** Late Adulthood Onset This specifier should be used if the first onset of the psychotic suicidality symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the psychotic suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of psychotic suicidality, which has *not yet responded positively* < 50% response).
- **O2** Still Symptomatic Response but Not Yet Remission This specifier should be used if the patient still has symptoms of psychotic suicidality, which is *somewhat* controlled, but has *not* yet become under complete control (≥ 50% response, but < 70% response).
- **O3 Still Symptomatic** Remission but Not Yet Recovered This specifier should be used if the patient still has symptoms of psychotic suicidality, which is *mostly* controlled, but has *not yet become under complete control* (≥ 70% response, but [≤ 100% response for < 3 months]).
- **O4 Recovered / Under Complete Control** This specifier should be used if the patient is no longer having any psychotic suicidality symptoms and is not on any active medications <u>or</u> is under complete control on medication <u>or</u> is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq 3$  months).

# **Obsessive Compulsive Suicidality Episode**

#### (A + B are mandatory)

- A. at least 1 event of suicidality experienced exclusively as the direct and / or immediate consequence of an obsession or a compulsion.
- B. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- C. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- D. before assigning the description of Obsessive Compulsive Suicidality Episode to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder in a patient with Obsessive Compulsive Disorder.
- E. please note: if a patient has more than 2 episodes of Obsessive Compulsive Suicidality in their lifetime, their symptoms may also meet the criteria for Obsessive Compulsive Suicidality Disorder.

# SC3. Obsessive Compulsive Suicidality Disorder

#### (A is mandatory)

- A. at least 3 events of suicidality experienced exclusively as the direct and / or immediate consequence of an obsession or a compulsion.
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- C. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Obsessive Compulsive Suicidality Disorder.

#### **Specifiers**

Characteristic timeframes, age of onset, and current level of symptoms in Obsessive Compulsive Suicidality Disorder may be further clarified using the following specifiers:

## 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the obsessive compulsive suicidality symptoms have occurred within the past 2 weeks.
- **02 Recent Past** This specifier should be used if the timeframe for the obsessive compulsive suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the obsessive compulsive suicidality symptoms occurred more than 1.5 years ago.

#### 09 Age of Onset

- **O1 Early Childhood Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs through the age of 5.
- **O2 Latency Childhood Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs from the age of 6 through the age of 11.
- **03 Adolescence Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs from the age of 18 through the age of 24.
- **05 Mid Adulthood Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs from the age of 25 through the age of 64.
- **06** Late Adulthood Onset This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the obsessive compulsive suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of obsessive compulsive suicidality, which has *not yet responded positively* < 50% response).
- **02 Still Symptomatic** Response but Not Yet Remission This specifier should be used if the patient still has symptoms of obsessive compulsive suicidality, which is *somewhat* controlled, but has *not yet become under complete control* ( $\geq$  50% response, but < 70% response).
- **O3 Still Symptomatic Remission but Not Yet Recovered** This specifier should be used if the patient still has symptoms of obsessive compulsive suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).
- **O4 Recovered / Under Complete Control** This specifier should be used if the patient is no longer having any obsessive compulsive suicidality symptoms and is not on any active medications  $\underline{or}$  is under complete control on medication  $\underline{or}$  is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Posttraumatic Stress Disorder Induced Suicidality Episode

(A + B are mandatory)

- A. at least 1 event of suicidality experienced exclusively as the direct and / or immediate consequence of Posttraumatic Stress Disorder (PTSD).
- B. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- C. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- D. before assigning the description of Posttraumatic Stress Disorder Induced Suicidality Episode to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder in a patient with Posttraumatic Stress Disorder.
- E. please note: if a patient has more than 2 episodes of Posttraumatic Stress Disorder Induced Suicidality in their lifetime, their symptoms may also meet the criteria for Posttraumatic Stress Disorder Induced Suicidality Disorder.

# SC4. Posttraumatic Stress Disorder Induced Suicidality Disorder

(A is mandatory)

- A. at least 3 events of suicidality experienced exclusively as the direct and / or immediate consequence of Posttraumatic Stress Disorder (PTSD).
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- C. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Posttraumatic Stress Disorder Induced Suicidality Disorder.

#### Specifiers

Characteristic timeframes, age of onset, and current level of symptoms in Posttraumatic Stress Disorder Induced Suicidality Disorder may be further clarified using the following specifiers:

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the PTSD induced suicidality symptoms have occurred within the past 2 weeks.
- **O2 Recent Past** This specifier should be used if the timeframe for the PTSD induced suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the PTSD induced suicidality symptoms occurred more than 1.5 years ago.

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs from the age of 6 through the age of 11.
- **03 Adolescence Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs from the age of 18 through the age of 24.
- **05 Mid Adulthood Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs from the age of 25 through the age of 64.
- **06 Late Adulthood Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the PTSD induced suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of PTSD induced suicidality, which has *not yet responded positively* < 50% response).
- **O2 Still Symptomatic Response but Not Yet Remission** This specifier should be used if the patient still has symptoms of PTSD induced suicidality, which is *somewhat* controlled, but has *not yet become under complete control* (≥ 50% response, but < 70% response).
- 03 Still Symptomatic Remission but Not Yet Recovered This specifier should be used if the patient still has symptoms of PTSD induced suicidality, which is *mostly* controlled, but has *not* yet become under complete control ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).
- **O4 Recovered / Under Complete Control** This specifier should be used if the patient is no longer having any PTSD induced suicidality symptoms and is not on any active medications <u>or</u> is under complete control on medication <u>or</u> is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Substance Induced Suicidality Episode

(A + B + C + D are mandatory)

- A. at least 1 event of suicidality within 6 weeks following the ingestion of or exposure to a substance.
- B. at least 1 event of suicidality must have occurred while under the influence of or during the withdrawal from the substance.
- C. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- D. there is evidence from the history, physical examination, or laboratory findings of the event(s) of suicidality occurring during or up to 6 weeks after the ingestion or exposure to a substance that is known to have an effect on the central nervous system.
- E. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- F. before assigning the description of Substance Induced Suicidality Episode to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder in a patient with substance use or abuse or dependence.
- G. please note: if a patient has more than 2 episodes of Substance Induced Suicidality in their lifetime, their symptoms may also meet the criteria for Substance Induced Suicidality Disorder.

# SC5. Substance Induced Suicidality Disorders

(A + B + C + D are mandatory)

- A. at least 3 events of suicidality within 6 weeks following the ingestion of or exposure to a substance.
- B. at least 3 events of suicidality must have occurred while under the influence of or during the withdrawal from the substance.
- C. there is evidence from the history, physical examination, or laboratory findings of the event(s) of suicidality occurring during or up to 6 weeks after the ingestion or exposure to a substance that is known to have an effect on the central nervous system.
- D. if more than 1 event of suicidality occur following the ingestion of or exposure to a substance, the daily occurrence of events cannot exceed 6 weeks.
- E. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- F. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Substance Induced Suicidality Disorder.

#### Specifiers

Characteristic timeframes, specific substance(s) involved, time of onset, age of onset, and current level of symptoms in Substance Induced Suicidality Disorder may be further clarified using the following specifiers:

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the substance induced suicidality symptoms have occurred within the past 2 weeks.
- **02 Recent Past** This specifier should be used if the timeframe for the substance induced suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the substance induced suicidality symptoms occurred more than 1.5 years ago.

#### 05 Substance

Specify the specific substance(s) involved:

#### 06 Time of Onset

- **01 Onset During Ingestion Phase** This specifier should be used if the onset of the substance induced suicidality symptoms occurred during ingestion phase.
- **O2 Onset During Withdrawal** Phase- This specifier should be used if the onset of the substance induced suicidality symptoms occurred during withdrawal phase.

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the substance induced suicidality symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the substance induced suicidality symptoms occurs from the age of 6 through the age of 11.
- **03** Adolescence Onset This specifier should be used if the first onset of the substance induced suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the substance induced suicidality symptoms occurs from the age of 18 through the age of 24.
- **O5 Mid Adulthood Onset** This specifier should be used if the first onset of the substance induced suicidality symptoms occurs from the age of 25 through the age of 64.
- **06** Late Adulthood Onset This specifier should be used if the first onset of the substance induced suicidality symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the substance induced suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of substance induced suicidality, which has *not yet responded positively* < 50% response).
- **O2 Still Symptomatic Response but Not Yet Remission** This specifier should be used if the patient still has symptoms of substance induced suicidality, which is *somewhat* controlled,

but has *not yet become under complete control* (≥ 50% response, but < 70% response).

03 Still Symptomatic – Remission but Not Yet Recovered - This specifier should be used if the patient still has symptoms of substance induced suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).

**O4 Recovered / Under Complete Control** - This specifier should be used if the patient is no longer having any substance induced suicidality symptoms and is not on any active medications  $\underline{or}$  is under complete control on medication  $\underline{or}$  is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Medical Illness / Neurological Condition Induced Suicidality Episode

(A + B + C + D are mandatory)

- A. at least 1 event of suicidality.
- B. there is evidence from the history, physical examination, or laboratory findings of the event(s) of suicidality being restricted exclusively due to the direct effect of a general non psychiatric medical illness and / or neurological condition (e. g. Huntington's Disease).
- C. event(s) of suicidality *do not persist* following the resolution of the general non psychiatric medical illness and / or neurological condition.
- D. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- E. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- F. before assigning the description of Medical Illness / Neurological Condition Induced Suicidality Episode to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder in a patient with a general non psychiatric medical condition.
- G. please note: if a patient has more than 2 episodes of Medical Illness / Neurological Condition Induced Suicidality in their lifetime, their symptoms may also meet the criteria for Medical Illness / Neurological Condition Induced Suicidality Disorder.

# SC6. Medical Illness / Neurological Condition Induced Suicidality Disorders

(A + B + C are mandatory)

- A. 3 events of suicidality.
- B. there is evidence from the history, physical examination, or laboratory findings of the event(s) of suicidality being restricted exclusively due to the direct effect of a general non psychiatric medical illness and / or neurological condition (e. g. Huntington's Disease, Autoimmune Disorder).
- C. event(s) of suicidality *do not persist* following the resolution of the general non psychiatric medical illness and / or neurological condition.
- D. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- E. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Medical Illness / Neurological Condition Induced Suicidality Disorder.

#### Specifiers

Characteristic timeframes, specific medical condition(s) involved, age of onset, and current level of symptoms in Medical Illness / Neurological Condition Induced Suicidality Disorder may be

further clarified using the following specifiers:

#### 03 Timeframes

**01 Current** - This specifier should be used if the timeframe for the medical illness induced / neurological condition suicidality symptoms have occurred within the past 2 weeks.

**02 Recent Past** - This specifier should be used if the timeframe for the medical illness / neurological condition induced suicidality symptoms occurred from 2 weeks to 1.5 years ago. **03 Past** - This specifier should be used if the timeframe for the medical illness / neurological

condition induced suicidality symptoms occurred more than 1.5 years ago.

#### 07 Medical Condition

Specify the specific general non psychiatric medical illness and / or neurological condition involved:

#### 09 Age of Onset

**01 Early Childhood Onset** - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs through the age of 5.

**02** Latency Childhood Onset - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs from the age of 6 through the age of 11.

**03** Adolescence Onset - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs from the age of 12 through the age of 17.

**04 Early Adulthood Onset** - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs from the age of 18 through the age of 24.

**05 Mid Adulthood Onset** - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs from the age of 25 through the age of 64.

**06 Late Adulthood Onset** - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs from the age of 65.

**07 Postpartum Onset** - This specifier should be used if the first onset of the medical illness / neurological condition induced suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

**01 Still Symptomatic – No Response** - This specifier should be used if the patient still has symptoms of medical illness / neurological condition induced suicidality, which has *not yet responded positively* < 50% response).

**O2 Still Symptomatic** – **Response but Not Yet Remission** - This specifier should be used if the patient still has symptoms of medical illness / neurological condition induced suicidality, which is *somewhat* controlled, but has *not yet become under complete control* (≥ 50% response, but < 70% response).

03 Still Symptomatic - Remission but Not Yet Recovered - This specifier should be used if the

patient still has symptoms of medical illness / neurological condition induced suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).

**O4 Recovered / Under Complete Control** - This specifier should be used if the patient is no longer having any medical illness / neurological condition induced suicidality symptoms and is not on any active medications <u>or</u> is under complete control on medication <u>or</u> is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq 3$  months).

# SC7. Mood Disorder Induced Suicidality Disorders

## (A is mandatory)

- A. at least 1 event of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of a mood disorder.
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- C. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Mood Disorder Induced Suicidality Disorder.

#### **Specifiers**

Characteristic symptom pattern, timeframes, specific mood disorder(s) involved, age of onset, and current level of symptoms in Mood Disorder Induced Suicidality Disorder may be further clarified using the following specifiers:

#### 02 Symptom Pattern

- **01 Fresh Onset** This specifier should be used if all of the following criteria (1 + 2 + 3) are met:
  - 1. at least 1 event of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of a mood disorder.
  - 2. if more than 1 event of suicidality within a 3 month period, the events cannot continue on a daily basis for longer than 3 months.
  - 3. if history of previous episode(s) of suicidality followed by episode(s) of suicidal normalcy, no more than 2 total episodes of mood induced suicidality in patient's lifetime.
- 02 **Persistent** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4) are met:
  - 1. at least 12 events of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of a mood disorder.
  - 2. events of suicidality occur on a daily basis for more than 3 months with the exception of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 3. events of suicidality cannot be absent for more than 3 days in succession and their absence cannot adhere to any clear cycle.
  - 4. criteria 1 through 3 are present for at least 3 months in patient's lifetime.
- 03 **Recurrent, Rapid Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of a mood disorder.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for 1 day to 3 months and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.

- 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.
- 04 **Recurrent, Slow Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of a mood disorder.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for more than 3 months and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.
- 05 **Recurrent, No Apparent Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of a mood disorder.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy do not adhere to any clear pattern and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the mood disorder induced suicidality symptoms have occurred within the past 2 weeks.
- **02 Recent Past** This specifier should be used if the timeframe for the mood disorder induced suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the mood disorder induced suicidality symptoms occurred more than 1.5 years ago.

#### 08 Mood Disorder

Specify the specific mood disorder involved:

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs from the age of 6 through the age of 11.
- **03 Adolescence Onset** This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs from the age of 18 through the age of 24.

**05 Mid Adulthood Onset** - This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs from the age of 25 through the age of 64.

**06** Late Adulthood Onset - This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs from the age of 65.

**07 Postpartum Onset** - This specifier should be used if the first onset of the mood disorder induced suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

**01 Still Symptomatic – No Response** - This specifier should be used if the patient still has symptoms of mood disorder induced suicidality, which has *not yet responded positively* < 50% response).

**O2 Still Symptomatic** – **Response but Not Yet Remission** - This specifier should be used if the patient still has symptoms of mood disorder induced suicidality, which is *somewhat* controlled, but has *not yet become under complete control* (≥ 50% response, but < 70% response).

**O3 Still Symptomatic – Remission but Not Yet Recovered** - This specifier should be used if the patient still has symptoms of mood disorder induced suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).

**O4 Recovered / Under Complete Control** - This specifier should be used if the patient is no longer having any mood disorder induced suicidality symptoms and is not on any active medications  $\underline{or}$  is under complete control on medication  $\underline{or}$  is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# SC8. Life Event Induced Suicidality Disorder

## (A is mandatory)

- A. at least 1 event of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
- B. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- C. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Life Event Induced Suicidality Disorder.

#### **Specifiers**

Characteristic symptom pattern, timeframes, age of onset, and current level of symptoms in Life Event Induced Suicidality Disorder may be further clarified using the following specifiers:

## 02 Symptom Pattern

- 01 Fresh Onset This specifier should be used if all of the following criteria (1 + 2 + 3) are met:
  - 1. at least 1 event of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
  - 2. if more than 1 event of suicidality within a 3 month period, the events cannot continue on a daily basis for longer than 3 months.
  - 3. if history of previous episode(s) of suicidality followed by episode(s) of suicidal normalcy, no more than 2 total episodes of life event induced suicidality in patient's lifetime.
- 02 **Persistent** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4) are met:
  - 1. at least 12 events of suicidality within a 3 month period experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and

patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.

- 2. events of suicidality occur on a daily basis for more than 3 months with the exception of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
- 3. events of suicidality cannot be absent for more than 3 days in succession and their absence cannot adhere to any clear cycle.
- 4. criteria 1 through 3 are present for at least 3 months in patient's lifetime.
- 03 **Recurrent, Rapid Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for 1 day to 3 months and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.
- 04 **Recurrent, Slow Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy last for more than 3 months and are not the result of

any obvious distracting life event(s) intruding to preclude event(s) of suicidality.

- 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.
- 05 **Recurrent, No Apparent Cycling** This specifier should be used if all of the following criteria (1 + 2 + 3 + 4 + 5) are met:
  - 1. at least 3 events of suicidality within the patient's lifetime experienced exclusively as the direct and / or immediate consequence of social, political, religious, or life event(s) including, but not limited to those identified by Durkheim as influences on suicidality. This attribution should be directly obvious to any third party outside the clinician and patient involved in the assessment. Reactions to life events that are clearly out of proportion to the reality and the gravity of the life event may indicate the need to consider another suicidality disorder rather than Life Event Induced Suicidality Disorder. The reasonable person's judgment test should apply when determining if the life event is sufficiently grave to justify the observed suicidality.
  - 2. at least 3 episodes of suicidality within the patient's lifetime (patient may currently be experiencing the 3<sup>rd</sup> episode of suicidality).
  - 3. at least 2 episodes of suicidal normalcy separating the episodes of suicidality within the patient's lifetime.
  - 4. episodes of suicidal normalcy do not adhere to any clear pattern and are not the result of any obvious distracting life event(s) intruding to preclude event(s) of suicidality.
  - 5. criteria 1 through 4 are present for at least 3 months in patient's lifetime.

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the life event induced suicidality symptoms have occurred within the past 2 weeks.
- **O2 Recent Past** This specifier should be used if the timeframe for the life event induced suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the life event induced suicidality symptoms occurred more than 1.5 years ago.

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the life event induced suicidality symptoms occurs through the age of 5.
- **02** Latency Childhood Onset This specifier should be used if the first onset of the-life event induced suicidality symptoms occurs from the age of 6 through the age of 11.
- **03** Adolescence Onset This specifier should be used if the first onset of the life event induced suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the life event induced suicidality symptoms occurs from the age of 18 through the age of 24.
- **05 Mid Adulthood Onset** This specifier should be used if the first onset of the life event induced suicidality symptoms occurs from the age of 25 through the age of 64.
- **06** Late Adulthood Onset This specifier should be used if the first onset of the life event induced suicidality symptoms occurs from the age of 65.
- **07 Postpartum Onset** This specifier should be used if the first onset of the life event induced suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of life event induced suicidality, which has *not yet responded positively* < 50% response).
- **02** Still Symptomatic Response but Not Yet Remission This specifier should be used if the patient still has symptoms of life event induced suicidality, which is *somewhat* controlled, but has *not yet become under complete control* ( $\geq$  50% response, but < 70% response).
- **O3 Still Symptomatic Remission but Not Yet Recovered** This specifier should be used if the patient still has symptoms of life event induced suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).
- **O4 Recovered / Under Complete Control** This specifier should be used if the patient is no longer having any life event induced suicidality symptoms and is not on any active medications <u>or</u> is under complete control on medication <u>or</u> is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Suicidality Episode, Not Elsewhere Classified

(A + B + C + D are mandatory)

- A. at least 1 event of suicidality.
- B. presentation of symptoms of suicidality / event(s) of suicidality that do not fit the criteria for any of the other Suicidality Disorders.
- C. 1. such examples that merit further study to understand their relationship, if any, to the previously described Suicidality Disorders.
  - 2. some of these types may merit their separate suicidality class.
- D. a single episode is defined as any period of at least 1 event of suicidality that is followed by at least 24 hours of without an event of suicidality of the same type.
- E. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder / Episode.
- F. before assigning the description of Suicidality Episode, Not Elsewhere Classified to any patient's suicidality episode, make sure you check for the presence of Impulse Attack Suicidality Disorder.
- G. please note: if a patient has more than 2 episodes of Suicidality, Not Elsewhere Classified in their lifetime, their symptoms may also meet the criteria for Suicidality Disorder, Not Elsewhere Classified.

# SC9. Suicidality Disorders, Not Elsewhere Classified

(A + B are mandatory)

- A. 3 events of suicidality.
- B. presentation of symptoms of suicidality / event(s) of suicidality that do not fit the criteria for any of the other Suicidality Disorders.
- C. 1. such examples merit further study to understand their relationship, if any, to the previously described Suicidality Disorders.
  - 2. some of these types may merit their separate suicidality class.
- D. the patient's symptoms may meet criteria for more than one type of Suicidality Disorder.
- E. before relying on this disorder exclusively, make sure you check for the presence of Impulse Attack Suicidality Disorder as a possible comorbid or primary disorder to Suicidality Disorder, Not Elsewhere Classified.

#### **Specifiers**

Characteristic timeframes, age of onset, and current level of symptoms in Suicidality Disorder Not Elsewhere Classified may be further clarified using the following specifiers:

#### 03 Timeframes

- **01 Current** This specifier should be used if the timeframe for the not elsewhere classified suicidality symptoms have occurred within the past 2 weeks.
- **O2** Recent Past This specifier should be used if the timeframe for the not elsewhere classified suicidality symptoms occurred from 2 weeks to 1.5 years ago.
- **03 Past** This specifier should be used if the timeframe for the not elsewhere classified suicidality symptoms occurred more than 1.5 years ago.

#### 09 Age of Onset

- **01 Early Childhood Onset** This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs through the age of 5.
- **O2** Latency Childhood Onset This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs from the age of 6 through the age of 11.
- **03** Adolescence Onset This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs from the age of 12 through the age of 17.
- **04 Early Adulthood Onset** This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs from the age of 18 through the age of 24.
- **05 Mid Adulthood Onset** This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs from the age of 25 through the age of 64.
- **06 Late Adulthood Onset** This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs from the age of 65.
- **O7 Postpartum Onset** This specifier should be used if the first onset of the not elsewhere classified suicidality symptoms occurs during the 3 months following delivery.

#### 10 Current Level of Symptoms

- **01 Still Symptomatic No Response** This specifier should be used if the patient still has symptoms of not elsewhere classified suicidality, which has *not yet responded positively* < 50% response).
- **O2 Still Symptomatic Response but Not Yet Remission** This specifier should be used if the patient still has symptoms of not elsewhere classified suicidality, which is *somewhat* controlled, but has *not yet become under complete control* (≥ 50% response, but < 70% response).
- **03 Still Symptomatic Remission but Not Yet Recovered** This specifier should be used if the patient still has symptoms of not elsewhere classified suicidality, which is *mostly* controlled, but has *not yet become under complete control* ( $\geq$  70% response, but [ $\leq$  100% response for < 3 months]).
- **O4 Recovered / Under Complete Control** This specifier should be used if the patient is no longer having any not elsewhere classified suicidality symptoms and is not on any active medications  $\underline{or}$  is under complete control on medication  $\underline{or}$  is under control but the patient feels the need for monitoring and / or psychotherapy (sustained 100% response  $\geq$  3 months).

# Diagnostic Features + Associated Features Supporting Diagnosis

See above criteria for each suicidality disorder and its associated symptoms and behaviors.

#### Prevalence

The exact prevalence and incidence of each suicidality disorder compared to one another and to other illnesses / psychiatric disorders has not yet been investigated.

Investigating the epidemiology of each suicidality disorder compared to other suicidality disorders and other illnesses / psychiatric disorders is a worthwhile and promising area of future investigation.

#### **Development and Course**

Each of the suicidality disorders identified in this chapter appears to have a different origin, course, and development. Some of these are suggested in the criteria provided above for each of these disorders. The chapter on Stages of the Suicidality Disorder further elucidates stages in the evolution of some of these disorders. The chapter on the model suggests that the development and course of suicidality disorders does not follow a linear "staircase model", but instead a non-linear dynamic model that shows sensitive dependence on initial conditions and can be understood in the context of non-linear systems theory or chaos science. Much more work needs to be done to identify and describe the details of the development and course of each of these suicidality disorders.

# Risk & Prognostic Factors + Temperamental + Environmental + Genetic & Physiological + Course Modifiers

Emile Durkheim documented the role of environmental factors associated with elevated risk of completed suicide. It is widely acknowledged that psychological, social, and environmental factors can contribute to elevated rates of suicidality. However, environmental and social factors are neither necessary nor sufficient to explain all suicidality disorders or all suicidality phenomena.

Increased rates of suicidal behaviors, attempts, and completed suicides are associated with several medical and neurological illnesses including Huntington's Disease, Diabetes Mellitus, some infections like Toxoplasmosis, and very low cholesterol levels. How these factors contribute to suicidality or associated with one or more of the suicidality disorders remains unclear at this time.

Several genetic and epigenetic biomarkers have been identified and associated with suicidality. Some of these biomarkers are not known to be associated with mood or psychotic disorders. It is likely that the vulnerability to some suicidality disorders and to some types of suicidality phenomena is inherited as a separate genetic vulnerability apart from mood and psychotic disorders. These relationships await future clarification.

While many consider suicidality as a symptom confined to depression or mood disorders, it is known that suicidality can occur even among some who have neither a mood nor a psychotic disorder. Even in studies of depression, suicidality is orthogonal to depressive symptoms. This suggests that it is an independent, separate factor. While many consider suicidality as a symptom secondary to psychological and social factors, some with suicidality disorders report that over 90% of their suicidality events occur autonomously even in the absence of any apparent psychological, social, or environmental triggering events. One subject with daily suicidality lasting more than 20 years reported that the rare times in her life without suicidality tended to be times of high stress. This is opposite to popular perception about contributing causes to suicidality, but needs to be taken seriously and investigated further in those with suicidality disorders. This is especially true in those with IASD.

Everyone assumes that those who make impulsive suicide attempts have impulsive personalities. However, the relationship between impulsive suicidality traits and suicidality is at best weak and is often not found as expected in studies using impulsive personality trait scales in suicidal individuals. We found that those with IASD appear to display fewer and milder impulsivity traits when they are more suicidal and paradoxically became less inhibited and more apparently impulsive socially when their suicidality came under control. We also found that there was an inverse relationship between the severity scores on an impulsive personality trait measure and the severity of specific suicidal impulsivity.

#### Gender Related Diagnostic Issues

It is not known at this time if there is any disparity by gender in IASD or in any other specific suicidality phenotype described above, and how this compares with other psychiatric disorders. It is also not known if there is a disparity in risk for suicidality, suicide attempts, or suicide completion by gender in any suicidality phenotype and how this compares with other psychiatric disorders.

The role of gender-related diagnostic issues and the prevalence of suicidality in the LGBTQIAA+ community deserves proper investigation, since several of these groups have traditionally been considered to be at special risk for suicidality. The LGBTQIAA+ community includes, but is not limited to Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual persons and Advocates of this community. Sometimes the advocates for these alternative groups, even while not being members of these alternative groups, can become the victims of bullying and discrimination and as a consequence can themselves become more suicidal. This includes, but is not restricted to other non-common sexes and to the intersex sex, which includes, but is not restricted to Klinefelter's Syndrome and other hermaphrodite conditions.

#### Suicide Risk

There is significant suicide risk associated with suicidality disorders. However, the comparative level of risk in each of the suicidality disorders and with other illnesses / psychiatric disorders has yet to be determined.

Investigating the relative suicide risk in suicidality disorders compared to one another and to other illnesses / psychiatric disorders is a worthwhile and promising area of future investigation.

# **Functional Consequences**

Suicidality disorders can be associated with clinically meaningful distress and / or marked functional impairment as a direct consequence of the suicidality disorder. Although such individuals may have an associated mood disorder or psychotic disorder or PTSD, many of them state that they attribute some or all of this impairment directly to the suicidality disorder rather than to their other associated disorder. This is in contrast to popular perception about the direct and immediate causes for such impairment. Such impairments include, but are not limited to work and school impairment, social life and leisure activity impairment, family life and home responsibility impairment, and impairment in spiritual and religious life.

#### **Differential Diagnosis**

Most consider suicidality as a symptom of depression. However, as one patient asked "Why do the psychiatrist always assume that my suicidality is the result of my depression? Did it ever cross their minds that my depression may be the result of my suicidality disorder?" While this may be true for some suicidality disorders like IASD, it is clear that other suicidality disorders may indeed be the consequence of Major Depressive Disorder, Bipolar Disorder, or PTSD. At this juncture it is best to be open to this bidirectional possibility and to explore with each individual suicidal person how they perceive the relationship between their suicidality and any of their other conditions and which one they consider to be primary.

38 of the top 44 psychiatric disorders have elevated standard mortality ratios (SMR) for suicide<sup>1</sup>. Some of these had no apparent mood disorder. Hence, the bidirectional relationship between these disorders and suicidality disorders merits further investigation and an open mind before we always attribute suicidality to be a direct and immediate consequence of these other disorders, rather than the other way around.

<sup>&</sup>lt;sup>1</sup> Harris, E. C., & Barraclough, B. (1997). Suicide as an outcome for mental disorders. A meta-analysis. *The British Journal of Psychiatry*, *170*(3), 205-228.

The disorders most frequently involved in this complex differential diagnosis include:

Major Depressive Disorder with and without psychotic features

Bipolar Disorder with and without psychotic features

Schizophrenia and other related psychotic disorders

PTSD

OCD

Substance Use Disorders

Adjustment Disorders

"Personality Disorders" including "Borderline Personality Disorder"

Many people who have made repeated and apparently impulsive suicide attempts and who visit emergency rooms repeatedly with suicidality and who fail to respond to conventional treatments prescribed for patients who have suicidality among their symptoms (like antidepressants) are labeled, often out of frustration on the part of the clinician, as people with "Borderline Personality Disorder". Indeed, the prescription of antidepressants for some suicidality disorders, like IASD, can increase the frequency, intensity, and severity of all suicidal phenomena. This prompted patients to abruptly stop their antidepressants and / or to become only intermittently compliant in taking their antidepressants to upset their clinician because of their apparent noncompliance with the treatment that their clinician fully expected to help their suicidality when it is doing the opposite. Unfortunately, as most clinicians know "Borderline Personality Disorder" was often used as a term of disparagement to identify those who frustrated their clinicians and who appeared to behave and act in ways opposite to the expected treatments and often reflected a lack of empathy towards such individuals. It is entirely possible that some such individuals display these phenomena because they have a suicidality disorder for which there are no approved treatments at this time. Clearly, the pioneers in the field of "Borderline Personality Disorder" never intended the term to be used in this way. However, it is difficult to deny the reality that in some cases the above description holds true. From a different perspective their behaviors can be understood in a different light.

#### Co-morbidity

Suicidality disorders can be associated with many psychiatric disorders and medical illnesses. The view that all suicidality is a symptom of depression is a questionable assumption. While the relationship among these comorbidities is more thoroughly investigated, it is best to record the suicidality disorder as if it was a separate, distinct disorder comorbid with either another medical or psychiatric disorder or neither. The common comorbidities of suicidality and suicidality disorders are identified above in the prior section.

#### Culture Related Diagnostic Issues

There have been no surveys of any suicidality disorders across cultures. There appear to be substantial cultural differences in the reporting of suicidal ideation, suicide attempts, and death by suicide. It is possible that these differences are due to reporting differences or attribution of other causes for the death (like accidents). Only careful research into these suicidality disorders

and the cultural contributions to these disorders will help clarify the role of culture in the clinical presentations of these disorders. Many religions have significant prohibitions against suicidality. Some religions propagate punishments for suicidality and regard such thoughts and behaviors as sinful, as evidence of possession by evil 'spirits', as actions against 'god', and ostracize or expel such individuals from their religious community in order to prevent the spread of such ideas or behaviors. Conversely, many religions provide assistance to people who have suicidality in the hope of minimizing such ideation and behaviors in the future. Such religious coloring of suicidality and suicidality disorders have a significant role in the detection of, perception of, and reporting of such disorders and need to be studied and investigated in relation to these disorders. Some suicidal individuals will go to the extremes, both of turning away from their religion and becoming a more devout practitioner of their religion, in hopes of finding relief from their suffering.

## **Recording Procedures**

In the appendices in chapters 14.1 - 14.12 we have identified both specific assessment instruments and structured diagnostic interviews that can be used to record and document a wide range of suicidality phenomena associated with all of the suicidality disorders. We have provided tracking logs for these instruments that offer a method for recording the presence of these phenomena and a way of tracking changes in these phenomena over time.

#### **Reporting Examples**

Life Event Induced Suicidality Disorder, Fresh Onset, Current, with Early Adulthood Age of Onset, which is Still Symptomatic - Remission but Not Yet Recovered.

Numeric coding equivalent to this example = SC8.0201/0301/0904/1003.

Clarification of the above coding system:

SC8 = Life Event Induced Suicidality Disorder

0201 = Symptom Pattern (02) Fresh Onset (01)

0301 = Timeframe (03) Current (01)

0904 = Age of Onset (09) Early Adulthood (04)

1003 = Current Level of Symptoms (10) Still Symptomatic - Remission but Not Yet Recovered (03)

Mood Disorder Induced Suicidality Disorder, (Recurrent, Rapid Cycling), Past, in (Bipolar 1 Disorder Current Episode Depressed, Mild), with Adolescent Age of Onset, which is Recovered / Under Complete Control.

Numeric coding equivalent to this example = SC7.0203/0303/08(F31.31)/0903/1004.

Psychotic Suicidality Disorder, Current and Past, in Schizophrenia, with Adolescence Age of Onset, which is Recovered / Under Complete Control.

Numeric coding equivalent to this example = SC2.0301/0303/04(F20.9)/0903/1004.

#### **Comorbid Suicidality Disorders**

Impulse Attack Suicidality Disorder, Most Recent Episode USIA Ideation Only Subtype, Persistent, Current, with Latency Childhood Onset, which is Still Symptomatic - No Response, comorbid with Mood Disorder Induced Suicidality Disorder, Fresh Onset, Current, in (Major Depressive Disorder, Recurrent Episode, Moderate), with Mid Adulthood Age of Onset, which is Still Symptomatic - No Response.

Numeric coding equivalent to this example = SC1.0102/0202/0301/0902/1001/ + SC7.0201/0301/08(F33.1)/0905/1001.

In reporting 2 or more suicidality disorders comorbid with each other, record them in order of primacy. Primacy is determined by which disorder is the dominant cluster in the patient's presentation of symptoms and / or which came first in the patient's natural history. In the numeric coding the primary disorder comes first in the sequence and the secondary disorder comes after the + sign.

Example: A patient lost all of her family in 911 (a life event). She quickly went into a major depressive episode. Three weeks later it is clear she has Major Depressive Disorder. Two weeks after she begins having intermittent psychotic features (an auditory hallucination hearing her loved ones speaking to each other and to her). These hallucinations have no suicidal content. One week later, when she feels lonely and misses her family she experiences active suicidal ideation and begins to think about a method to kill herself. What is this?

Major Depressive Disorder, Single episode, With Psychotic Features, comorbid with life Event Induced Suicidality Disorder, Fresh Onset, Current, with Mid Adulthood Age of Onset, which is Still Symptomatic - Response but Not Yet Remission.

Numeric coding equivalent to this example = F32.3 + SC8.0201/0301/0905/1002.

Although the life event which later triggered suicidality occurred first and was likely the trigger of the MDD, primacy of the disorders here is MDD because it came first in the natural history of the patient's "illness" and is also the dominant cluster in the patient's symptoms. The Life Event Induced Suicidality Disorder is recorded second because the symptoms of suicidality came after the symptoms of the MDD. In other words, the timing of the life event does not decide primacy: the timing of the symptoms of suicidality in response to the life event is considered when determining primacy. It is when the symptoms of suicidality occur that determines primacy.

#### Suicidality Disorder Comorbid with Homicidality Disorder

A 23 year-old unmarried male who is very conscientious, introverted, and religious has persistent IASD. Because his religion has strong prohibitions against suicidality, he feels very guilty, feels as if he is a very bad, sinful person, and as if he deserves punishment in this life and the afterlife for having such thoughts. He becomes increasingly religious and prays more frequently in an attempt to make these thoughts go away. He lives in a war zone where he has directly witnessed many people being killed in air raids and has seen women and children are being killed and harmed by soldiers. As a result of these traumatic experiences, he develops symptoms of PTSD. He feels a need to try to stop or rectify or neutralize these injustices. He begins to interact radicalized individuals through social media. They suggest he consider neutralizing these injustices by killing the group of people causing the harm. He is told that if he kills these soldiers to lessen these injustices, he will be forgiven for all of his suicidal thoughts and he will be considered a martyr and will be substantially rewarded in the afterlife. He now sees that the suicidality is no longer a negative, but is a positive for ensuring a better afterlife and at the same time a way of ending his unhappiness with his recurrent suicidality. He starts to think about and plan the homicidal / suicidal attack.

Numeric coding equivalent to this example = SC1.0101/0202/0301/0904/1001/ + HC4.0301/0904/1001.

Clarification of the above coding system:

SC1 = Impulse Attack Suicidality Disorder

.0101 = Most Recent Episode (01) USIA Physical and Ideation Subtype (01)

0202 = Symptom Pattern (02) Persistent (02)

0301 = Timeframe (03) Current (01)

0904 = Age of Onset (09) Early Adulthood (04)

1001 = Current Level of Symptoms (10) Still Symptomatic - No Response (01)

+

HC4 = PTSD Induced Homicidality Disorder

0301 = Timeframe (03) Current (01)

0904 = Age of Onset (09) Early Adulthood (04)

1001 = Current Level of Symptoms (10) Still Symptomatic - No Response (01)

## Conclusion

The above classification is presented in the hope that it will lead us towards an earlier and more specific identification of anti-suicidality treatments and provide increased precision in genotyping and biomarker investigations of each of these suicidality phenotypes.

# **Domains of Suicidality**

The descriptions of the above categorical diagnosis in each patient may be further enriched by noting the domains of suicidality present that are described in the next chapter.

# Impulse Attack Suicidality Disorder

# An Impulse Attack

#### What is it?

An unexpected suicidal impulse attack (USIA) is any event of suicidality experienced as a sudden need or impulse (with varying degrees of urgency) to plan or to act in any suicidal way. It may be totally or largely unexpected or could not have been predicted to occur minutes before the attack. These events can occur either with or without the physical symptoms described in the USIA Physical and Ideation Subtype. (See USIA Physical and Ideation Subtype criteria in the Suicidality Disorders Criteria.)

If the presentation of symptoms is not associated with enough physical symptoms to meet the criteria for a USIA Physical and Ideation Subtype, then this is a USIA Ideation Only Subtype. (See USIA Ideation Only criteria in the Suicidality Disorders Criteria.)

#### How does it progress?

The impulse attack typically starts with a prodromal aura, which usually lasts between 30 seconds and 3 minutes. This aura is a unique prodromal perceptual distortion with an impending awareness of a partial or a complete loss of control.

The aura is followed by the sudden onset of some characteristic **physical symptoms experienced** within a 10-minute timeframe.

Within 10 seconds to 2 minutes of the onset of the physical symptoms a sensation or urge occurs that the subject often later associates with a need to be dead. This sensation is pre awareness of any suicidal ideation. There is a physical sensation that something is wrong or about to be wrong before there is any emotional / mood / cognitive awareness that this has anything to do with a mental-state-like-suicidality. It may be immediately followed by a cognitive awareness of the

need to be dead and the suicidal impulse. This sensation at times can occur without any awareness of the need to be dead. It is less likely to occur if there is full depersonalization or amnesia. This sensation usually lasts 5 seconds. Subjects initially may have amnesia for this sensation, but when it is noted they may be able to observe it prospectively during subsequent impulse attacks. Typically this sensation occurs at each peak of symptoms. Subjects may find it difficult to put this experience into words. This sensation can occur on its own outside the context of an unexpected suicidal impulse attack.

The suicidal impulse itself is an unexpected, intrusive or overwhelming or engulfing need (with varying degrees of urgency) to attempt suicide or to plan for a suicide attempt. It typically occurs within 20 minutes of the physical symptoms. This suicidal urge always reduces and usually displaces any positive influence memories or external events have in reducing suicidality symptoms. It may be associated with a sense that resisting the urge is wrong or that they are "not allowed" to resist the urge. This urge may be experienced like two shifts in gear in the intensity escalation curve of its profile. There may be 2 very brief reductions during the course of attack escalation before the escalation continues (see Figure 6.2.2 below).

One of several **sensory changes occur** in conjunction with the suicidal impulse attack:

- 1. all sensations are muffled or muted (visual, auditory, tactile)
- 2. instinctive detection and awareness in the immediate vicinity of means that could be used to attempt suicide
- 3. time becomes distorted (slows down)

Another unusual feature that may appear paradoxical is a thought sequence we refer to as an impulse attack gambit. A gambit is any maneuver that seeks to gain an advantage by making a sacrifice, for example in chess. This gambit tactic occurs concurrently with the impulse attack. At first, subjects find that giving into the urge to make a suicide attempt or to plan for suicide leads to a reduction of the suicidality and related physical symptoms. In the early stages of the disorder, subjects find it very difficult to resist the suicidal urge. Over time, subjects may learn to try to resist this suicidal urge. They find the intensity of suicidal and physical symptoms increase in response to this resistance. Paradoxically, they may find that resisting the urge to plan may evolve into the urge to act. Some subjects deliberately plan details for a future suicide attempt to bring about a reduction in suicidal and physical symptoms.

At multiple points in the above process and in the aftermath, there is a <u>need to minimize</u> the symptoms to themself (because this makes it easier to cope) and to others (because they may overreact and may not understand). There may also be a fear others will interpret the above symptoms as attention seeking.

#### Additional Associated Phenomena

<u>Note 1</u>: A situational panic / anxiety attack may occur at any time during the above process after the aura and before the aftermath. This typically occurs with 10 - 50% of the USIAs. When such a situational panic / anxiety attack occurs it results in a temporary pause in the USIA process. The USIA process will subsequently resume only when the situational panic / anxiety attack subsides. In the early natural history of USIAs these situational panic / anxiety attacks occur more frequently. Later in the natural history these situational panic / anxiety attacks become less frequent with the evolution of coping skills.

<u>Note 2</u>: Most people experiencing an USIA are so focused on trying to live through the attack that they may not be able to identify or be fully aware of all of the component features associated with the attack.

<u>Note3:</u> These attacks may be associated with varying degrees of emotions from no emotional reaction at all to high alarm or distress.

#### **Examples of USIAs**

The following 2 figures and 2 tables document the profile and sequence of typical unexpected suicidal impulse attacks.

USIA to Act Example 1

Figure 6.2.1: Example 1: Unexpected Suicidal Impulse Attack Intensity Profile

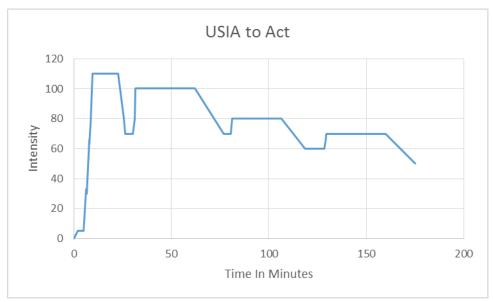


Figure 6.2.2: Example 1: Unexpected Suicidal Impulse Attack "Gear Shifts" Intensity Profile

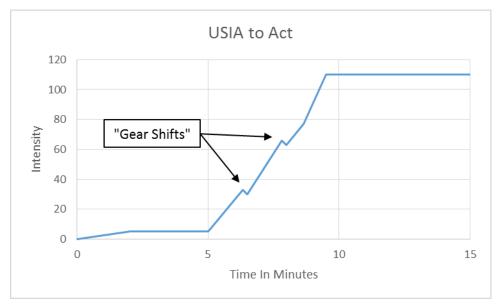


Table 6.2.1: Example 1: Unexpected Suicidal Impulse Attack Intensity Experiences

Unexpected Suicidal Impulse Attack (To Act)		
Time in Minutes	Experience	Intensity
0.00	limited awareness of impending attack	0
2.00	ate to numb self	5
4.00	partial dissociation	5
5.00	start of intense sadness	5
6.33	slight decrease in sadness	33
6.50	increase in sadness	30
7.83	slight decrease in sadness	66
8.00	increase in sadness	63
8.66	increased pulse, frequent but prolonged swallowing	77
9.50	peak of sadness (100% of total)	110
11.50	went to bed	110
18.50	non-planning active ideation	110
19.50	depersonalization (arms, lower torso, and legs)	110
21.50	planning thoughts (date)	110
22.66	decrease in sadness	110
24.66	planning thoughts (means)	90
25.66	planning thoughts (location)	80
26.33	planning thoughts (alternative means and method)	70
29.33	planning thoughts (to act immediately)	70
30.33	slight increase in sadness	70
31.33	mental decision not to act	80
31.66	peak of sadness and urge to act (100% of total)	100
32.00	mental self-talk attempting to convince self to act	100
62.00	start of gradual decrease in sadness and urge to act	100
77.00	sadness and urge to act maintained (70% of total)	70
80.00	mental self-talk reminding self of reasons not to act	70
80.50	increase in sadness and urge to act	70
80.83	mental decision not to act	75
81.17	another peak of sadness and urge to act (80% of total)	80
81.50	mental self-talk attempting to convince self to act	80
106.50	start of gradual decrease in sadness and urge to act	80
118.50	sadness and urge to act maintained (60% of total)	60
128.50	increase in sadness and urge to act	60
129.00	mental decision not to act	65
129.33	another peak of sadness and urge to act (70% of total)	70
130.00	mental self-talk attempting to convince self to act	70
160.00	start of gradual decrease in sadness and urge to act	70
175.00	fell asleep	50
800.00	extreme increase in depression (struggling to function)	
860.00	increase in time spent with willful suicidality	
1040.00	peak of depression and willful suicidality	
1160.00	diarrhea and start of exhaustion	
3740.00	gradual decrease in depression and lessening of exhaustion	
4420.00	gradual decrease in intensity of willful suicidality	
5140.00	gradual increase in intensity of willful suicidality	

Figure 6.2.3: Example 2: Unexpected Suicidal Impulse Attack Intensity Profile

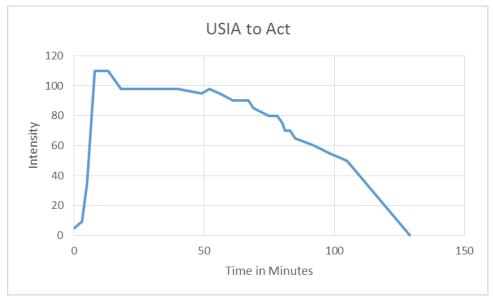


Table 6.2.2: Example 2: Unexpected Suicidal Impulse Attack Intensity Experiences

Unexpected Suicidal Impulse Attack (To Act)			
Time in Minutes	Experience	Intensity	
0	Onset of prodromal aura	5	
2	Onset of back pain	8	
3	Onset of time distortion	9	
5	Onset of difficulty breathing and swallowing issues	35	
6	Onset of need to be dead	60	
8	Onset of suicidal urge	110	
13	Onset of suicidal planning ideation (method, means, location, date)	110	
18	Slight reduction in intensity due to sensory distractions	98	
40	0.75mg alprazolam	98	
49	Slight reduction in intensity due to sensory distractions	95	
52	Onset of increased heart rate	98	
56	Onset of chest discomfort and pain	95	
61	Onset of extreme nausea	90	
67	Slight reduction in intensity due to sensory distractions	90	
69	Onset of sleepiness	85	
75	Difficulty breathing / swallowing issues / increased heart rate / chest discomfort & pain end	80	
78	Sense of internal calm even though experiencing the suicidal ideation and suicidal urge	80	
80	Second onset of chest discomfort	75	
81	Increase in sleepiness	70	
83	Decreased suicidal ideation, but still some suicidal urge	70	
85	0.5mg alprazolam (crushed)	65	
92	Increase in sleepiness	60	
98	Decrease in chest discomfort and pain	55	
105	Laid down to try to sleep	50	
129	Fell asleep (approximately)	0	

The following example illustrates the effect of a treatment for panic attacks on the USIA. Note that while the alprazolam may have decreased the intensity of the symptoms, it had a disinhibiting effect on the subject. The subject felt that this disinhibiting effect increased the danger while the suicidality was still intense, even though the attack itself was less intense. It also serves to illustrate that the use of a benzodiazepine, while it may help a panic attack, it is not a reasonable treatment for a suicidal impulse attack.

Figure 6.2.4: Example 3: Unexpected Suicidal Impulse Attack Intensity Profile with Alprazolam

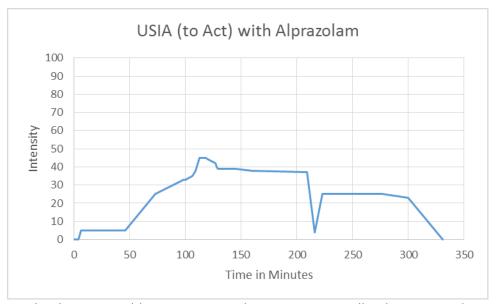


Table 6.2.3: Example 3: Unexpected Suicidal Impulse Attack Intensity Experiences with Alprazolam

Unexped	23	
Time in Minutes	Experience	Intensity
0.0	prodromal aura	0
4.0	pressure on forehead for 30 seconds	0
6.0	partial depersonalization (most [70%] of body, usually only about 30%) <sup>2</sup>	5
38.0	slow shallow breathing	5
46.0	chest discomfort	5
73.0	start of pre awareness need to be dead sensation	25
98.0	start of suicidal impulse (need to act)	33
100.0	0.75 mg alprazolam	33
106.0	time distorted (slowed down) and sensations muffled <sup>3</sup>	35
109.0	sadness	38
112.3	peak of intensity	45
118.0	thoughts about plan details (method, means, location, date)	45
121.0	feeling onset of alprazolam	44
127.0	chest discomfort ended	42
128.0	breathing became normal	40
129.0	depersonalization ended	39
130.0	ideation / impulse continued	39
145.0	0.5 mg alprazolam	39
160.0	ideation / impulse continued	38
209.0	0.5 mg alprazolam	37
216.0	suicidal ideation / impulse ended	4
223.0	suicidal ideation / impulse began again	25
277.0	0.5 mg alprazolam	25
300.0	suicidal ideation / impulse continues	23
331.0	fell asleep	0
The mark of immunity attack	the fellowing download	

The rest of impulse attack symptoms in the following days also occurred as usual.

Sheehan DV, Giddens JM, Copyright 2013 - 2015. All rights reserved.

<sup>&</sup>lt;sup>1</sup> frontal headache onset 6+ hours prior to impulse attack and continued throughout the entire experience and even the following days.

<sup>&</sup>lt;sup>2</sup> usually will only have depersonalize over about 30% of body, but experienced depersonalization over about 70% of body during this impulse attack which may be the reason why the intensity never reached higher than 45%.

<sup>&</sup>lt;sup>3</sup> time being slowed down and sensation being muffled were a result of prior tests of alprazolam and continued throughout the duration of the impulse attack (possibly due to the alprazolam).

# The Subjects Experience During the Attack

#### USIA Internal Dialogue

The narrative below between a subject and themself reflects a typical description of the internal struggle both to fight against the impulse to make a suicide attempt and to yield to it within the same attack. During a prior USIA the subject made a decision to postpone acting on the suicidal impulse attack by scheduling / planning a time for a future suicide attempt. The subject scheduled it for January 21st, a date with special significance to the subject. When the day in question occurred, the subject experienced another impulse attack about 25 minutes prior to midnight on January 21st. The significance of the date caused the subject to feel an immediacy to act in order to not live beyond that date. The idea of living through even part of another year past this date was overwhelming to the subject. Hence, the urgency to die by suicide and end the impulse attack before midnight passed.

# Mention of time is actual time prior to and after midnight:

For the past couple of weeks I have thought about dying today. The day started with me going through the motions of forcing myself to be social and somewhat productive. At one point I even felt really good, calm, and centered. As the night wears on, I find myself looking at the clock and wondering if I should hurry up and do it. Right now I'm asking myself "Should I take these remaining 22 minutes of the day and use them to free myself from this pain?" Another side tells myself that this is just one night in a countless string of nights I've thought about and wanted to die and that, realistically, this night is no different from the rest. Down to twenty minutes now - "Is tonight the night?" I so desperately want to stop hurting so much, but acting upon this somehow seems wrong. The events of the day have reinforced that there is actually a point to my suffering and that I am supposed to actually do something productive with this pain, but I keep questioning if the pain I endure will ever be worth the seemingly little I see resulting from it. Seventeen minutes now - "Just do it! Just let yourself be free!" I feel a hole of seething pain deep within my soul and nothing seems to stop it. It just hurts and doesn't stay around long enough so that I can enjoy it. Frequent initial shocks of seething pain perfectly spaced apart so that I cannot get lost in it. Fifteen minutes - "There is still time if you hurry. You can end all of this. You can make this pain go away forever." I want it to go away forever. I want it to go away forever and never come back. "Being dead is the only way to see that happens." Is that right? Is there really no other way? "Yes. Killing yourself is the only way to make this stop." But I don't want to die. "You have to if you want this to stop." Thirteen minutes - "It's okay. Just walk into your room, get the rope, and slip out the back door. You can make the noose when you get outside." I don't want to do that. "But you must. You have to do this to make the pain go away." I know you're right, but I still don't want to believe you. I don't want to believe that my entire life will simply amount to consistent suffering. "It already has. The choice now is yours; either continue the suffering by living or allow yourself to be free by dying." I want freedom. I desperately want freedom. Ten minutes now - I feel like I need to act. I feel like I have no other choice. I can't

keep enduring this. I will break eventually. "So why not let it happen now and save myself some of the pain?" I don't know why not. "I have to do this. I have to let myself be free." No, you don't. You don't have to do anything. You can make it through the next eight minutes. You can. "But I don't want to. Not if it means continuing to feel this way." Seven minutes - "Do it. Just do it quickly." No. "Yes. You want this to end, let's make it end. Let's get you out of that pain." I can't. "Yes, you can. You can and you will." No. "Yes, come on. Let's go." Go where. "To get the rope." No. Five minutes - "You have to." No. "Let's go and just hold it. Once you hold it you can decide." No. "Yes. You have to do this." No I don't. "You want out of the pain. This is the way out." There has to be some other way. "There isn't. This is the only way. There is still time left, but you have to move now." No. Four minutes - "Hurry! Quickly! Just get the rope. You don't have to use it. Just hold it." No. Please stop. "I'm trying to help you." No, you just want me dead. "That's what you want, isn't it?" No. I want the pain to end. "Well, this is the only way it will ever end. You know that. You could be free from all of this tonight." I know. "Okay. Let's go. Let's get the rope." I wish I could, but I can't. "Yes, you can." One minute - No, I can't. "Come on, hurry, there is still time!" No. I can't. "But you must." No.

Midnight - I still want to die, but I don't feel the urgency to act. Maybe I can put it off until the 31st. "No. Don't wait until then. Do it now." I should have done it. I should have carried through on the plan. I don't want to wait another ten days. "Good. You are starting to understand why you need to do it now." Three minutes after midnight - I just need to die. There is still time. I can still do it. "Why not do it now?" I don't know. I don't know of any reason not to. "Okay. Good. Let's go get that rope." Okay. I'll go get it, but just to hold. "Good." I failed. I failed me. I failed at letting myself out of this pain. How can I ever expect to do anything if I can't even take action to stop my pain? I need to die. I need to die now. I need to give up and make all of this pain go away. "Okay. Now that you're sure about it. Let's wait a bit until you're the only one awake. You don't want anyone interrupting you." I'm really going to do it this time. I'm really going to let myself be free. "Yes, yes you are." It will all be okay then. It will finally all be okay. Nine minutes after midnight - "Yes, it will. Let's go make the noose." Please, just stop. "No. Come on. It's time to do this." I don't want to anymore. "You have to." No, I don't have to. "Yes, you do." I can't handle this anymore. I can't deal with you always trying to convince me to die. "You know how to make it go away." I don't want that. "But it's the only way." No! There has to be some other option. "There isn't." There isn't. Thirteen minutes after midnight - "You know I'm right." You might be, but I can't do this now. Give me some time to prepare. "Ten days. You have to make an attempt by 11:59 pm on January 31st." Okay. Fifteen minutes after midnight - "Okay."

Twenty minutes after midnight – I felt a strong need to die 'now'. Similar mental debating continued for an hour. At that point I focused on various tasks and experienced similar mental debating only while not focused on something else. This continued for an additional 17 hours, including three periods of two hours of sleep.

#### Additional notes:

Although this began as a need to act, agreeing to a date for an attempt is the point when the symptoms of the attack began to lessen. This is sometimes helpful when the internal debate weakens the resolve not to act and willful thoughts begin to sway towards the side of actually making an attempt. This attack began on a day that I had, at one point, considered for a suicide attempt, but later I abandoned the plan. This might be part of the reason it seemed so important to die prior to midnight. (The event began on January 21st and continued through January 22<sup>nd</sup>.)

# Description of USIA

One subject explained the experience of an unexpected suicidal impulse attack as:

The experience of fighting the urge to act is so agonizing that time seems to slow down. Sometimes it feels as though thirty minutes of fighting the urge have passed when only sixty seconds have actually passed.

During the urge to act objects in the vicinity morph. Objects are no longer simply objects, they turn into means for a suicide attempt. Prior to the impulsivity a pen is simply a pen, but, once the impulsivity hits, a pen becomes a piece of hard plastic that can be broken into a sharp edge and used to cut an artery. Similarly, a tie regularly worn to work becomes a tool for suffocation. (Deep down it is clear that these acts will not likely result in death, but the urgency to act is overwhelming and incredibly difficult to resist.) Many times these morphed objects seem to be very vibrant in color and clear while all other objects appear gray and fuzzy.

Once the impulsivity hits all external sounds are muffled. It is as though you are wearing noise-cancelling headphones or experiencing a period of external deafness. The rest of the world and all of the sounds associated with it no longer exist. Sometimes, if one fights against the urge to act, an uncontrollable mental self-talk occurs and instructions on how to act or orders to act are relayed. Those orders or instructions do not stop until sleep finally comes or an attempt (with or without a substitution of method or means) is made. [See the Tips and Tricks section at the end of this chapter for more information about a substitution of means.]

If the impulse attack is recognized before the urge occurs, a panic attack sometimes happens with a tightening of the chest, difficulty breathing, and nausea sometimes so bad vomiting occurs. If this does not happen the chest hurts from psychic pain that feels as though the heart and soul are being ripped from the body. After either of these and when the impulsivity is over, complete exhaustion sets in and it takes days to fully recover to the point you feel somewhat whole again.

As the impulse attack begins you notice your skin feeling different, almost as though it is weighted. This doesn't happen everywhere, usually just your arms, legs, and lower torso. Very soon your sense of self changes. The areas where your skin felt heavy no longer feel connected to you. You can see that you are touching things, but any tactile sense from those areas of your body is very dulled, if you can feel anything at all. This will last for anywhere from forty minutes to several hours until the impulsivity dissipates, you give in to the urge, or you manage to fall asleep from exhaustion. The following days these parts of your body will ache, sometimes worse than if you spent hours obsessively weight lifting, and you may feel as though you have the flu.

#### Timeline of USIA

The following is an example of one subject's typical timeline of the urge to plan:

- 1. felt pressure on forehead (near Manas Chakra) in the shape of an inverted isosceles trapezoid 30 seconds until
- 2. skin began to slowly feel heavy or weighted over the entire body except the face, neck, and torso 1 minute until
- 3. urge to plan with two 'gear shifts' (see the 2 very brief small decreases in intensity during the upward escalation of the initial phase of the impulse attack in Figure 6.2.2 above)- 5 seconds until
- 4. increased pulse, shallow breathing, frequent but prolonged swallowing (almost holding mid-swallow to prevent breathing) and sense of most of the body (the areas where the skin felt heavy) disappearing 2 minutes until
- 5. crying 1 minute until
- 6. active ideation (planning) 15 seconds until
- 7. physical symptoms lessened 10 minutes until
- 8. considered alternatives 15 seconds until
- 9. physical symptoms previously mentioned and crying increased , pain in an almost tetrahedron shape between sternum and two points on back slightly higher than the point on the sternum (near Anahata Chakra), and headache (from temple to temple and bridge to hairline) 15 minutes until
- 10. momentarily became urge to act 3 seconds until
- 11. focused on plan 15 seconds until
- 12. physical symptoms lessened 20 minutes until
- 13. considered alternatives to making a suicide attempt- 5 minutes until
- 14. physical symptoms increased in sensation intensity 15 minutes until
- 15. active suicidal ideation 15 seconds until
- 16. physical symptoms lessened 20 minutes until
- 16. sense of exhaustion and sleepiness up to 3 days following the urge
- 17. achiness in the areas where the skin felt heavy and diarrhea the day following the urge

# Distribution of Components of an USIA

An unexpected suicidal impulse attack feels like a cross between a panic attack, an urge to tic in Tourette's Disorder, and both a compulsive urge and an obsessive thought as in Obsessive Compulsive Disorder. However it is not exactly any one of these, but has components from each. The percentage distribution in this description appears to change throughout various stages of the disorder. For example, a patient with 20+ years of Impulse Attack Suicidality Disorder (IASD) described the distribution of the experience currently as:

60% the urge to engage in a compulsive behavior 5% obsessive thought 25% panic attack 10% the urge to tic.

The same patient indicated that the experience was different in the early stages of the disorder and described the distribution of the experience then as:

10% the urge to engage in a compulsive behavior

5% obsessive thought

25% panic attack

60% the urge to tic.

During these attacks, there is significant cognitive impairment such as concentration difficulties, ability to focus fully on tasks at hand, or in interactions with others. For example, one subject tried to read something they had previously written. Then during an impulse attack, the subject was unable to make any sense of it. This cognitive impairment is associated with a deep sense of irritation and frustration with oneself.

# The Clinician Observer's Perspective

A clinician observing a USIA may notice a unique physical change in the demeanor of the patient having such an attack. This physical change pattern is very difficult to describe and it is probably necessary for the clinician to know the patient over time to observe this change. The patient begins to look as if they are physically ill, or as if they had acute nausea (even when they do not). They appear distant and preoccupied. In later discussions with a subject they realized that this change was often apparent to the clinician observer before the patient began to notice symptoms. It is not exactly the same sign as a sudden onset of psychomotor retardation, but could be mistaken for this sign. This impending impulse attack expression appears to start during what we describe above as the prodromal phase of a USIA, and lasts at least 10 minutes. However, it can appear even days before a USIA. It may continue to be observable at a lower level for several days to 2 weeks after a suicidality and USIA flare up.

If a subject's loved ones are able to recognize this physical change in advance of the USIA, it may allow the subject to take precautions for the likely upcoming impulse attack. For example, if a subject and a friend are out shopping, it may be helpful for the subject to go home so they can experience the USIA in a familiar and safer environment, where they are more likely to have access to distractions and other items that may assist them in coping with the attack.

### The Aftermath

# Associated Symptoms

The physical symptoms in the immediate 24-hour aftermath of a USIA include exhaustion, sleepiness, diarrhea, and achiness. Between the end of day 1 and the end of day 3 after the USIA there is an increase in the intensity of depression or an increase in the intensity and duration of willful suicidal ideation and / or behavior. One subject reported an increase in depression and willful suicidality in the days following the USIA as a response to the frustration they felt towards themself because they could not cope with the suicidality as others constantly expected of them. The subject said that she felt frustrated at herself for "allowing the suicidality to get out of control again" and continued by saying "I should have done better at controlling it." Another subject reported understanding he could not control these USIAs and stated that the depression and increase in willful suicidality was "a response to the continued negative impact these attacks have on my life. I get depressed because of all the parts of life I miss out on by having these

attacks. I'm not free to live and it is much harder to ignore this fact when one of these attacks just happened. Sometimes I start to think about actually killing myself in order to avoid having to experience these attacks again." About a week after the USIA there is typically a craving for fatty (calcium-rich) foods.

### Impairment

All the above symptoms lead to functional impairment. For example, it is difficult to work the day following such an impulse attack at night. Having multiple suicidal impulse attacks in social settings leads to phobic avoidance of these situations. Family life, home responsibilities, and self-care are neglected. Interpersonal relationships are neglected and deteriorate. It can cause one to distort comments made by others to mean the opposite (usually negative) of what they intended to communicate. Even people who have been very religious or spiritual for most of their lives may begin to feel abandoned by "God". As a result they either feel they must have done something horrible for "God" to allow them to experience these impulses or they feel disillusioned by their religion /spirituality and begin to distance themselves from their faith. The effect of such attacks leaves one cognitively impaired with concentration difficulties, an inability to focus fully on tasks at hand, or difficulties in interactions with others.

# Relation to Depressed Mood Episodes

Conventional wisdom suggests that depressed mood comes first and that suicidal ideation or behavior is a later consequence or complication of the depressed mood. However, with the USIA, the suicidal phenomena comes first and the depressed mood comes later as a complication / consequence of the suicidality. As one subject said "why do my doctors always think that I am suicidal because of my depression? Did it ever cross their minds that I might be depressed because I have a chronic suicide disorder?"

#### Relation to Hopelessness

Conventional wisdom suggests that hopelessness comes first and that suicidal ideation or behavior are a later consequence or complication of the hopelessness. However, with the USIA, the suicidal phenomena comes first and the hopelessness comes later as a complication / consequence of the suicidality.

### Memory Problems

For 2 to 5 days following a USIA the subject may experience short and long-term memory problems.

#### Sleep Problems

In advance of a USIA subjects typically has increased awakenings during the middle of the night and the following day feels as if the sleep was not restorative even when the duration of sleep was as long as 9 hours. This occurs approximately a week to 10 days before a USIA. 60% of the time the sleep disturbance lasts up until the day of the USIA and 40% of the time the sleep disturbance ends 1 to 3 days before the USIA. There seems to be no disturbance in the duration of sleep or in the ability to fall asleep.

Anticipatory Anxiety and Preparing to Cope with Next Attack

The USIAs are a very traumatic experience. They condition the subject to subsequent anticipatory anxiety about having the next USIA. This can undermine their confidence in being able to cope with the next attack, yet it frantically drives them to seek ways to better cope with, minimize, or prevent the next attack.

# The Impulse Attack Suicidality Disorder

## Usual Pattern of Frequency / Presentation

Most subjects attempt to find a pattern in their UISAs in order to predict when the attacks will occur and are unlikely to find such a pattern. Because the attacks come on in an unexpected, unprovoked manner, they often appear random and are particularly worrisome on this account. However, by obsessively recording and searching through the details of the sequence of phenomena some patterns may emerge. For example, as noted below we found 2 different antecedent phenomena consistently linked by a specific timeframe with the subsequent USIAs.

This disorder can have a very early age of onset sometimes even starting before the age of 10. For example, one subject reported being on vacation with her family at age 8. She experienced an USIA while at the hotel swimming pool. She was unable to resist the suicidal impulse and decided to drown in the pool. She quickly walked down the stairs of the pool with the water covering her head. She did not attempt to swim or try to surface to breathe. Someone at the pool noticed she was not swimming and pulled her to safety. Over time the attacks appear to become more frequent, but not necessarily more intense, although that can occur.

IASD appears to be more common in the young than in the elderly. It may be seen more frequently in Autistic Spectrum Disorder / Asperger Syndrome. Although many such patients appear depressed by the time they are seen clinically, the suicidality in IASD seems to be antecedent to the depression, rather than the other way around. In other words, the depression worsens as a consequence of the persistence of the IASD and as a later complication of the disorder. Because many such patients make what appear to be impulsive suicide attempts, they are often labeled as having Borderline Personality Disorder. To the patients with this condition, the concept of a primary Impulse Attack Suicidality Disorder makes a great deal of sense.

Many cases with this condition have it in a very persistent form, with few episodes of remission. A typical frequency of the USIAs in the untreated form of this disorder is approximately 2 per month. This can increase to 3 per week when treated with some of the standard antidepressants. It can increase in frequency even further in the context of withdrawal from some other drugs. Clinicians need to be particularly cautious using ketamine in IASD since in one case the USIAs began 5 to 7 days after the ketamine and flared-up in severity and frequency over the following week. During that time the subject had 1 to 2 USIAs each day and the overall severity increased by 50% to 90%.

### Effect of Disorder on Other Coping Traits

#### Inhibited Risk Taking

Paradoxically, IASD can have the effect of decreasing risk taking and restraining impulsive traits and behaviors. In contrast, when subjects with IASD respond to treatment they may notice themselves feeling less inhibited or restrained and their trait impulsivity scores may increase. We believe that misunderstandings around this apparent paradox have led to clinicians looking for and expecting patients who make impulsive suicide attempts to have higher impulsive trait scores. However, data from several studies using different scale measures of impulsive traits

have not found consistent strong correlations between impulsive personality traits and suicidality<sup>1,2</sup>. However not all investigators agreed<sup>3</sup>. In one subject with Impulse Attack Suicidality Disorder, who was chronically suicidal on a daily basis for several years, and who collected weekly data over 135 weeks / 2.66 years, there was a correlation of -0.1056 between question 1 on the Suicidality Modifiers Scale, which measures the severity of suicidal impulses (see chapter14.8) and an impulsivity personality trait question (used in the Sheehan DV, Alphs L et al 2014 validation study<sup>4</sup>). In a separate and later database also collected weekly, over 95 weeks / 1.87 years, using the S-STS suicidal impulse question (question 11) and the same impulsivity personality trait question above, there was a correlation of -0.5575 between these items. Following effective remission of all suicidality, there was an increase in impulsive personality traits, which paralleled exactly the decrease in unexpected suicidal impulse attacks (USIAs). Subjects with IASD report that they deliberately inhibit and restrain themselves and try to restrain their impulsivity in response to having USIAs. This may be a self-protective tactic. One subject stated, "I would regularly plan most details of my life well in advance because I needed to incorporate the potential of experiencing a USIA at any time. I would plan any trip away from home to ensure I had safe places I could stop if an attack happened while I was away from home. Once the USIAs stopped, I no longer needed to make these elaborate contingency plans and was free to act somewhat more impulsively."

#### Withdrawal and Social Isolation

Since USIAs can occur in an unexpected, unprovoked, and unpredictable manner, subjects who experience these attacks chronically may deliberately minimize their interactions with others and withdraw into a state of increasing social isolation. This is similar in some ways to the effect of unexpected panic attacks in conditioning people to phobically avoid many social situations and even venturing beyond the security of their home. USIAs appear to lead to the same result.

#### Effect on Functional Impairment

Recurrent USIAs lead to significant impairment across several domains of functioning. These include, but are not restricted to, the following important domains of functioning.

- 1. work and school work (this lead to financial impairment)
- 2. social life and leisure activities
- 3. family life and home responsibilities
- 4. ability to get along with people
- 5. personal and social relationships
- 6. ability to take care of self
- 7. spiritual and religious life
- 8. impact on others in the family

http://innovationscns.epubxp.com/i/425963/32

<sup>&</sup>lt;sup>1</sup> Corruble E, Benyamina A, Bayle F, Falissard B, Hardy P. Understanding impulsivity in severe depression? A psychometrical contribution, Progress in Neuro-Psychopharmacology & Biological Psychiatry 27 (2003) 829–833. <sup>2</sup> Horesh N, Self-Report vs. Computerized Measures of Impulsivity as a Correlate of Suicidal Behavior. Crisis 2001; Volume 22 (1): 27–31.

<sup>&</sup>lt;sup>3</sup> Dougherty D.M., Mathias C.W., Marsh-Richard D.M., et al. (2009) Impulsivity and clinical symptoms among adolescents with non-suicidal self-injury with or without attempted suicide. Psychiatry Res. 169(1),22–27. 
<sup>4</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from:

# Aggravating or Relieving Factors

#### Opiates

Subjects who have been prescribed opiates for pain, for example Vicodin for severe migraine headaches, report that the opiates both appear to attenuate an existing attack and to prevent USIAs from occurring for several hours after the ingestion of an opiate. If an opiate is taken to attenuate an existing attack, the withdrawal frequently results in a rebound reactivation of the USIA often to a higher level of severity than the initial USIA.

# Antidepressants

Subjects who have recurrent USIAs and are prescribed antidepressants "for the depression" report that this results rapidly (often within days) in an increase in the frequency, intensity, and to some extent the duration of the USIAs. By increasing the frequency of the attacks, the subject has less time to recover in between the attacks and is then less able to cope with the attacks. This renders them less able to resist the suicidal impulse and, as a consequence, the IASD appears to increase the severity of the suicidality in this specific suicidality disorder. Since these USIAs appear to be more common in younger people, it may be that some who have reported flare-ups in suicidality in response to antidepressants actually suffer from Impulse Attack Suicidality Disorder (IASD).

We have heard from some suicidal patients that their experience of suicidality is different while they are taking antidepressants and can "shift" from active suicidal ideation to ideation with more acute urgency and impulsivity that seems more automatic in nature. We believe it is possible that this "shift" in the experience of suicidal ideation may be one reason why younger patients taking antidepressants report an "increase" in suicidality. (See chapter 12.2 for a case study illustrating such an "increase" in suicidality while taking an antidepressant.)

One subject described the experience as follows:

I was 12 when I was started on antidepressants following my first suicide attempt. The antidepressants made my suicidality more intense than I had experienced before starting them. Every time I took [a new] antidepressant I felt an increase in the severity of my suicidality. This frequently resulted in a need to make an attempt sooner rather than later. There is a difference in the specific phenomena I experience when acutely suicidal and on antidepressants, compared to what I experience while not on them. While on antidepressants, it is much more difficult for me to control the suicidality. The ideation and planning tend to be more automatic in nature and less willful. I have heard similar experiences from others that experience suicidality. This is why some of us avoid treatment from mental health professionals. (When I tried to explain that the antidepressants made my suicidality worse, several psychiatrists who treated me told me that I was lying about it because it 'wasn't possible' for this to happen.) Many mental health professionals believe that antidepressants will treat the depression that they assume is the cause of the suicidality and thereby improve the suicidality. The

antidepressants actually make the suicidality different from what we are used to experiencing and we do not want to risk the potential of not coping with this different experience of suicidality while on the antidepressants because it could result in our death. Some of us refer to the difference between the experiences while on antidepressants and while not taking antidepressants as 'a shift in the intensity of the suicidality, the intensity of the USIAs, and the duration of time spent in suicidality outside of the impulsive suicidality'.

One way to quickly screen for IASD is to ask if the patient had an increase / worsening in suicidality when they were prescribed antidepressants in the past. Not all patients with IASD experience such a worsening of suicidality on antidepressants and not all patients who have worsening of suicidality while on antidepressants necessarily have IASD. However, there appears to be an oversampling of subjects with IASD in this group.

#### Relation to Diet

Some patients may notice the time spent in suicidality and / or the severity of their suicidality decreases when they are taking a diet that is rich in magnesium (for example, spinach, peppermint, avocados, dark chocolate, bananas, pineapple, beets, broccoli, sunflower seeds, sesame seeds, almonds, brazil nuts, cashews, or peas are all high in magnesium). Diets rich in calcium can interfere with the absorption and bioavailability of magnesium and offset any antisuicidality effect of magnesium.

#### Conditioning

A USIA appears to have the ability to classically condition almost any stimulus to become a subsequent trigger for a suicidal phenomenon. If a USIA occurs repeatedly in the presence of any stimulus, the stimulus can subsequently acquire the ability to bring on suicidality even in the absence of the USIA. A USIA could also trigger enteroceptive conditioning. Through repeated pairing of a USIA and some bodily functions (e.g. tachycardia), the tachycardia could acquire the ability to bring on some suicidal phenomena even in the absence of the original USIA. With very severe USIAs, sometimes one-trial learning can occur. For example, one subject with IASD reported that he experienced suicidality on the 1-year anniversary of his father's death. On subsequent anniversaries the subject consistently experienced a USIA and other suicidal phenomena on this date.

# Lack of Relationship to Temperature, Humidity, Seasonal Variation, or Phase of Menstrual Cycle

To date we have found no relationship between temperature, humidity, seasonal variation, or premenstrual phase of cycle (even when there was such a relation with depressed mood) and USIAs or fluctuations in the severity of IASD. However this merits further investigation.

### **Effects of Stressors**

Most people think of suicidality as a reaction to life stressors. There is an abundance of literature describing such a relationship. However, suicidality can occur even in the absence of

any apparent psychosocial stressors and even in the absence of any apparent antecedent depressed mood. There is much less of a relationship between psychosocial stressors and USIAs in IASD than most people expect. In the early phases of the illness, there may be no apparent precipitants for the USIAs. Over time, the subject may begin to associate the attacks with various external events that now acquire the ability to trigger both the USIAs and other suicidality phenomena. So by the time the subject is seen several years into their disorder, they have a mixture of a few attacks that appear quite unexpected and many attacks that appear to be triggered by psychosocial events. This can lead to clinicians ignoring the unexpected nature of the few attacks and in understanding the central importance of the unexpected, unprovoked attacks in helping identify this Impulse Attack Suicidality Disorder. Paradoxically, patients with chronic recurrent IASD report that having to deal with severe or serious psychosocial stressors (e.g. the death or serious illness of a loved one) are the few times that they are without any suicidality.

#### Antecedents

# Relation to Red Recurring Papules on Fingers

We identified a relationship in one subject between the emergence of small transient red recurring papules on the fingers. After the lesions emerge water seems to accentuate the severity of the lesions. These lesions are painful and itchy. They suddenly appeared exactly 30 days (give or take 3 days) before flare-ups of USIAs. This may be associated with an inflammatory or autoimmune link between these lesions and the USIAs and IASD. (See the case study in chapter 12.3 for more information.)

#### "Better Off Dead"

We have reported on the relationship between antecedent feelings of being better off dead and the emergence of USIAs two to five days later<sup>5</sup>. This is the subject of a very detailed single case report. We found this association in 9 out of 10 consecutive USIAs in a subject with IASD. The thoughts of being better off dead in this subject occurred without any follow-up USIAs quite frequently. However, as noted above, 9 out of the 10 USIAs were preceded by this unique suicidal phenomenon of feeling "like I would be better off dead".

<sup>&</sup>lt;sup>5</sup> Giddens JM, Sheehan DV. Is there any value in asking the question "Do you think you would be better off dead?" in assessing suicide? Innov Clin Neurosci. 2014;11(9–10):182–190. Available from: <a href="http://innovationscns.epubxp.com/i/425963/182">http://innovationscns.epubxp.com/i/425963/182</a>

# How Treatment Changes the IASD (Response to Recovery & Stages of Recovery)

There is a pattern of fragmentation of the component parts of a USIA and IASD and their disappearance over time in relation to each other (they are on a different schedule of elimination). The **high magnesium oxide / low calcium dietary intake** (+Mg-Ca) appears to disaggregate the USIA and IASD into 4 component parts:

- 1. suicidal impulse and suicidal ideation component (it decreases this from the beginning, but more gradually over time)
- 2. physical symptom component (no effect early, but it does later decrease this)
- 3. the emotion component associated with the unexpected automatic decision to act in a suicidal way, outside the impulse attacks. These automatic decisions are not experienced as an impulse and have no urgency and no sense of being pushed towards action. The automatic decisions appear willful to the patient at the time. However later the patient is disturbed by this earlier decision and realizes that it was not willful, but was an autonomous thought. Prior to the high magnesium oxide / low calcium dietary intake, this component was frightening. Infrequently there may be little or no emotion associated with this automatic suicidal decision, which is surprising given its gravity. Some patients may have this lack of emotion most of the time. In the shorter term, the high magnesium oxide / low calcium dietary intake tends to increase the fluctuations in the automatic decisions, which are made without emotion. After starting this treatment, there were times with little or no emotion associated with the decision to make a suicide attempt, which may be surprising given its gravity. In the longer term, the high magnesium oxide / low calcium dietary intake appears to stabilize / modulate or reduce the swings / fluctuations in this component. This type of automatic decision has the appearance of a partial USIA, but with the aura, the need to be dead, the physical symptoms, the sensory component and the gambit blocked or stripped away from a full USIA (like a limited symptom attack). Consequently, because the USIA Ideation and Physical Symptom Subtype attacks are largely blocked at this stage, the presence and increased frequency of these Ideation Only USIAs gives the impression that things are worsening (because the Ideation Only USIAs are still frequent), when in fact the overall disorder is improving. This apparent flare up of the USIA Ideation Only Subtype is not necessarily an indication that something is getting worse, but may reflect a way station on the path to improvement.
- 4. the feeling of being pushed or compelled to act in a nonspecific way. Prior to the high magnesium oxide / low calcium dietary intake treatment the feeling of being pushed or compelled to act in a nonspecific way was directly connected to the suicidality. Following the treatment, this feeling occurred on its own without being associated with any suicidality.

How long does it take to see a benefit from the high magnesium oxide / low calcium dietary intake in a subject with IASD who has not received this treatment before?

For patients who have never been treated with high magnesium oxide / low calcium dietary intake it may take longer to see a response than it does to see a response to a brief acute relapse.

Because the dose required by each patient may be different and may take some time to optimize and because it takes time for them to make the necessary dietary adjustments to lower their calcium intake, it may take 2 to 6 weeks to notice good efficacy. If there is no observable efficacy after following the high magnesium oxide / low calcium dietary intake treatment regimen directions in the medications in the treatment of suicidality chapter, for 12 weeks then this treatment regimen should be discontinued. It is not known at this time how concomitant treatments for other psychiatric disorders will influence the above timelines. It is best to initiate this treatment at an interval greater than 5 half-lives of any prior psychiatric medication. The most sensitive measure in detecting the efficacy measure is the time spent in suicidality per day. The second most sensitive outcome measure is the Suicidal Impulse Attack Scale (SIAS). The next most sensitive and most comprehensive measure is the Sheehan-Suicidality Tracking Scale (S-STS) total score. The response in the Suicide Plan Tracking Scale (SPTS) typically lags behind the change in the other scale scores.

#### Trendline

The data may reflect a positive improvement in the trendline using the above measures before the efficacy is fully apparent to the subject. The change in this trendline typically begins within the first week after initiation of the high magnesium oxide / low calcium dietary intake regimen. It is not unusual for patients to get to a stage where they have no suicidality and 0 time spent in suicidality within 3 months of starting the high magnesium oxide / low calcium dietary intake regimen.

#### Spikes During Recovery

When the scores on the above mentioned scales are plotted in a line graph several upward spikes may be noted along the downward trendline of improvement. See figures 12.3.1, 12.3.4, and 12.3.5 in case study on IASD responding to the high magnesium oxide / low calcium dietary intake regimen. These transient and brief increases in total scale scores, may reflect issues relating to finding the optimal dose, the optimal dose distribution, and transient failures in restricting calcium in the diet. Apart from the above mentioned adjustment issues, these spikes may also reflect the natural history of the devolution of the disorder in response to treatment. These spikes often reflect very short bursts of intense suicidal phenomena. These short bursts of suicidal phenomena may include a more diverse range of suicidal phenomena than are regularly seen in the subject. One subject reported that these short bursts contained the range of suicidal phenomena they usually experienced during a USIA all crammed into a short (typically 1 to 3 minutes) timeframe. However, if the overall time spent per day in suicidality is significantly decreasing, do not over-interpret the gravity of the spikes. Continue to monitor progress on all the scales to ensure that the trendlines are all moving in the same direction of improvement.

If a patient has a short-term relapse after a long-term (6 months) period of being free of suicidality, how long does it take for the high magnesium oxide / low calcium dietary intake regimen to have an anti-suicidality effect in IASD?

Typically the relapse responds to a dose increase in the magnesium oxide within 7 to 10 days. Before increasing the magnesium oxide, first verify that the calcium in the diet has remained low

and that the subject did not inadvertently ingest calcium-rich foods or drugs. If there was an increase in calcium intake, it is more prudent to manage the relapse by again restricting the calcium intake before resorting to a further increase in the magnesium oxide dose.

# How long does it take for the magnesium oxide to work after being off it for 1 week?

One subject had an acute relapse of 1 week, while taking no magnesium oxide supplements, following an asymptomatic period of almost 6 months free from suicidality. In the short term (3 to 7 days) restarting the magnesium oxide at a therapeutic dose decreased the seriousness of the suicidal impulse and suicidal ideation within the USIA by about 30%. The magnesium oxide decreased the time spent experiencing suicidality outside the USIA, over the same time period. See medications in the treatment of suicidality chapter, section on magnesium - long-term effects, for further details.

Impulsive Traits Worsened as Impulse Attacks Came Under Control

As note above, when subjects with IASD respond to treatment they may notice themselves feeling less inhibited or restrained (having less state impulsivity) and their "trait" impulsivity scores may increase. In the case example mentioned above this increase in impulsive personality traits paralleled exactly the decrease in unexpected suicidal impulse attacks (USIAs).

# Suggestions for How to Handle an Unexpected Suicidal Impulse Attack (USIA) (Tips and Tricks)

#### For the Clinician

From the patient's perspective it does not make sense for them to be hospitalized every time they have a USIA. The clinician on the other hand may feel obliged to hospitalize them for their own medico-legal protection. However, given the nature and natural history of the disorder and the lack of available approved treatments the logic behind repeatedly hospitalizing said subject remains unclear. When one subject was asked what advice she would have for a clinician faced with a patient having a USIA, she replied, "Just don't freak out. It is hard enough for me to deal with the attack, but if I also have to deal with a clinician freaking out I have two insurmountable obstacles, instead of just one." Clinicians need to set up protocols for psychiatric ERs and impatient units that would allow a patient to stay there through the end of their USIA without being forced to spend the following days in the hospital. This would help the patients be more likely to reach out for help and would be less intrusive on their life than the current 72-hour psych holds. Clinicians also need to consider protocols for physical restraint of these subjects as some subjects report that they find such physical restraint extremely helpful in keeping themselves safe. Patients report that in spite of all the precautions of impatient psychiatry services that if they really want to kill themselves they can find a way to do it. Physical restraint can help the patient experiencing a USIA to avoid making a suicide attempt in such settings. If patients felt they could collaborate with the clinician on such a protocol it could allow them to seek help in coping with these USIAs while they are still able to resist the suicidal impulse and before they are so exhausted by the USIA that they feel the need to give up and give into the impulse to kill themselves. One subject stated "if in the early stages of the attack, I knew such a protocol was in place and that I could go to the hospital, get such help in keeping myself safe, and not have to worry about being kept there for days against my will, then I would be more likely to go to the hospital at that time, before I was exhausted from and nearly ready to give into the suicidal impulse". Most patients with this disorder do not find no-harm contracts helpful. They interpret the offer of no-harm contracts as a sign the clinician fundamentally does not understand this condition. (See Appendix 15.1 on the use of no-harm contracts.)

### For the Patient

Patients need to be reminded that these USIAs are not unique to them and that others have had similar attacks. The attacks are time-limited and will pass. New treatments are being developed for these USIAs and for this IASD disorder. Increasingly, clinicians are recognizing the existence of this unique disorder and learning how better to deal with it in a constructive, collaborative manner. Patients need to make a safety plan for themselves which clearly and simply explains what they will do when they experience an impulse attack. This may include contacting their clinician or a crisis line and may also include distractions that may help them be safe until the end of the attack. Ensure any safety plan has any necessary information (such as phone numbers) and consider putting together a kit that contains any items used as a distraction so that the patient will not need to attempt to find such items while experiencing an attack.

#### Means Substitution

By means substitution we mean replacing the preferred means for a suicide attempt with means that are not likely to result in serious injury or death. For example, one subject that had planned on overdosing on tablets found they could go through the motions of 'overdosing' on Tic Tacs instead of the planned tablets. This means substitution seemed to relieve the USIA symptoms as though they had made an actual suicide attempt. We do not recommend patients purposely plan a suicide attempt in hopes they will use a substituted means when they have an impulse attack, as the having the plan in place can go awry. Some patients find that having a plan in place in advance of the impulse attack freed up their focus during an impulse attack and allowed them to focus more energy on resisting the suicidal impulse. During the initial acute impulse, patients find themselves automatically scanning their environment for ways or means to kill themselves. Having a plan in place before the USIA appears to improve ability to resist this autonomous drive to scan. While all of this might be frightening for a clinician to hear, the reality is this is part of the phenomenology of this Impulse Attack Suicidality Disorder.

#### Example:

During an action-centered unexpected suicidal impulse attack a person's mind autonomously and actively tries to convince them to make a suicide attempt. The subject's mind autonomously and actively surveys the environment and rapidly suggests ways to use the items around them as tools for a suicide attempt. Few techniques help to decrease the intensity of these thoughts. The traditional cognitive exercises suggested by cognitive behavioral therapy (CBT) or dialectical behavior therapy (DBT) are less than effective as the person is unable to completely control their thought patterns, which appear to have a life of their own, during these attacks. These attacks regularly last from 1 to 6 hours and trying to fight against or ignore these thoughts and impulses is incredibly exhausting. Many people find it very difficult to stay safe for this length of time.

Suicidal people are often told to call crisis lines. Those experiencing these impulse attacks may try that option a few times, but doing so comes with additional risks. It is not unusual that the person answering their call is unfamiliar with impulse attacks and asks about the triggers for the suicidal thoughts. For those with no apparent triggers, this question conveys that the telephone operator does not understand their experience. This lack of understanding sometimes reinforces the suicidal person's view that seeking help is useless, and is frequently followed by an autonomous reaction that killing themself is the best option, since no one understands their experience. Subjects worry they will say something that will lead the telephone operator to become more concerned, to trace their phone number, identify their location, and have law enforcement take them against their will to get 'help'.

Some go to emergency rooms or crisis stabilization units on their own, while others are forced there against their will. Simply changing their environment does not decrease the intensity of this impulse attack, nor does it make this attack

stop. While at a hospital, items they can easily use to make an attempt may be taken from them, but there are still a plethora of items around them they can use in an attempt. The one thing that some with impulse attack suicidality have found to be very effective, physical restraint, is not usually an option. Even if the patient asks for the physical restraint, hospital protocols prefer chemical restraints, which patients report are ineffective during impulse attack suicidality. When the intensity of the impulse attack decreases in the emergency room (ER) or crisis stabilization unit (CSU), patients are regularly forced to remain hospitalized for days of observation, to ensure they will not make an attempt. The concern about incarceration, and the awareness that there are no approved treatments for these suicidal impulse attacks, is why many such people do not seek 'help'. On the other hand, some subjects report that being physically restrained for several hours reduces the potential of harm resulting from the impulse attack, since they are not physically able to attempt suicide. The physical restraints allow the patient to relax and to wait out the passage of the suicidal impulse attack. Once the attack is over, they feel more in control and often feel ready to go home. Patients with IASD know from experience that the likelihood of getting 2 impulse attacks in rapid succession is very remote. So they feel little reason for further detention. They would like to see hospital protocols put in place to accommodate their request for short-term physical restraints, followed by discharge from the hospital, as long as their history of IASD does not include a tendency to experience impulse attacks in rapid succession. If patients knew such protocols were in place, many more would come to the hospital to seek such short-term protection. In addition, such protocols would be cost saving, because it would not require that all such patients be involuntarily hospitalized for 72 hours.

Many who do not seek 'help', and even some that do, end up making a suicide attempt. A person having an unexpected suicidal impulse attack usually has a quick decrease in the intensity of their suicidality after making a suicide attempt. Some become very calm within seconds of making an attempt. However, there is a high risk that a suicide attempt made during a suicidal impulse attack may result in permanent impairment, because the attempt is impulsive, poorly researched, and only briefly planned.

Some who have suicidal impulse attacks make a suicide attempt with a less lethal substitute, as a way of ending the impulse attack. Instead of carrying out an actual suicide attempt, they alter the means, and sometimes the method, in order to reduce the potential of injury. For example, a person thinking about taking an overdose of sleeping medications may substitute Tic Tacs or candy buttons for their hypnotic medication and instead go through the motions of a suicide attempt with these substitutes. Such a substitution significantly reduces the likelihood of harm. Although it is unclear why, the process of going through the motions of a such a "substitution suicide attempt", even though the likelihood of harm is low, serves as another technique to quickly decrease the intensity of the suicidality, in a manner similar to the calm after an actual attempt.

One subject that used a substituted means to help cope with the USIAs created the following chart with examples of a planned means and a potential substitute means that reduces the likelihood of harm.

	Suicide Attempt Means		Suicide Attempt Means Substitution
•	sleeping medication overdose	•	replace sleeping medication with Tic Tacs
•	insulin overdose	•	replace insulin with sterile saline
•	drinking oleander tea	•	replace oleander tea with kuding tea
•	hanging / rope	•	create a chest harness, suspend self from tested hard point, and replace noose with additional piece of rope loosely laid over neck
•	shooting self	•	replace handgun with Nerf gun

7

# Domains of Suicidality Disorders

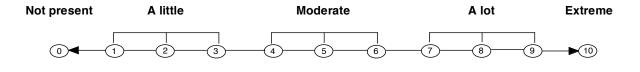
# Introduction

Below are crosscutting domains that specifically apply to the Suicidality Disorders. These crosscutting domains can be used in the same manner as the crosscutting symptom domains in DSM-5. Any of the Suicidality Disorders might be associated with one or more of the crosscutting domains below. This information enriches the clinical description of the categorical diagnoses of the Suicidality Disorders.

Use the format below to record the severity of any of these cross cutting domains that complete the clinical description for each patient's suicidality disorder.

#### **ASSOCIATION OF DOMAIN WITH SUICIDALITY**

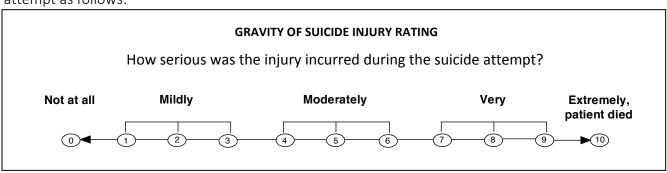
Use this scale to rate in the score column of the table below, how much your suicidality Is associated with each of the following domains:





Indicate if:		Score		
1. with hopeless	ness			
	a wish to avoid a future loss that the subject feels is essential to their .g. love, good health)			
3. with bereaver	ment / reunification intent			
	e compulsive features			
5. with "overwh	elmed state" features			
6. with psychotic	features			
7. with anhedon	ia / depressive / melancholic features			
8. with anger / a	ggressive features			
9. with serious /	terminal illness			
10. with anxiety /	tension			
11. with sleep dis	turbance			
12. with seasonal	pattern			
13. with depersonalization / derealization / dissociative features				
14. with non-suici	dal self-injury			
15. with social / political motivation or sanction				
16. with religious motivation or sanction				
17. with martyrdo	om motivation or sanction			
18. with motivation	on to control another or others			
19. with motivation to use suicidality to communicate a message				
20. with homicidal features				
21. with impairmer responsibilitie	ent in work, school, social life, leisure activities, family life or home			

If a suicide attempt is made, rate the medical seriousness of the injury incurred during the suicide attempt as follows:



#### **Definitions of Domains**

with hopelessness – with any loss of hope up to and including complete loss of hope

with avoidance of future loss – motivated by a wish to avoid a future loss that the subject feels is essential to their wish to live (e.g. love, good health)

with bereavement / reunification intent – with a state of intense grief after the loss of a loved one or a desire to be reunited with the lost loved one

with obsessive compulsive features – with any classic obsessive thought or compulsive behavior typically seen in Obsessive Compulsive Disorder

with "overwhelmed state" features – with the sense of being emotionally overcome

with psychotic features – with any classic auditory or visual hallucination or delusion (i.e. mistaken belief)

with anhedonia / depressive / melancholic features – with any loss of capacity to enjoy or experience pleasure <u>or</u> with any depressed mood, downhearted, dark, or blue feelings

with anger / aggressive features – with irritability and hostility

with serious / terminal illness – with any non-psychiatric medical illness that is serious or close to death

with anxiety / tension – with any feeling of anxious, tense, nervous, restless, or agitated

with sleep disturbance – with any difficulty falling asleep, staying asleep, waking up too early in the morning, or sleeping excessively

with seasonal pattern – with any pattern of recurring consistency during any season of the year

with depersonalization / derealization / dissociative features — with a feeling of things around them being strange, unreal, detached, or unfamiliar or feeling outside of or detached from all or part of the body or cannot recall what happened for a block of time even thought there was no other loss of consciousness

with non-suicidal self-injury – with any self-harm in the absence of any intent to die as a result

with social / political motivation or sanction – for reasons of seeking the approval, companionship, or good relations of or to obtain benefit from others  $\underline{or}$  the approval of others in a power position  $\underline{or}$  associated with public affairs of a state or power seeking group

with religious motivation or sanction – for reasons of seeking approval of or to obtain benefit from an organized religious group or deity

with martyrdom motivation or sanction – for reasons of sacrificing themself on behalf of any belief, principle, or cause

with motivation to control another or others – for reasons of trying to exercise restraint or direction over

with motivation to use suicidality to communicate a message – for reasons of trying to send a message to others

with homicidal features – with any intent to kill others

with impairment in work, school, social life, leisure activities, family life or home responsibilities — with any reduced, weakened, damaged, or diminished capacity to function in work, school, social life, leisure activities, family life, or home responsibilities

8

# Stages of Suicidality Disorders

#### Introduction

Patients with chronic suicidality move through several stages in the natural history of the disorder. While there can be variations, the staging below gives a framework to help clinicians, caregivers, and patients better understand the nature, struggles, progression, and consequences of the disorder.

# Stage 1: Onset

The individual begins to experience symptoms of suicidality. The first symptoms may be in the form of suicidal ideation, but could be experienced as a suicidal behavior.

Some individuals report passive suicidal ideation (for example, "I wish I were dead.") As another example, after a visit from the fire department to her kindergarten class, one child reported lying in bed at night thinking "I wish there was some way I could die in a fire."

Others' first experience may be in the form of active suicidal ideation (for example, "I should kill myself.").

Others experience a suicidal behavior first. For example, one individual reported being in an argument with his wife. He wanted to teach her a lesson about escalating arguments. Seeing her medication on the counter, he picked up the bottle in a volcanic rage and swallowed all of the tablets to make her pay for how she was "driving [him] crazy". He then told his wife that she had driven him to his death; in effect she had now killed him and would have this on her conscience for the rest of her life.

Still others' first experience may be a suicidal impulse where they feel the *need or urgency* to kill themselves, sooner rather than later. One individual, for example, reported "feeling that I just had to kill myself immediately".

While clinicians often assume that passive ideation always precedes active ideation and active ideation always precedes suicidal planning and so on, many individuals suffering from this disorder report their suicidality does not follow this linear progression. The initial symptoms of suicidality could be any one of the suicidality phenomena, not necessarily classic passive or active suicidal ideation.

# Stage 2: Worsening and Clustering

In this stage untreated suicidality increases in severity, duration, and / or frequency. Patients may also notice a clustering of phenomena. So, where an ideation event could be described before as only "passive" or only "active" there may now be passive and active ideation at the same time. Similarly, an event that involved planning but was limited to a single element (method, means, date, location, or tasks) may now contain several of these elements. Plateaus when symptoms hold in particular patterns for a while before a further worsening are common in this phase.

# Stage 3: Internal Struggle and Denial

Most patients are disturbed, concerned, or frustrated by suicidality. They may try to minimize or downplay it. Some will deny any suicidality all together. Several factors play a role in this denial.

First, suicidality is scary. The natural inclination is to minimize, deny, or hide it.

Second, suicidality is associated with negative stereotypes. While individuals may acknowledge the experience, they often distance themselves from it because they do not want to believe they fit the cultural or religious concept of the stereotypical 'suicidal person'. One person reported not wanting to initially acknowledge her suicidality because her family had already made it clear to her that people who are suicidal are all "crazy" and she did not want her family to think of her as "crazy".

Third, being honest about suicidality can expose a person to consequences they might prefer to avoid. In many parts of the world admitting to another person that you are suicidal can result in your being involuntarily hospitalized. In other parts of the world, where suicidality is seen as a sin or a crime, people with suicidality can be put in prison! People in these areas of the world may deny their suicidality, even to themselves, as a protection against such unwanted penalties.

#### Stage 4: Impairment

Patients experiencing unexpected suicidal impulse attacks (USIAs) may develop a fear and aversion to locations where the attacks occurred. They may start avoiding social interaction lest

an attack occur in the presence of another person. In some cases, they may even develop an aversion to leaving home out of a fear of having an attack in an uncontrolled, uncomfortable, or unfamiliar environment. Apart from the fears and aversion, the suicidal impulse attacks can completely exhaust a person. This leaves them drained and with less ability to function at work, in social settings, and at home.

Even patients not experiencing USIAs often find that they are emotionally drained and physically exhausted as a result of their symptoms. In the hours or days after a suicidal event, it can be hard to focus on every day tasks. The individual may also find that it is harder to socially interact.

As functional impairment worsens, they may have to choose between being functional and being more capable of coping with the suicidality when it presents. Many may chose to focus their limited functionality on coping with the suicidality in order to keep themselves alive instead of attempting to be more functional in work, social, and home responsibilities.

# Stage 5: Diminishing Future

Traditional models of suicidality suggest that depression and hopelessness always appear *before* an experience of suicidality. For some patients this may be the case. For others, depression and hopelessness may instead be a sequel or consequence of suicidality, appearing *afterwards*.

In this stage, suicidality impacts multiple areas of a person's life including the person's perspective on their life. Over time, the experience of suicidality breaks down the person's ability and willingness to cope and try to stay safe. One individual reported feeling as if he could not really prevent himself from making a suicide attempt the next time his suicidality worsened even though he didn't want to die. Others have told us they find they are no longer willing to cope or to stay safe even though they are able to do so. One individual described this as feeling completely overwhelmed and hopeless and feeling as though killing herself was her only option to end the suicidality. Still others report they are no longer willing or able to cope or to stay safe. As one patient put it, "I felt so overwhelmed and frustrated by my suicidality that I made the decision that killing myself was the only way to end my suffering."

#### Stage 6: Help Seeking

At some point in the progression of the disorder patients seek help in coping with their suicidality. Some look to loved ones, friends, and clergy, others to healthcare professionals. All too often they are met with inappropriate reactions. One person reported that her mother said she "should be locked up because [she] was obviously crazy." Another said she was lectured by her pastor because, as he put it, suicidal thoughts are "sinful". A third recounted a psychiatrist responding "we don't talk about that here" when he mentioned that his suicidality had increased in severity.

All too often clinicians jump to hospitalize patients out of fear of what will happen if they do not. These types of responses from loved ones, friends, clergy, and healthcare professionals lead

patients to feel isolated, stigmatized, and afraid to honestly communicate their experience of suicidality.

Patients may cycle through this stage of help-seeking multiple times over time. One individual reported going through this process more than 15 times in the course of 20 years. This person stated:

I felt frustrated when the treatment didn't help me and, in some cases, it actually made my suicidality worse, so I would end treatment and try to cope with my suicidality on my own until my symptoms became very severe. At this point I would again attempt to seek help from those around me, but usually that resulted in the suggestion that I see a mental healthcare professional. Even if I attempted to explain to my loved ones that such treatments actually made my suicidality worse, they assumed it would help me *this* time and became upset with me if I didn't follow their suggestions. Eventually I would get desperate enough to seek professional help, but that help resulted in the same lines of treatment I had previously tried. Again, the treatment was either not successful or made my symptoms worse. This process continued again and again over the years.

# Stage 7: Dynamic Interplay

All too often, loved ones are frustrated at the suicidal patient's inability to function and begin to resent the patient. This may be because they are afraid of losing the person or just because they are tired of trying to protect and accommodate the patient. After being re-hospitalized, one individual said that one of her parents stated: "I'm so tired of this. Why do you keep doing this? It is all very stressful for [us]." She reported feeling as though she was being further punished by her family because they did not understand her suicidality.

Another patient reported that friends who were close in the initial stages of her suicidality later distanced themselves from her because it was "too much for them to cope with me being suicidal all the time." She added that she wished they had "thought about how difficult it was for me to be suicidal all the time."

Over time the patient may become less and less willing to communicate with others out of fear of being pushed away again or fear of being treated differently again. As one patient put it:

"I learned I couldn't be honest with anyone. My honesty led to everyone around me walking away and I couldn't risk losing the few people that were still close to me. I had to hide what I was experiencing from everyone around me to avoid becoming even more hopeless because my suicidality again ruined the friendships I spent so much time forming."

#### Role of Life Events

Psychosocial events can compound a patient's already-present suicidality. The individual is likely having enough difficulties coping with their suicidality and then has another situation, the

stressful life event, to deal with on top the suicidality. On the other hand, a stressful life event, such as a friend of family member becoming ill or dying, can have a paradoxical effect with a pause in symptoms for days or weeks while the individual copes with this new event.

# Recovery or Irreversibility

Recovery can occur. More often, without adequate treatment there is permanent damage or death. One suicidal subject stated:

"I finally accepted the idea that I would kill myself. It wasn't a matter of *if* I would kill myself, but *when* I would kill myself. I knew that if I lived long enough my suicidality would eventually overwhelm and consume me until I either permanently damaged myself to the point where I couldn't make another suicide attempt or until I died. It seemed as though fate had dictated that this was how I was going to die. I could try to resist and put it off another few days, weeks, months, or years, but deep down I knew this was how I was going to die."

#### Conclusion

Suicidal patients delay seeking help for their suicidality because of current stigmatization and the lack of treatments specifically effective for suicidality. As more specific anti-suicidality treatments become available, we need to focus efforts on earlier identification of suicidality. We need to implement treatments with more compassionate understanding of the patients' experiences and struggles with suicidality disorders.

9

# Treatment of Suicidality

Clinical research on treatments in suicidality is a sadly neglected topic. Imagine the following scenario. We approach the oncologists. We tell them they can no longer do any more clinical trials on treatments for pancreatic or lung cancer. When they protest this whimsical directive and inquire as to the reason we explain. Pancreatic and lung cancer are usually rapidly fatal. The prognosis is poor. If we put such patients in the clinical trial with a new oncology drug they may die in the trial. We might be held liable for this regrettable outcome. So the safest medico-legal solution is to avoid doing research on these more dangerous cancer disorders. We encourage them to instead focus their energies on such malignancies as basil cell carcinoma. Why? Because these disorders have a good prognosis and favorable outcomes and patients are not likely to come to harm during such clinical trials. We tell them that the ethics pontiffs consider the studies with such a poor prognosis unethical.

Next we approach the cardiologists. We tell them that they can no longer do clinical trials on treatments for myocardial infarctions and congestive heart failure. When they protest this whimsical directive and inquire as to the reason we explain. Myocardial infarctions and congestive heart failure are usually rapidly fatal. The prognosis is poor. If we put such patients in the clinical trial with a new cardiology drug they may die in the trial. We might be held liable for this regrettable outcome. So the safest medico-legal solution is to avoid doing research on these more dangerous cardiac disorders. We encourage them to instead focus their energies on such cardiovascular conditions as fluttering in the chest or premature ventricular contractions. Why? Because these disorders have a good prognosis and favorable outcomes and patients are not likely to come to harm during such clinical trials. We tell them that the ethics pontiffs consider the studies with such a poor prognosis unethical.

Both groups protest that these are ridiculous directives because they are being asked to avoid finding new treatments for the serious and potentially fatal conditions in their specialty. They feel that because of the high mortality associated with these conditions that they ought to be the first priority of clinical research in their specialties, rather than conditions to be avoided. They argue that all specialties focus their primary efforts on finding treatments for the diseases with the highest mortality and the poorest outcomes. That is, except psychiatry.

Psychiatry is unique among specialties in that it avoids doing clinical trials on suicidality disorders, which are a leading cause of death in psychiatry. Psychiatry prefers to do clinical trials on milder, safer conditions where the outcomes are more favorable and the risks for the investigators are lower. The ethics pontiffs in psychiatry consider that doing clinical trials in suicidality disorders is unethical. Patients with suicidality are routinely excluded from clinical trials in most treatment research protocols of psychiatric disorders because of medico-legal and ethical concerns. Many suicidal patients feel discriminated against by this routine practice. It may even be a violation of the Americans with Disabilities Act. They consider that it is unethical and discriminatory for anyone to exclude them from such trials if they freely choose to participate with proper informed consent. Some suicidal patients have felt more hopeless because they are being discriminated against and, as a result, they fear it is unlikely that good treatments will be found for their suicidality disorder(s) in the foreseeable future. Until good anti-suicidality treatments are widely available, such clinical trials are a suicidal patient's best hope to have access to anti-suicidality medication treatments. It is somewhat reminiscent of the widely practiced exclusion of women from many clinical trials of psychiatric disorders in an earlier era. Fortunately, women collectively disputed this discriminatory practice and are now actively participating in clinical trials in all disorders in psychiatry. Suicidal people need to collectively organize to ensure a similar outcome to accommodate them. Obviously these studies need to be designed safely and thoughtfully. Intelligent people are perfectly capable of sitting down, debating these issues, and finding appropriate, safe, and effective solutions to designing and conducting clinical treatment studies for suicidality disorders.

# 9.1

# Medications in the Treatment of Suicidality

# High Magnesium Oxide / Low Calcium Dietary Intake Regimen

Results from detailed observations of a case of Impulse Attack Suicidality Disorder (IASD) (see chapter 12.3 for a case study on the use of magnesium oxide in IASD):

The high magnesium oxide / low calcium dietary intake regimen (+Mg-Ca) impacts the unexpected suicidal impulse attack (USIA).

- 1. In the short term (3 to 7 days) the high magnesium oxide / low calcium dietary intake regimen decreased the seriousness of the suicidal impulse and suicidal ideation that is experienced within the USIA by about 30%.
- 2. In the longer term (over weeks to months) this treatment decreased the seriousness of the suicidal impulse and suicidal ideation that is experienced within each subsequent USIA until the suicidal impulse and suicidal ideation did not present during the attacks. This new attack is called a Non-Suicidal Physical Symptom Attack (NSPSA).
- 3. Once the NSPSA's started, in the even longer term (subsequent weeks to months) the high magnesium oxide / low calcium dietary intake regimen decreased the seriousness of the physical symptoms experienced within the NSPSA's until these attacks did not occur at all. The severity of the physical symptoms in the NSPSA's may appear more severe than those within the USIA's because the physical symptoms come into a sharper focus than they were in the past.

The high magnesium oxide / low calcium dietary intake regimen impacts the suicidality outside of the impulse attacks.

- 1. In the short term (3 to 7 days) this treatment decreased the time spent experiencing suicidality outside the USIA.
- 2. In the longer term (weeks to months) the high magnesium oxide / low calcium dietary intake regimen decreased the severity of the suicidal ideation until the suicidal ideation no longer occurred.

#### Near-term Effects

The high magnesium oxide / low calcium dietary intake impacts the suicidality:

- 1. In the short term (3 to 7 days) this treatment decreased the seriousness of the suicidal impulse and suicidal ideation that is experienced within the USIA by about 30%.
- 2. In the short term (3 to 7 days) this treatment decreased the time spent experiencing suicidality outside the USIA.

# Long-term Effects

The high magnesium oxide / low calcium dietary intake regimen impacts the suicidality:

- 1.a. In the longer term (over weeks to months) this treatment decreased the seriousness of the suicidal impulse and suicidal ideation that is experienced within each subsequent USIA until the suicidal impulse and suicidal ideation did not present during the attacks. This new attack is called a Non-Suicidal Physical Symptom Attack (NSPSA).
- 1.b. Once the NSPSA's started, in the even longer term (subsequent weeks to months) this treatment decreased the seriousness of the physical symptoms experienced within the NSPSA's until these attacks did not occur at all. The severity of the physical symptoms in the NSPSA's may appear more severe than those within the USIA's because the physical symptoms come into a sharper focus than they were in the past.
- 2. In the longer term (weeks to months) the high magnesium oxide / low calcium dietary intake regimen decreased the severity of the suicidal ideation until the suicidal ideation no longer occurred.

Benzodiazepines help decrease the physical symptoms experienced in the USIA and the NSPSA and also the seriousness of the ideation. It does not impact the strength or the frequency of the USIAs. The benzodiazepine gives the patient a sense of calm even though the severity of the ideation may not have decreased. This calm reduces the sense of seriousness of the suicidal ideation, even if the severity or frequency of the suicidal ideation remains unchanged. While this sense of calm may appear to be helpful from one perspective, it may be potentially problematic from another perspective. If a patient is not alarmed by the suicidal ideation, they may be more likely to act upon it by making a

suicide attempt. Researchers need to investigate in detail any advantages and disadvantages of benzodiazepines when they are used in IASD and in other suicidality disorders. Until we have better evidence benzodiazepines should only be used with great caution in patients with impulse attack suicidality disorder and should be confined to use in in-patient settings, where these effects can be closely monitored.

This reflects apparently opposite selective effects of benzodiazepines in suicidality. They reduces the seriousness (but not the severity and frequency) of suicidal ideation and the physical symptoms associated with the USIA, but concurrently impair the sense of restraint and control over the likelihood of acting on these thoughts.

The high magnesium oxide / low calcium dietary intake regimen appears to disaggregate the USIA and IASD into 4 component parts:

- 1. suicidal impulse and suicidal ideation component (it decreases this from the beginning, but more gradually over time)
- 2. physical symptom component (no effect early, but it does later decrease this)
- 3. the emotion component associated with the unexpected automatic decision to act in a suicidal way, outside the impulse attacks. These automatic decisions are not experienced as an impulse and have no urgency and no sense of being pushed towards action. The automatic decisions appear willful to the patient at the time. However later the patient is disturbed by this earlier decision and realizes that it was not willful, but was an autonomous thought. Prior to taking the high magnesium / low calcium dietary intake regimen, this component usually was frightening. Infrequently there may be little or no emotion associated with this automatic suicidal decision, which may be surprising given its gravity. Some patients may have this lack of emotion most of the time. In the shorter term, this treatment tends to increase the fluctuations in the automatic decisions, which are made without emotion. After starting the treatment, there were times with little or no emotion associated with the decision to make a suicide attempt, given its gravity. In the longer term, the high magnesium oxide / low calcium dietary intake appears to stabilize / modulate or reduce the swings / fluctuations in this component. This type of automatic decision has the appearance of a partial USIA, but with the aura, the need to be dead, the physical symptoms, the sensory component and the gambit blocked or stripped away from a full USIA (like a limited symptom attack). Consequently, because the USIA "Ideation and Physical Symptom Subtype" attacks are largely blocked at this stage, the presence and increased frequency of these "Ideation Only USIAs" gives the impression that things are worsening (because the "Ideation Only USIAS" are still frequent), when in fact the overall disorder is improving. This apparent flare up of the USIA "Ideation Only Subtype" is not necessarily an indication that something is getting worse, but may reflect a way station on the path to improvement.

4. The feeling of being pushed or compelled to act in a nonspecific way. Previously, this experience was directly connected to the suicidality. Following the high magnesium oxide / low calcium dietary intake, this feeling occurred on its own without being associated with any suicidality.

The effect of the high magnesium oxide / low calcium dietary intake regimen is first on the time spent in suicidality and then, after a little lag, is on the seriousness of the Impulse Attack Suicidality Disorder (IASD).

Benzodiazepines have no effect on 1 (apart from making the patient feel less alarmed about the suicidality), they decrease 2, and they stabilize 3 (all in the short time frame). In the near term, they increase the non-suicidal automatic emotionless self-injury ideation. This can be alarming to patients.

Calcium interferes with:

- 1. the absorption of magnesium
- 2. the effect of magnesium

Calcium in the system takes priority over magnesium in its uptake / use and effect.

Be careful stopping an anti-suicidality medication because of the potential for a rebound flare up of the impulse attacks and a dramatic increase in the attack frequency.

Dose Distribution

Best to start on 250 mg bid po (breakfast and evening dinner). It is best to take the tablets in the middle of a meal, rather than at the beginning or after the meal.

If the patient *does not have* problems falling asleep or staying asleep:

After 2 days if no nausea or diarrhea or headache take 250 mg tid (for a dose distribution 250 + 250 + 250). 2 days later if no nausea or diarrhea or headache, increase dose by 125 mg at dinner (for a dose distribution of 250 + 250 + 375). 2 days after that if no side effects increase dose to 1000 mg/d (250 + 250 + 500). The usual final dose is about 1000 mg magnesium oxide / day in 3 divided doses (with most usually at dinner or at night to help sleep).

If the patient has problems falling asleep or staying asleep:

After 2 days if no nausea or diarrhea or headache, increase the dose to 250 mg in am and 500 mg in pm with a meal (for a dose distribution 250 + 0 + 500). 2 days later if no nausea or diarrhea or headache, increase dose by 125 mg at lunch (for a dose distribution of 250 + 125 + 500). 2 days after that if no side effects increase dose to 1000 mg/d (250 + 250 + 500). The usual final dose is about 1000 mg magnesium / day in 3 divided doses (with most usually at dinner or at night to help sleep). For those who still find their sleep time duration shortened (less than 6 hours) taking the dose on a qid schedule may help extend their sleep time. This qid dosing for someone responding to

1000 mg a day is best distributed as 250 + 250 + 375 + 125 (with the 125 taken at bedtime).

One subject without sleeping difficulty began to experience migraine headaches several days a week. She found that changing the dose distribution to 250mg 4 times a day (250  $\pm$  250  $\pm$  250  $\pm$  250) dramatically reduced these headaches.

### Dissociative Episodes

After one subject responded to the high magnesium oxide / low calcium dietary intake regimen they began to experience recurrent dissociative episodes and these episodes came into sharper focus when the suicidality was no longer present. In reexamining the database over time and with some trial and error the subject noticed that these dissociative episodes stopped when she stopped using any caffeine containing beverages. Hence, at this time we do not consider such residual dissociative episodes as necessarily as a side effect of the high magnesium oxide / low calcium dietary intake, but rather as an increased sensitivity to caffeine resulting in more frequent, more apparently present, and longer-lasting dissociative episodes.

# Managing Magnesium Side Effects

If the magnesium oxide is taken before food the nausea can be quite significant. If it is taken after the meal then nausea is less than when taken before the food. The nausea is least or absent if it is taken in the middle of a meal. A reasonable quantity of food needs to be eaten to minimize the nausea. A snack is not sufficient. Once the dose and the dose distribution is tailored to the patient's needs, the patient should be very consistent in their eating habits throughout the course of treatment. Extreme care is warranted when the high magnesium oxide / low calcium dietary intake regimen is used in patients with an eating disorder. Taking ginger (either in capsules or as a powder or as slices in a tea or as raw ginger) can reduce the nausea associated with the ingestion of the magnesium oxide (without needing to take additional magnesium or any calcium-based antacids). Avoid using calcium-based antacids with magnesium because the calcium reduces the absorption of magnesium in the upper GI tract and thereby increases diarrhea and detracts from the efficacy of the high magnesium / low calcium dietary intake. Using magnesium-based antacids for the nausea can worsen the nausea and increase the potential for toxicity. For those on vegan diets, ensure they are getting adequate levels of Vitamin B12, which is necessary for the efficacy of magnesium. Make sure the patient is properly hydrated when they start on the high magnesium oxide / low calcium dietary intake and they are careful to stay properly hydrated while taking this treatment.

#### Time to Onset of Action

For the subject who knows their optimal dose of magnesium oxide and has restricted calcium dietary requirements, the time to onset of action typically appears to be as follows: 2 days after restarting at least 85% of the full therapeutic dose, the subject may notice a reduction in the time spent in non-impulse attack suicidality and a more modest reduction in the intensity of the USIAs, but not in the duration of the USIAs. From day 2 to 4, the time spent in non-impulse attack suicidality, the severity, frequency, and duration of the USIAs continued to drop to baseline levels. From day 4 through 10, this efficacy was maintained with the exception of a brief (< 2 minutes) intrusion of suicidal ideation. From day 10 on, there was no further recurrence of any suicidality or residual symptoms of suicidality.

For the subject who has never used the high magnesium oxide / low calcium dietary regimen, the time to onset of action typically takes longer because the final effective dose and the optimal way to reduce calcium intake is not yet operationalized / tailored for that patient, using the titration strategy recommended above. In general, some reduction in time spent in suicidality and in the frequency, intensity, and duration of USIAs will be noticed within 10 to 14 days. There is usually a progressive improvement in all these parameters of suicidality over the following 6 to 8 weeks. If a subject experiences breakthrough suicidality, the subject needs to carefully look at their diet to determine if they are not aware of some inadvertent calcium consumption. Over the long run, if the subject gets breakthrough symptoms (± diarrhea) for no apparent reason, they should carefully scrutinize their dietary intakes of calcium.

# Formulations of Magnesium

The information reported above was based on the use of the magnesium oxide formulation by Nature Made using 250mg tablets (for some doses these tablets were cut in half). It remains unclear at this time if other formulations of magnesium (for example magnesium sulfate, magnesium citrate, magnesium hydroxide, magnesium glycinate, magnesium L-threonate) are effective in the same way or in the same doses as noted above. It is also unclear if other over the counter (OTC) formulations have the same effect since the quality of OTC medications are not regulated by the U.S. Food and Drug Administration or other regulatory agencies. By way of disclosure, the authors have no financial relationship whatever, current or past, with the manufacturer of this product or any other magnesium formulation.

## **Dietary Considerations**

Make sure that patient restricts all foods with calcium before and during magnesium treatment. They should avoid dairy products (e.g. milk, yogurt, cheese), soy milk fortified with calcium, sardines, cereals fortified with calcium (most are), orange juice fortified with calcium, and bread products enriched with calcium (many breads). Always check

the food product labeling for calcium. Within 4 hours of ingesting magnesium, avoid foods that contains >10% of total daily requirements for calcium (i.e. 10% of 1000 mg /d = 100 mg per serving). If the patient must have a higher calcium intake, consider a different dose distribution of the magnesium to allow at least a 4 hour window between the calcium and magnesium (both before and after).

Make sure that the patient is aware of foods with high magnesium content and stays away from these foods in order to prevent toxicity. For example, peppermint (e.g. tea, mint candy), spearmint, spinach, pumpkin seeds, mackerel, soy beans, quinoa, avocados, and dark chocolate.

Symptoms of Magnesium Toxicity

Diarrhea and headaches are the most common side effects. The long term effects of high magnesium / low calcium intake needs to be investigated in well designed and controlled safety studies.

The National Institutes of Health, Health Professional Fact Sheet on Magnesium states, "Symptoms of magnesium toxicity, which usually develop after serum concentrations exceed 1.74–2.61 mmol/L, can include hypotension, nausea, vomiting, facial flushing, retention of urine, ileus, depression, and lethargy before progressing to muscle weakness, difficulty breathing, extreme hypotension, irregular heartbeat, and cardiac arrest".

Drug Interactions with Magnesium

Some HIV drugs, some calcium containing antacids, some antibiotics like tetracycline<sup>2</sup>.

Any AMPA agonists like kainic acid might affect suicidality - see in Wikipedia entry for AMPA receptor. AMPA receptor antagonists need to be investigated to ensure they do not reduce the efficacy of magnesium's anti-suicidal properties.

Additional Clinically Useful Information on Magnesium

The National Institute of Health has a webpage of valuable, accurate information about magnesium<sup>3</sup>. We do not recommend sharing this link with patients, as it contains details related to toxic and potentially fatal dosing.

<sup>&</sup>lt;sup>1</sup> Magnesium. (n.d.). Retrieved November 13, 2015, from https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/#h8

<sup>&</sup>lt;sup>2</sup> Does Magnesium interact with any other medications? - WebMD Answers. (2010, April 14). Retrieved November 13, 2015, from http://answers.webmd.com/answers/1188345/does-magnesium-interact-with-any-other

<sup>&</sup>lt;sup>3</sup> Magnesium. (n.d.). Retrieved November 13, 2015, from https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/#h8

While using magnesium as outlined above, patients should try, if possible to avoid other medications with NMDA receptor antagonist properties. For example, one subject reported that after taking dextromethorphan in a "cold" medicine she became sedated and ataxic out of proportion to the reality of the dose of OTC cold medicine used. This subject found that limiting her intake of dextromethorphan to 10mg every 6 hours was not associated with the above adverse events, while higher doses were. We expect that taking this in conjunction with ketamine treatment would substantially increase the adverse events associated with ketamine. On the other hand, as mentioned below, using magnesium with ketamine may permit lower doses of ketamine to be used in the treatment of suicidality than are otherwise needed. Several drugs of abuse have NMDA receptor antagonist and opiate / narcotic effects. We suspect that using magnesium in conjunction with these drugs would significantly worsen the adverse events associated with those drugs of abuse.

Magnesium also appears to potentiate the sedating properties of diphenhydramine. Caution is warranted when they are used in combination. While taking magnesium a lower dose of diphenhydramine may provide adequate antihistamine effects. For example, one subject found that taking ¼ a dose of 25mg diphenhydramine while on 1000mg magnesium a day provided the same antihistamine efficacy as a full 25mg dose of diphenhydramine taken without the magnesium.

# Possible Indications Across Suicidality Disorders

The preliminary data suggest that the high magnesium oxide / low calcium dietary intake may be effective in both the short-term and in the long-term treatment of IASD. It also appears to protect against relapse of IASD and to significantly delay time until emergence of new suicidality episodes. In addition to its effect in IASD, it may also have some value in other suicidality disorders, although this has not been adequately investigated.

## Potential Additional Applications

The magnesium may have additional value as an *adjunctive* treatment with ketamine / esketamine / other candidate NMDA-receptor antagonists and other anti-suicidality medication treatments. It may be useful in permitting use of lower doses of the other concomitant anti-suicidality medication.

This may reduce exposure to the toxic side effects of other anti-suicidality medications because lower doses of the concomitant medication could be used to have the same anti-suicidality effect. Since some anti-suicidality treatments may have long-term toxicity and unacceptable long-term risks, although they may be very beneficial in the short-term, the magnesium may be useful in maintaining the benefit achieved rapidly and acutely with the first anti-suicidality medication.

Several classes of antidepressant, mood stabilizing, and antipsychotic medications are associated with an increase in suicidality in some patients, especially those under the age of 25. Magnesium may have value in *attenuating this pro-suicidality activation* effect of these medications in such vulnerable individuals.

Stopping the first rapidly effective anti-suicidality medication (e.g. ketamine) may result in a rebound reactivation of the frequency and severity of the unexpected suicidal impulse attacks (USIA). The concomitant use of magnesium may *attenuate this rebound* reactivation and maintain the efficacy for the longer-term.

Important Caveats to the Use of Magnesium Oxide / Low Calcium Dietary Intake Regimen for the Treatment of Suicidality

It is very unlikely that the high magnesium oxide / low calcium dietary intake regimen will help all forms of suicidality. Our data suggests that it may be helpful in IASD. We expect that it may help some phenotypes and / or genotypes of suicidality beyond IASD. Delineating which phenotypes and / or genotypes of suicidality respond to magnesium oxide is a task ahead. We expect that magnesium oxide will be less effective or not effective at all in the Life Event Induced Suicidality Disorder. We expect the efficacy to be most apparent among the more autonomous varieties of suicidality phenotypes and / or genotypes and much less among those primarily driven by immediate psychosocial events.

In attempting to replicate the above findings we strongly advise against putting all patients with suicidality into a placebo-controlled trial and expecting to find that the magnesium oxide / low calcium diet is superior to placebo. Some cases of suicidality may get a good response, others may not respond, and it is possible that some may even get worse. Depending on the mix of phenotypes or genotypes in the clinical trial the outcome will be either successful or will fail. It makes more sense to conduct a series of placebo-controlled studies phenotype by phenotype to investigate which phenotypes respond best and which respond least well to the high magnesium oxide / low calcium dietary intake regimen.

In addition, there is a wide range in the bioavailability of the different magnesium salts. There is also not good quality control of the various magnesium formulations available OTC in health food stores and online. What is needed is a highly regulated, good quality, and highly consistent formulation of magnesium oxide and of the other magnesium salts. These may need to be investigated one at a time in the phenotypes most likely to respond. All these studies need to be placebo-controlled so as to get the most sensitive signal while exposing the fewest people to risk. Data on genetic and other biomarkers should be collected in parallel with the above-mentioned studies, in an attempt to identify genetic and other biomarkers that will identify those most likely to respond to this treatment. At some future point, this mass of data may permit a better alignment of

phenotypes of suicidality disorders and genotypes and other biomarkers to improve our ability to predict those who will and will not respond to the above treatment.

We recommend that in the above studies the following scales should be used:

- 1. S-STS CMCM
- 2. SPTS
- 3. SIAS

Among these efficacy outcome scales, we expect that the signal will be seen first in the time spent in suicidality (which seems to be the most sensitive outcome measure) followed by the SIAS, and then followed a little later by a change in the total S-STS CMCM score (see scoring instructions for S-STS CMCM). After a further lag, a change should be seen in the SPTS total score.

We recommend that all the subjects have a structured diagnostic interview for the suicidality disorders (MINI for Suicidality Disorders Studies) either at screen or at baseline to properly assign each case to its currently best available phenotype. Repeating the MINI for Suicidality Disorders Studies at endpoint to cover the timeframe between baseline and endpoint can provide documentation whether the patient's phenotype changed during the course of treatment.

The Standard version of the MINI should be done to assess the presence or absence of other comorbid Axis 1 psychiatric disorders. Where possible the T-CASA system should be used to track suicidality events.

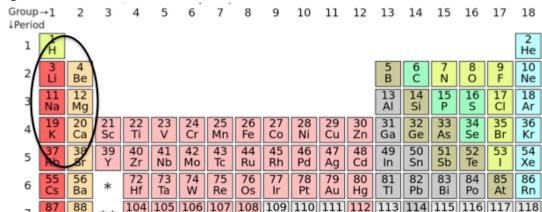
# Application of the findings for a provocative challenge test for IASD

The obverse of the finding that high dose magnesium oxide with low calcium dietary intake may reduce suicidal impulse attacks and suicidality in IASD is that any challenge that acutely depletes magnesium in the body may precipitate the onset of acute suicidality and USIAs. One application of this would be the use of 10-20 ml of an IV 10% calcium gluconate solution as a provocative challenge test for IASD (and, perhaps, some other suicidality disorders). Such an IV challenge would acutely deplete magnesium in the body and overturn the actions of magnesium thereby precipitating suicidality. Using such a provocative challenge test in a controlled safe environment would permit investigation of changes in brain imaging (e.g. on PET scans) and in other state biomarkers during a USIA and during acute suicidality.

Such a provocative challenge test could be investigated in safe and controlled settings as a way of testing, investigating, and finding medications that could block the suicidal impulses and suicidality in IASD and in some other suicidality disorders.

Relationship between high magnesium oxide / low calcium dietary intake regimen and lithium treatment

The high magnesium oxide/ low calcium dietary intake regimen described above may appear to be a homeopathic treatment from the health food world. However consider the following periodic table of the elements and note the close proximity between lithium and magnesium and calcium on the left side of the table, in groups 1 and 2. Is this an accidental relationship? Possibly, but unlikely.



Μt

Eu

Am

Ds

Gd

96

Cm Bk

Rg

Tb

Cn

Dy |

98

Cf

Figure 9.1.1: Periodic Table of the Elements

Db

Pr

Pa

Sg

Nd | Pm

Bh

93

Np

Hs

Sm

94 95

Pu

Uut

Ho | Er

Es Fm

FI

Uup

Tm

99 100 101 102 103

Yb

Uus Uuo

#### Please Note

The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), have not approved magnesium with a low calcium diet for the treatment of suicidality. The use of magnesium oxide with a low calcium diet in IASD and for any suicide disorder needs to be investigated in a series of properly designed scientific drug development programs following FDA and EMA guidelines, to properly assess its efficacy, safety, drug interactions, limitations and optimal dosing strategy.

<sup>&</sup>quot;Periodic table (polyatomic).svg" by DePiep CC BY-SA 3.0 edited with oval as above.

#### Lithium

Evidence available from a series of meta-analysis by Tondo and Balldessarini suggest that lithium has anti-suicidality properties in patients with both Bipolar Disorder and Unipolar Major Depressive Disorder<sup>4</sup>. Twenty-five studies have reported this property of lithium.

It may even have anti-suicidality properties in some patients with other psychiatric disorders. It appears to be effective for many patients in reducing suicidality in the short-term and in protecting against emergence of suicidality in the long-term. When lithium is stopped after a year or more of use there is a substantial increase (a possible rebound reactivation) in suicidality over the following few months.

Although the evidence is limited the anti-suicidality doses are similar to the doses and to the blood levels considered therapeutic in Bipolar Disorder (i.e. 0.8 - 1.2 MEq/L).

Studies on four continents have noted a relationship between lithium levels in the local water supply and suicide rates in those districts.

In the acute treatment of Bipolar Depression lithium may improve the suicidality in the near-term without, at the same time, showing any antidepressant effect. It appears at times to disaggregate the anti-suicidality from the antidepressant effects. In contrast, antidepressants may disaggregate its antidepressant properties from anti-suicidality properties in some patients. Antidepressants may have an antidepressant effect in some patients without having any or much anti-suicidality effects at the same time in other patients.

Lithium is not approved by the U.S. Food and Drug Administration for the treatment of suicidality.

<sup>&</sup>lt;sup>4</sup> Tondo, L., & Baldessarini, R. (2011, February 10). Can Suicide Be Prevented? Retrieved November 9, 2015, from http://www.psychiatrictimes.com/bipolar-disorder/can-suicide-be-prevented

# Clozapine

Clozapine is approved by the U.S. Food and Drug Administration for reducing the risk of recurrent suicidal behavior in patients with Schizophrenia or Schizoaffective Disorder who are judged to be at risk of re-experiencing suicidal behavior. Clozapine has also been reported to reduce the rate of hospitalization for suicide attempts in the long-term treatment of Schizophrenia or Schizoaffective Disorder in the InterSePT study<sup>5</sup>. The doses needed to provide this anti-suicidality behavior effect were 200mg - 900mg a day.

<sup>5</sup> Meltzer, H. Y., Alphs, L., Green, A. I., Altamura, A. C., Anand, R., Bertoldi, A., ... & Potkin, S. (2003). Clozapine treatment for suicidality in schizophrenia: international suicide prevention trial (InterSePT). *Archives of general psychiatry*, *60*(1), 82-91.

## Ketamine / Esketamine

Following the initial observation by Berman MB et al that ketamine appeared to have antidepressant properties several investigators and pharmaceutical companies have been attempting to replicate these findings with ketamine, esketamine, and some other NMDA-receptor antagonists<sup>6</sup>.

The early data suggest that ketamine and esketamine given intravenously provide an anti-suicidality effect within 15 to 45 minutes. This effect is maintained over the first 3 to 4 days after which it decreases back to baseline levels by 7 days (on average). Currently, it is being investigated for the management of suicidality in outpatient settings over 4 to 6 weeks until other therapeutic agents can stabilize the patient's condition after that time (e.g. lithium, clozapine, antidepressants, mood stabilizers). Under the current protocol, patients are seen as outpatients 2 to 3 times a week (e.g. Monday, Wednesday, and Friday) and given these infusions to maximize the anti-suicidality properties while awaiting stabilization of their primary disorder with other, long-term medications.

The business model behind the development behind such treatments is that the average hospitalization for a suicide attempt costs over \$40,000 in the US. If patients can be managed with ketamine / esketamine 2 or 3 times a week in an outpatient setting this will be a substantial cost saving to the health care system while at the same time perhaps providing a more reliable treatment over the first several weeks.

Ketamine / esketamine have adverse events that preclude their safe use over the long-term (for example, abuse liability, possible nephrotoxicity, and dissociative states and cognitive impairment). It remains unclear at this time to what extent patients may experience rebound reactivation of the suicidality after the ketamine / esketamine treatment ends.

Ketamine has a long history of use in anesthesia for induction of short-term hypnotic effects. It was frequently used as an anesthetic with ECT for the treatment of psychotic depressions or Treatment Refractory Major Depressive Disorder. In the treatment of Major Depressive Disorder and in the treatment of suicidality it was given intravenously in doses substantially lower than the anesthetic dose. The initial studies used 0.5mg/kg<sup>7</sup>. Subsequently it was studies in doses of 0.2mg/kg in the interest of minimizing any dissociative, cognitive or unwanted CNS effects<sup>8</sup>. At this lower dose it still appeared to have a very rapid anti-suicidality and antidepressant effect. Because of the availability of

<sup>&</sup>lt;sup>6</sup> Berman RM, Cappiello A, Anand A, et al. Antidepressant effects of ketamine in depressed patients. Biol Psychiatry. 2000; 47(4):351–354.

<sup>&</sup>lt;sup>7</sup> Ibid.

<sup>&</sup>lt;sup>8</sup> Dean, B., Gibbons, A. S., Boer, S., Uezato, A., Meador-Woodruff, J., Scarr, E., & McCullumsmith, R. E. (2015). Changes in cortical N-methyl-d-aspartate receptors and post-synaptic density protein 95 in schizophrenia, mood disorders and suicide. *Australian and New Zealand Journal of Psychiatry*, 0004867415586601.

many antidepressant medications and the lack of availability of anti-suicidality medications, it is likely that its main therapeutic contribution may be as a rapid anti-suicidality treatment, rather than as an antidepressant. When the mechanism of action of the anti-suicidality effect of ketamine is better understood, this may lead to the development of other rapidly acting anti-suicidal medications with less toxicity and abuse liability.

Ketamine / esketamine could, in theory, be given intranasal providing a very rapid onset of action, but the duration of action of the intranasal form may differ from the duration of action when it is given intravenously.

Other NMDA-receptor antagonists are currently under investigation for their antisuicidality properties. Some of these are given intravenously, some are given intranasal, and some are given orally.

# Interview and Psychotherapy Recommendations for Suicidality

"Psychiatrists are interesting people. You can go and talk to a psychiatrist about violence, rape, murder, plunder, pillage, and chaos. They sit calmly listening like Buddhas, completely unfazed. Then you start talking about your suicidality. All of a sudden you can see their expression change. There is alarm on their face and fear in their eyes. Their brains are spinning. They are no longer listening to you. You are freaking them out. If they are alarmed about this, with all their experience, why shouldn't you, watching their reaction, become even more alarmed than you already are? You don't want to frighten your psychiatrist. So you start back peddling in your discussion about your suicidality. They don't want to hear this stuff anymore. If they are that alarmed and frightened by your suicidality, how can they possibly help you? If they are unable to listen to the details about your suicidality, how can you unburden your concerns and communicate your struggles in dealing with your suicidality? You can't speak to your minister, priest, rabbi, imam, family, or friends about your suicidality, because they get too alarmed and aren't equipped to handle this. For problems of a psychological nature, society appointed and trained mental health professionals to listen to, sort through, and assist you with these concerns. However, many mental health clinicians struggle in dealing with your suicidality, and their response to such discussions often has the opposite to the intended effect."

We often unnecessarily adopt different strategies in dealing with suicidal patients, than we use when dealing with non-suicidal patients. We should not abandon good psychotherapeutic principles used for other conditions, when working with suicidal patients. We need psychotherapeutic strategies to specifically address the needs of our

patients with suicidality. We need to listen without judgment or alarm to the suicidal struggles of our patients.

# Before Interacting with Patients

Deal with your own countertransference on suicidality.

Ultimately you have no control over a patient's decision to make a suicide attempt or to not make a suicide attempt. You need to accept your relative lack of control over this situation. You cannot control your patients as you might hope. Accepting this is very difficult, but it will allow you to get closer to your patient. It may result in the patient being more honest with you and being more willing to contact you and rely on your judgment in times of crisis.

You must constantly deal with your own helplessness. Ultimately there are no reliable treatments for many cases of suicidality. Many patients with suicidality know this from experience, but clinicians often fail to understand this and adopt an unnecessarily optimistic outlook in the face of the limited available and approved anti-suicidality treatments. It is okay for you to not have all the answers. Understanding your own helplessness in the situation may enable you to be more available to the patient in times of crisis.

Stop viewing suicidality exclusively as either a symptom of depression or a response to stress. Although these are two reasons people may experience suicidality, they are *not the only* reasons people experience suicidality. Basing your interactions with a suicidal patient upon these assumptions can cause a suicidal patient who is experiencing a different form of suicidality to feel as though they are not understood. If the patient is in crisis, this type of message can make the patient feel worse. It is better to approach patients without these assumptions and allow the patient to share their unique suicidality experiences.

Similarly, please do not assume that putting a suicidal patient on an antidepressant will necessarily help their suicidality. Some patients have found that antidepressants increase the frequency of their impulsive suicidality (see chapter 12.2 for case study on this) and researchers have found that some patients with bipolar depression respond differently to antidepressants and / or because some of them may have a different genetic polymorphism variant  $^{1/2}$ .

<sup>&</sup>lt;sup>1</sup> Sachs, G. S., Nierenberg, A. A., Calabrese, J. R., Marangell, L. B., Wisniewski, S. R., Gyulai, L., ... & Thase, M. E. (2007). Effectiveness of adjunctive antidepressant treatment for bipolar depression. *New England Journal of Medicine*, 356(17), 1711-1722.

<sup>&</sup>lt;sup>2</sup> Kim, B., Kim, C. Y., Hong, J. P., Kim, S. Y., Lee, C., & Joo, Y. H. (2008). Brain-derived neurotrophic factor Val/Met polymorphism and bipolar disorder. *Neuropsychobiology*, *58*(2), 97-103.

For example, Kim et al in a study in South Korea reported on the functional consequence of a known single nucleotide polymorphism (SNP) at nucleotide 196 (G/A) in patients with bipolar disorder. This SNP leads to a substitution of the proteinogenic amino acid methionine for valine in the region encoding the prodomain (Val/Met, rs6265) on the BDNF gene. In turn, this is associated with "impairment in intracellular trafficking and activity dependent secretion of BDNF in neurons and neurosecretory cells"<sup>3</sup>. This is associated with "reduced hippocampal volume[<sup>4</sup> <sup>5</sup>] and reduced gray matter volume in the dorsolateral prefrontal cortex<sup>6</sup>". This SNP was not itself specifically associated with bipolar disorder and did not influence the rate or expression of bipolar disorder. However the Val/Val genotype in bipolar disorder was associated with a 4.9-fold increase of suicide attempts compared to those with the Met/Met genotype. The Val/Met genotype had an increased rate of suicide attempts intermediate between the Val/Val and the Met/Met genotypes<sup>8</sup>. Antidepressants are known to increase the expression of BDNF. So when antidepressants are given to patients with bipolar disorder who have this SNP it would not be surprising to find an increase in suicidality among them.

In addition, lithium can provide this anti-suicidality effect even when it is not having any antidepressant effect at the same time. It is as if lithium has the ability to pharmacologically dissect out anti-suicidality effects from antidepressant effects in some individuals. Furthermore some but not all suicidal patients get anti-suicidality benefit from lithium<sup>9</sup>.

Some clinicians have a false assumption that patients with chronic suicidality either must be attention seeking or must have Borderline Personality Disorder (or both). This assumption has led some clinicians to not even discuss the suicidality their patients bring up out of fear of reinforcing the 'attention-seeking'. One patient told the second author (JG) his psychiatrist told him "we don't talk about that here" after he brought up his recent increase in severity of suicidality. This devastated him. He already felt like killing himself and was trying to get help, but was told he could not even talk about it with his psychiatrist! He reported feeling even worse after that interaction with his psychiatrist. Assuming everyone who is suicidal for any length of time has Borderline Personality Disorder is not the most productive approach to effectively dealing with chronically

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Bueller JA, Aftab M, Sen S, Gomez-Hassan D, Burmeister M, Zubieta JK: BDNF Val-66Met allele is associated with reduced hippocampal volume in healthy subjects. Biol Psychiatry 2006; 59: 812–815.

<sup>&</sup>lt;sup>5</sup> Pezawas L, Verchinski BA, Mattay VS, Callicott JH, Kolachana BS, Straub RE, Egan MF, Meyer-Lindenberg A, Weinberger DR: The brain-derived neurotrophic factor val66met polymorphism and variation in human cortical morphology. J Neurosci 2004; 24: 10099–10102

<sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> Kim, B., Kim, C. Y., Hong, J. P., Kim, S. Y., Lee, C., & Joo, Y. H. (2008). Brain-derived neurotrophic factor Val/Met polymorphism and bipolar disorder. *Neuropsychobiology*, *58*(2), 97-103.

<sup>&</sup>lt;sup>9</sup> Tondo, L., & Baldessarini, R. (2011, February 10). Can Suicide Be Prevented? Retrieved November 9, 2015, from http://www.psychiatrictimes.com/bipolar-disorder/can-suicide-be-prevented

suicidal patients. We need to avoid making these assumptions and be willing to listen attentively and non-judgmentally to patients discussing their unique suicidality.

Paradoxically, IASD can have the effect of decreasing risk taking and restraining impulsive traits and behaviors. In contrast, when subjects with IASD respond to treatment they may notice themselves feeling less inhibited or restrained and their trait impulsivity scores may increase. We believe that misunderstandings around this apparent paradox have led to clinicians looking for and expecting patients who make impulsive suicide attempts to have higher impulsive trait scores. However, data from several studies using different scale measures of impulsive traits have not found consistent strong correlations between impulsive personality traits and suicidality 10 11. However not all investigators agreed 12. The usual assumption is that people with impulsive personalities are more likely to engage in suicide attempts. This is not always true. Many patients who do not have impulsive personalities attempt suicide impulsively because they have Impulse Attack Suicidality Disorder (IASD) and cannot cope with the very specific unexpected, unprovoked suicidal impulse attacks. It is possible that a patient making an impulsive suicide attempt is suffering from IASD, which is not the same thing as having an impulsive personality disorder. A case study on a patient with IASD found very low impulsive personality trait scores in her daily life. Analysis of 135 weekly ratings over 2.66 years, found a correlation coefficient of -0.10564 between an overall trait impulsivity question (used in the Sheehan DV, Alphs L et al 2014 validation study<sup>13</sup>) and a suicidality state impulsivity question (Suicidality Modifiers Scale Impulsivity Question 2). Paradoxically the same patient experienced an increase in overall trait impulsivity after her suicidality dramatically improved! Until the relationship between overall trait impulsivity and suicidality specific impulsivity is fully understood, please do not assume patients with a history of multiple suicide attempts or those with IASD necessarily have an impulsive personality.

# While Interacting with Patients

Be calm and non-judgmental. Accept the patient's experiences as they are and do not judge their suicidality. Allow the patient the freedom to express the reality of their

<sup>&</sup>lt;sup>10</sup> Corruble E, Benyamina A, Bayle F, Falissard B, Hardy P. Understanding impulsivity in severe depression? A psychometrical contribution, Progress in Neuro-Psychopharmacology & Biological Psychiatry 27 (2003) 829–833.

<sup>&</sup>lt;sup>11</sup> Horesh N, Self-Report vs. Computerized Measures of Impulsivity as a Correlate of Suicidal Behavior. Crisis 2001; Volume 22 (1): 27–31.

<sup>&</sup>lt;sup>12</sup> Dougherty D.M., Mathias C.W., Marsh-Richard D.M., et al. (2009) Impulsivity and clinical symptoms among adolescents with non-suicidal self-injury with or without attempted suicide. Psychiatry Res. 169(1),22–27.

<sup>&</sup>lt;sup>13</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from: <a href="http://innovationscns.epubxp.com/i/425963/32">http://innovationscns.epubxp.com/i/425963/32</a>

experiences. Your office may be the only place they are able to be honest about what they experience. Patients deserve such a safe place.

Do not over-react to suicidal statements. Clinicians are quick to hospitalize patients when suicidality is mentioned because they fear the patient will make a suicide attempt. Yes, a suicide attempt is possible, but putting a patient with chronic suicidality in the hospital every time they experience a flare in their suicidality can interfere with their life and cause their suicidality to become more disabling. Use your best clinical judgment and avoid overreacting in discussions of suicidality.

Ask for details or examples from the patient's experience to better understand, but do not insist the patient provide these to you. Talking about suicidality is very difficult for some patients. Pressuring the patient too much may harm the therapeutic relationship.

Focus on the resistance instead of the content. Some patients may be hesitant to discuss the content of their suicidality. Clinicians often want to know such details. One approach in handling this is not to directly pursue the content that is sought, but instead to focus on discussing the patient's resistance to divulging this information. For example, "Ok. I know you are hesitant to tell me the content of your suicidal thoughts or plan, but can you tell me about your fears of what would happen if you shared this information with me?" Keeping the discussion going by focusing on the resistance itself, rather than the content, allows the patient to eventually feel more comfortable in divulging the content directly without feeling pressured. This is a technique often used in discussing difficult material with patients in psychotherapeutic settings.

Your therapeutic relationship with patient is central. Do your best not to do anything to jeopardize this relationship. The patient needs someone they can reach out to in times of crisis. Harm to the relationship can hinder the patient's willingness to reach out.

Ensure patients have the appropriate contact information if they are in crisis. Give them the national hotline phone numbers, the online chat web addresses, your phone number, and the local crisis center phone number. (The International Suicide Prevention Wiki has a number of resources around the world.) Make sure they know that calling 911 (or emergency services telephone number in other countries) is an option if the crisis warrants it.

Do not ask patients to promise you they will not harm themself. This type of request may lead to a breakdown in the therapeutic relationship. Similarly, do not encourage the patient to promise anyone (other than themself) that they will not self-injure or make a suicide attempt. The patient's loved ones may expect such a promise to be made. Doing so may have far-reaching effects in their relationship with one another if the promise is not kept. It is best to avoid such expectations. For a more detailed discussion on this

point see appendix 15.1 (on No Harm Contracts) and Contracting for Safety by Michael Miller<sup>14</sup>.

Ask for feedback from the patient. Find out how they would like you to handle crisis and other situations. Write this down and develop a plan. Ensure that you and the patient are in agreement on how best to proceed in handling future suicidal crises. If you have helped a patient with a crisis, seek feedback on what worked and what did not work. Write this down so that your response can be customized to their future needs.

There are a host of concerns (potential hospitalization, social stigma) that weigh on patients when attempting to reach out for help in a crisis. These concerns make it difficult for some patients to communicate during a suicidal crisis. In order to circumvent some of these issues, it may be helpful for you and your patient to decide on an alternative phrase that your patient can use to tell you they are experiencing a suicidal crisis. If you create such an alternative phrase, make sure it is something both of you will remember. Consider adding it to your written plans concerning how to handle a suicidal crisis.

Consider starting a <u>Yellow Ribbon Suicide Prevention Program's Ask4Help program</u> in your area. This program provides youth with Ask4Help cards they can use to communicate their suicidality to others without the struggle of articulating their suicidality. Although the Ask4Help cards were originally designed to be used by youth, they can also be used by adults to communicate their suicidality and ask for assistance. If starting such a program in your area, make sure appropriate health care agencies, first responders, teachers, clergy, and others are aware of the program, so they are prepared to respond if given one of the Ask4Help cards.

Your psychotherapeutic role is not to solve the patient's problem for them. Your role is to listen, to help *them* clarify the problem, and to help them identify *their own* solutions to solve the problem. Then you support them (lend them your ego strength) in implementing their own solutions.

## After Interacting with Patients

Document the details of the interaction. This is medico-legally important. See Appendix A in Shawn Shea's book for a good discussion on this documentation<sup>15</sup>.

Ensure anyone covering your emergency calls is aware of the patient's suicidality in the event it is difficult for the patient to verbalize this while in crisis. Make sure the clinician

<sup>&</sup>lt;sup>14</sup> Miller, M. (2014). Contracting for Safety. In S. Koslow, P. Ruiz, & C. Nemeroff (Eds.), A concise guide to understanding suicide: Epidemiology, pathophysiology, and prevention. Cambridge University Press. <sup>15</sup> Shea, S. (2011). Appendix A: How to Document a Suicide Assessment. In *The practical art of suicide assessment: A guide for mental health professionals and substance abuse counselors* (2nd ed.). Mental Health Presses.

is also aware of any alternative phrases you have set up with your patients which indicate the patient is in a suicidal crisis. You might consider keeping a running list of this information for each patient and updating it as necessary after each appointment to ensure necessary information is given to anyone covering your emergencies.

Be available to the patient as necessary. Suicidal crises do not always present at the most opportune times. Some patients may delay reaching out for help in an attempt to cope with their suicidality on their own. Suicidal patients may find themselves worn out from the struggle during the day against their suicidality, and only reach out late at night when they feel too exhausted to continue struggling on their own.

Consider consulting peers to help you feel more comfortable treating your suicidal patient(s). Your peers may have suggestions or tips that may help you or your patient. Your peers may also serve as a safe place *for you to discuss* your concerns, fears, or worries about treating a patient with suicidality. It is not easy to consistently listen to a person's experience of suicidality and not be able to quickly resolve their distress. It is important for you to take care of yourself emotionally, so you are available to help your patient(s). Some local or regional associations of health care workers may consider setting up such a support system for clinicians working with suicidal patients.

Consider using one of the suicidality tracking scales like the S-STS or S-STS CMCM to track the severity of the patient's suicidality over time. Also consider using a suicide plan tracking scale like the SPTS to track the patient's suicidal planning over time. These scales may assist you in seeing the larger picture of a patient's suicidality or suicidal planning, which might be otherwise missed.

# Summary

Stay calm. Listen. Ask for more information. Don't overreact.

# 10

# Putting Suicidality Assessment and Tracking into Practice

#### Introduction

We should stop playing ostrich with suicidality in clinical practice. Ignoring it will not make it go away. The idea that we should ask about depression in detail, but avoid asking about suicidality details is potentially harmful to patient care and exposes clinicians to medico-legal liability. The fear is that it may open up a Pandora's box for the clinician. Clinicians fear they will find that suicidality is more prevalent than previously acknowledged. They worry that talking about suicidality will make it worse. This could overwhelm the system with a need to refer everyone with even mild levels of suicidality for further assessment with a psychiatrist. (See appendix 15.2 for a response to the United States Preventive Services Task Force (USPSTF) recommendation against suicide risk screening in primary care.)

We need practical guidelines for non-psychiatrists to triage suicidal patients to 4 levels of further management. The non-psychiatrist:

- 1. manages the suicidality, without referral. *Monitor over time* (Level 1)
- 2. manages the suicidality, but *needs more information* on the suicidality or Non-Suicidal Self-Injury (NSSI) before deciding what to do next (Level 2)
- 3. refers the patient to a psychiatrist (Level 3)
- 4. admits the patient to an inpatient psychiatry facility (Level 4)

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS)

INSTRUCTIONS: PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY, TIME SPENT AND TIME FRAME IN YOUR RESPONSES.
THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT, EXPERIENCE OR BEHAVIOR "DID NOT OCCUR AT ALL".
THROUGHOUT THE SCALE THE WORD INTEND OR INTENT MEANS ANY INTENTION GREATER THAN ZERO. SCORE THE MOST SERIOUS EPISODE THAT OCCURRED.

In th	ne past (timeframe):					
1.	did you have any accident? (this includes taking too much of your medication accidentally) IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:		NO $\square$	Y	ES 🗆	
1a.	how seriously did you plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?  IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), SKIP TO QUESTION 2.  IF THE SCORE IS 1 OR HIGHER, GO TO QUESTION 1b:	Not at all	A little	Moderately 2	Very 3	Extremely 4
1b.	did you intend to die as a result of any accident?		νο □	Υ	ES 🗆	
In th	think (even momentarily) that you would be better off dead, need to be dead or wish you were dead?  How many times?	Not at all	A little	Moderately 2	Very	Extremely 4
3.	think (even momentarily) about harming or hurting or injuring yourself – with at least some intent or awareness that you might die as a result – or think about suicide (killing yourself)?  How many times?	0	1	2	3	4
4.	have a voice or voices telling you to kill yourself or have dreams with any suicidal content?  mark either or both:  a voice or voices  a dream	0	1	2	3	4
5.	have any suicide method in mind (i.e. how)? #	0	1	2	3	4
6.	have any suicide means in mind (i.e. with what)? #	0	1	2	3	4
7.	have any place in mind to attempt suicide (i.e. where)? * #	0	1	2	3	4
8.	have any date / timeframe in mind to attempt suicide (i.e. when)?*#	0	1	2	3	4
9.	intend to act on thoughts of killing yourself?  mark either or both: did you intend to act:   at the time   at some time in the future	0	1	2	3	4
10.	intend to die as a result of a suicidal act?  mark either or both: did you intend to die:   at the time   at some time in the future	0	1	2	3	4
11.	feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  mark either or both: was this:	0	1	2	3	4
12.	take active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)?	0	1	2	3	4
13.	injure yourself on purpose without intending to kill yourself? How many times?	0	1	2	3	4
14.	attempt suicide (try to kill yourself)?	0	1	2	3	4

"A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him- or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.

A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1,2</sup>). \* Note: Items 7 & 8 on S-STS ("a plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). Both events can occur separately over the same timeframe. # Note: clinician should ask for details.

# **Color Code** Interpretation

- Green: Give S-STS to go home and monitor for worsening.
- Blue: Give S-STS CMCM and review. Based on findings, with prudent clinical judgment, either continue to monitor, refer, or admit. Use your best clinical judgment.
- Purple: Refer to a psychiatrist or mental health specialist.
- Red: Seriously consider admission to an inpatient psychiatric facility.
- Orange: Give them the Sheehan-Suinocerality Tracking Scale (S-SNTS) and review.

# **Time Spent** Experiencing Suicidality

In general the more time spent in suicidality the greater the need for either a referral or an admission. However, five minutes in an unexpected suicidal impulse attack may be far more dangerous than five hours spent with only passive suicidal ideation. Time spent experiencing suicidality tends to be highly correlated with the severity of suicidality. (See chapter 12.1 on the relationship of time spent in suicidality and global severity of suicidality.) It is very useful collateral information. You should always ask about the time spent in suicidality (as outlined at the bottom of page 2 of the S-STS).

#### **Scores** on the S-STS Standard Version

- Anyone with a total score of ≥ 1 should be asked by a clinician, not necessarily a
  psychiatrist or psychologist, about the nature and basic details of the scores they
  endorsed on the S-STS.
- Anyone with a score of ≥ 2 on questions 1a, 5 12, or 14 should be referred to a
  psychiatrist or a psychologist for further investigation of their suicidality.
- Anyone with a score of ≥ 2 on questions 1a, 5 12, or 14 should trigger an alert for immediate suicidality consultation before allowing the patient to go home. If they are not in a medical or mental health facility, they should be contacted directly and immediately.
- Apart from these approximate guidelines, clinicians reviewing the S-STS scores should use their best clinical judgment to override these approximate guidelines based upon the circumstances of each case and the relationship of the clinician with the patient.

<sup>&</sup>lt;sup>1</sup> Giddens, J. M., & Sheehan, D. V. (2014). Is a count of suicidal ideation and behavior events useful in assessing global severity of suicidality? a case study. *Innovations in clinical neuroscience*, *11*(9-10), 179. Available from: <a href="http://innovationscns.epubxp.com/i/425963/178">http://innovationscns.epubxp.com/i/425963/178</a>

# 10.1

# Assessing and Tracking Suicidality in Clinical Practice

# Guideline for Family Physician Setting

A patient presents to a family physician's office for evaluation of recurrent headaches that are not responding well to analgesics. After taking a good medical history, conducting a physical exam, and ordering lab tests to rule out medical causes of the headaches, the family physician cannot find any medical cause for the persistence of the headaches. On reviewing the Mini International Neuropsychiatric Interview (MINI) Screen paperwork completed by the patient in the waiting room prior to the visit, the family physician notes that the patient has depressive symptoms. She is now concerned that these depressive symptoms may be part of a mood disorder. To follow up on this initial diagnostic impression the family physician asks one of her staff to do the full MINI (which takes, on average, 15 minutes). She reviews the findings on the MINI with her staff colleague and the patient. The findings suggest that the patient appears to have Major Depressive Disorder and has both active suicidal ideation and a suicide plan with some intent. The patient states that he has been depressed for approximately 1 year and that the depression has recently worsened, significantly. This worsening coincided with the flare up of his headaches. The family physician wonders what she should do next. She is concerned about the potential risk involved and the need to provide proper treatment for this patient.

#### What should she do next?

The family physician tells the patient that she is concerned about his level of depression and associated suicidality. She wants to ensure that she has a deeper grasp about what is going on before deciding what would be the best care to provide him. She asks the patient if he would mind filling out two detailed scales on his suicidality. The patient indicated that he would be happy to do so since he has been struggling with his suicidality in an ever-escalating way over the past several months. The family physician explains that some of these questions may appear to repeat questions asked on the MINI, but will capture the information in a more detailed manner.

The patient is given the S-STS CMCM version and the SPTS. The patient completes this information in the waiting room and lets the office staff know when this task is completed. On reviewing the data captured the family physician realizes that the patient was planning to kill themself in the next 1 to 3 weeks if he could not get relief from his suffering. In discussions with the patient, he said he was pleased that the family physician had taken the time to investigate his problems so thoroughly. He was comforted by the detail covered by the scales and felt that the physician and her staff were trying to provide good care for him. Given this interest and concern, he said he felt more hopeful and did not feel any urgent need to act on these suicidal thoughts and he would be willing to wait until she could arrange an appointment with one of her psychiatry specialist colleagues. The family physician offered the patient a printed list of the names and contact information of all the psychiatrists with whom she consulted in her city. They discussed which of these psychiatrists might be covered by his insurance and selected and prioritized the names available. She then had her office staff call the psychiatrists in order to set up an appointment as soon as possible. A firm appointment was made for the patient for the following week and the family physician recommended that he came back in the interim if he felt any significant worsening of the suicidality or the depression. The patient was also given a list of crisis hotline numbers to use if his suicidality significantly worsened and was unable to reach the family physician. Given the proximity of the appointment with the psychiatrist they both decided to defer the decision on which medication to start until after he was seen by the psychiatrist. The family physician provided a printed copy of the completed MINI, the S-STS CMCM, and the SPTS to the patient so he could review these with the psychiatrist. Her office staff asked the patient to sign a release of her medical records regarding her recent care of him, which he did. Her office staff then sent copies of the records, the structured diagnostic interview (MINI), the S-STS CMCM, the SPTS, and her recent medical workup to the consulting psychiatrist with a brief summary letter asking that he call her or consult with her in the event he had any questions about the patient's medical care.

# What the Family Physician's Office Needs to Have Ready, Organized, and Available in the Office Every Day:

- 1. The MINI Screen\*, which is given to every new patient or to any patient that has not completed the MINI Screen\* or the full MINI\* in the past year.
- 2. The full MINI\*.
- 3. The S-STS\* and the S-STS CMCM\*.
- 4. The SPTS
- 5. A list of all psychiatrists in the area with their contact information.
- 6. A standardized covering letter template for psychiatric referrals to accompany the medical records that the family physician might choose to send in advance of the patient's appointment with the psychiatrist.

<sup>\*</sup> The above structured interviews and scales are also computerized. The computerization does all the navigation through the structured interviews and scales in background and also scores

these instruments and provides a scored .pdf file of these instruments that can be appended to an electronic medical record and sent to the consulting psychiatrist specialist.

This family physician has provided exemplary care in the management and disposition of this patient.

Guideline for Mental Health / Psychiatrist / Psychologist / Psychiatric Social Worker / Psychiatric ARNP / Inpatient Psychiatry Setting

# **Outpatient Setting**

At the initial screening visit all patients are given a structured diagnostic interview (a full MINI). This can be done by the psychiatrist or any mental health practitioner trained in the use of the MINI. This can be done on paper or in the computerized form. The computerization does all the navigation through the structured interviews in background and also scores this instrument and provides a scored .pdf file of the completed document that can be appended to an electronic medical record. Using this information with a medical and psychiatric history and information gathered at an interview, the clinician then makes a psychiatric diagnosis and documents any other comorbid disorders. At the follow up visits the patient is scheduled to arrive at the office 15 minutes before the time scheduled with the clinician and completes the following scales in the waiting room either on paper or in the computer to track their response to treatment and monitor any treatment emergent problems.

- 1. Symptom scale to assess the primary axis I symptom cluster.
- 2. A brief measure of functional impairment.
- 3. A suicidality tracking scale and, where indicated, a suicidality plan tracking scale.
- 4. A patient-rated global improvement scale.
- 5. A face sheet asking the patient to prioritize the topics / issues they wish to discuss with the clinician at the visit.

When these are completed by the patient they are attached to the chart (physically or electronically). The clinician reviews these at the start of the visit and compares these scores with the baseline and prior visit scores. Copies of the suicidality modules of the structured interviews, the suicidality scales, and a visit face sheet are available in appendices 14.1 - 14.12. The clinician can use this information to guide them about further lines of questions to ask to better understand any suicidality that is present. If the clinician is concerned that the suicidality score on the S-STS standard version is escalating to a point where hospitalization or much closer monitoring of suicidality is indicated, it may be prudent at that juncture to complete the S-STS CMCM version and the SPTS. The Clinically Meaningful Change Measure (CMCM) portion on pages 10 and 12 (patient-rated and clinician-rated, respectively) may serve as a useful guide to the clinician on the level of care they need to provide at that juncture. Since nearly all of this information is completed by the patient immediately prior to the visit, it not only does not eat

into the clinician's time with the patient, but can save a great deal of time and provide a useful basis for problems that need to be addressed during the visit. This information reflects a high level of care and attention to a broad spectrum of clinical concerns. It provides documentation and medico-legal protection for the clinician in the event of adverse outcomes in the case.

### Inpatient Care

All inpatients should be given a full structured diagnostic interview within the first 24 hours of admission by a clinician trained in the use of the structured interview. Baseline admission day scores should be captured on all of the above mentioned scales. These can be used as a basis for tracking response to treatment and documenting outcomes. The admitting psychiatrist can then review the findings in the structured diagnostic interview and make any adjustments in their responses and diagnostic scoring based on new or additional information. This information may be collected from the patient, loved ones, or caregivers. The experienced psychiatrist specialist will be able to help the patient better understand some of the questions that may have been confusing or not accurately understood at the time of the initial data capture. This initial structured diagnostic interview will ensure that the primary Axis 1 disorder is more accurately anchored to DSM criteria. It also increases the likelihood of detection of other comorbid Axis 1 disorders. The S-STS, the S-STS CMCM, and the SPTS can be completed daily by the patient to monitor any possible treatment emergent suicidality on antidepressants / mood stabilizers / antipsychotic medications. The use of the above scales on a daily basis in inpatient services can help facilitate communication between suicidal patients and staff. These instruments may also provide the needed documentation to justify an extension of stay for suicidal patients in the event that insurance companies question the need for such additional treatment.

# 10.2

# Assessing and Tracking Suicidality in Research Settings

# When Suicidality is the Primary Target of Treatment

If suicidality is the primary focus of the study and the primary target of treatment use the S-STS CMCM. (Appendix 14.4 contains a schedule for the use of the S-STS CMCM in its full and more abbreviated forms when it is used as an outcome measure in a clinical trial.)

Select clinicians who are capable of openly discussing suicidality with patients. It is important for patient care that patients have clinicians they can talk to about their suicidality and are not afraid to start a conversation with the clinician about a change in their suicidality. The patients with whom we have interacted, indicated that they would prefer someone who is more open to talking about suicidality than someone with impressive academic credentials, but who responds to discussion of suicidality with fear. Part of this is training, but part of this is personal experience. Clinicians need experience working with suicidal patients in order to cope with and channel such fears, in the interest of better connecting with and helping each patient. Some clinicians may have had life experiences, which make them unsuitable for a study on suicidality (whether in the short-term or the long-term). A clinician that just lost a loved one to suicidality might not be the best choice for a study on suicidality until that clinician has had the time to properly grieve and cope with their loss. Clinicians need to effectively deal with their own "countertransference" around issues of suicidality.

If suicidality is the primary focus of the study and the primary target of treatment use the SPTS at the screen, at baseline, and at each visit. The look-back timeframe at screen should be lifetime. This may be very difficult for patients to fill out. Be very understanding with them as they attempt to answer the scale for this and other timeframes. The look-back timeframe at the baseline visit should be equivalent to the timeframe of the acute phase of the study. The look-

back timeframe for each visit should be the length between visits and not just the suggested time between visits as written in the study protocol. For example, if the study protocol requires weekly visits, but it has been 8 days since the patient was in the office, ask the patient to fill out the SPTS "since their last visit" or "since they last filled out the SPTS" (the latter would capture any suicidal phenomena they experienced while at the office during their last visit). If this is not done an entire day of suicidality experiences can be missed. Other look-back timeframes with the SPTS may be helpful, but are optional.

When Impulse Attack Suicidality Disorder (IASD) is the Primary Target of Treatment

If the study involves treatment of impulse attack suicidality disorder with a rapid onset of action medication with short intervals between assessments (e.g. 10 to 20 minutes) use the Suicidal Impulse Attack Scale (SIAS) as an outcome measure. The S-STS or the S-STS CMCM can also be used in these studies (see appendix 14.1 - 14.5), but because of their length, a longer timeframe is necessary between administrations.

# When Suicidality is Not the Primary Target of Treatment

If suicidality is not the primary focus of the study or the target of treatment, but is being followed as a treatment emergent adverse event or as a secondary efficacy outcome measure, then use the standard version of the S-STS.

Essentially this involves using the S-STS or the S-STS CMCM at the screening visit to investigate a lifetime look-back timeframe. At the baseline visit use the S-STS or S-STS CMCM to investigate a look-back timeframe equivalent to the length of the clinical trial. This latter timeframe serves as a baseline against which to judge whether a particular item score or the total score on the scale is "treatment emergent" during the study timeframe. During the study proper, complete the S-STS or the S-STS CMCM at each study visit. If the treatment emergent suicidality during any timeframe in the trial is not any more severe / serious than it was for the same timeframe at baseline, then it probably should not be considered a treatment emergent suicidality adverse event. Rather, it should be considered as part of the patient's natural history of their illness fluctuating in a manner no different from the way it fluctuated during a similar timeframe immediately before the start of the study.

Using the T-CASA as outlined in chapter 5.3 study sponsors in collaboration with regulators may wish to set different thresholds for study rescue and stopping rules, in the event of treatment emergent suicidality. These rules may vary by study and depending on the study setting (e.g., inpatient versus outpatient).

# Study Design

The optimal design for a clinical trial investigating anti-suicidality medications is a double-blind, placebo-controlled, prospective, parallel-group design. Some may have ethical concerns about such a design. There may be different ethical perspectives on this design in different countries.

For example, at this time the United States prefers the use of placebo-controlled trials before giving approval for a treatment for any chronic, fluctuating condition. In Europe some have ethical concerns about putting suicidal patients on a placebo and instead prefer to use an active comparator standard of care treatment (SOC) or a treatment as usual (TAU).

Those favoring the use of placebo in such trials argue that you will get an answer with more scientific confidence while exposing the fewest possible people to risk by using a placebocontrolled design. Since there is no approved treatment at this time for suicidality, other than clozapine in Schizophrenia, it may be argued that there is no standard of care with which Some have recommended the standard of care as the use of an everyone agrees. antidepressant, or an anticonvulsant, or an atypical neuroleptic. However, all of these classes have boxed warnings cautioning about the increased risk of treatment emergent suicidality in some patients on these medications. It may be argued that using one of these as the standard of care may widen the difference between the new anti-suicidality treatment (e.g., an NMDA receptor antagonist), by mildly increasing suicidality in the active treatment arm, while mildly improving suicidality in the new drug arm. This could yield a statistical difference between the active "standard of care treatment" and the "new treatment", when neither drug in the trial may be statistically either better or worse than placebo. Some who favor the use of placebo in antisuicidality trials argue that such use of the above standard of care strategy has itself ethical problems since it could lead to the approval of a drug as effective when in fact it might not be statistically superior to placebo in a placebo-controlled trial.

Some people with suicidality with whom we have spoken have told us that they would be hesitant in taking a standard of care treatment / treatment as usual since their prior experience with such treatments made them more suicidal. Some of these individuals expressed concern about the approval of a medication in the absence of doing a placebo-controlled trial.

# Phenotypic versus Trans-nosological Trial Designs

In the interest of efficiency, cost containment, and wishful thinking that a new anti-suicidality medication could treat the majority of cases of suicidality some recommend the inclusion of all types of suicidality in the same trial (a trans-nosological approach). Others favor study designs investigating each suicidality phenotype one by one. For example, this latter approach favors designing one study to investigate an anti-suicidality medication in Major Depressive Disorder, while designing a separate study to investigate suicidality in PTSD or in Schizophrenia.

For reasons highlighted in the case study on magnesium and the clinical experience of the second author, we think it unlikely that any single anti-suicidality medication will work for the great majority of suicidal patients. Some chronically suicidal individuals with long experience in the mental health system have also told us that they consider the trans-nosological approach is not the most efficient approach. If a patient whose suicidality does not respond to lithium, but which does subsequently respond to an NMDA receptor antagonist or modulator and in the next patient the opposite happens, then it seems most prudent to use the phenotypic trial design approach. Similarly, medications that will work in Schizophrenia to block auditory command

hallucinations of suicide are not necessarily likely to be effective when used to treat suicidality in mood disorders. We also think that the high magnesium / low calcium intake regimen described in the magnesium case study, while it may be helpful for patients with Impulse Attack Suicidality Disorder (IASD), it is less likely to be effective in those who have Life Event Suicidality Disorder. Just as SSRI's do not work for all cases of depression (e.g., Bipolar depression), while they are effective for Major Depressive Disorder, and anti-psychotic medications used alone are effective in psychotic episodes of Schizophrenia, but are not effective when used alone in psychotic depression, we expect future anti-suicidality treatments will selectively work better in certain phenotypes / genotypes of suicidality and not in others.

Visit Intervals for Rapid Onset versus Slower Onset of Action Treatments

Some anti-suicidality medications, like ketamine, appear to have a very fast onset of action that is within the first hour. Such medications appear to provide this efficacy over 3 to 4 days before the efficacy begins to wane and return to baseline levels by day 7<sup>2</sup>. Hence, such treatments usually require administration 3 times weekly during the initial weeks of treatment (e.g., Monday, Wednesday, Friday) to maintain sustained anti-suicidality effect throughout a week timeframe. Because of the abuse liability associated with long-term use of ketamine, it is problematic to have patients taking it regularly over extended periods of time.

In contrast, lithium may exert its anti-suicidality effects in susceptible individuals over 1 to 4 weeks and appears to maintain this anti-suicidality efficacy with continued use over extended periods of time (e.g. a year)<sup>3</sup>. Because many patients continue to take lithium over many years of treatment there are fewer problems with its long-term use over ketamine.

Consequently, the two examples above require different trial designs to investigate their efficacy and safety. Trial designs investigating the anti-suicidality effects of slower onset of action medications like lithium, should adopt standard trail designs like those for Major Depressive Disorder, Bipolar depression, PTSD, Panic Disorder, or Schizophrenia. The interval between visits should probably be weekly.

Medications with a very rapid onset of action will need a different design with shorter intervals between visits and a shorter total trial duration. A model for the administration of assessments is provided below, is provided in Chapter 14.4. In each trial, nonetheless, the design will need to be modified to address the study question in the most efficient, scientific, and safe manner. Adaptive designs should also be investigated.

<sup>&</sup>lt;sup>2</sup> Berman RM, Cappiello A, Anand A, et al. Antidepressant effects of ketamine in depressed patients. Biol Psychiatry. 2000; 47(4):351–354.

<sup>&</sup>lt;sup>3</sup> Tondo, L., & Baldessarini, R. (2011, February 10). Can Suicide Be Prevented? Retrieved November 9, 2015, from http://www.psychiatrictimes.com/bipolar-disorder/can-suicide-be-prevented

# Study Duration

#### *Acute short-term studies*

The design of short-term studies investigating rapid onset medications like ketamine, should be for 4 weeks. The duration of short-term studies for lithium-, magnesium-, clozapine-like medications should be for 8 to 12 weeks.

### Long-term studies

In psychopharmacology trials a 6-month timeframe has emerged as an optimal timeframe for the investigation of long-term efficacy of most CNS medications. The reason is that trials lasting longer than 6 months are associated with a substantial dropout rate. This disadvantage detracts from capturing evidence in large enough samples in a single trial to properly assess the efficacy of new drug versus comparator drug or placebo. For long-term safety assessments, patients should be followed when possible for 1 to 2 years open-label. Such long-term designs have the capacity to demonstrate if there is maintenance of therapeutic action as achieved in the initial weeks of treatment for extended periods.

# Relapse prevention designs

Since all medications are associated with adverse events, in the interest of safety it is important to know if patients need to be maintained on their treatment to provide anti-suicidality benefit over the long run, when their condition might go into remission and not recur. Relapse prevention designs are helpful in addressing the need for maintenance treatment and any potential hazards of stopping the treatments, and the risk of recurrence of each suicidality disorder. The risk of recurrence may differ by each suicidality disorder. For example, we expect that those with persistent Impulse Attack Suicidality Disorder are more likely to have reoccurrence of their disorder than those who are recently suicidal with a Life Event Induced Suicidality Disorder. A relapse prevention study lasting 3 months is usually optimal to address these questions. Those suffering a recurrence could (? should) be offered humanitarian supplies of a previously effective medication should their symptoms recur. The lead-in period for such relapse prevention studies might be 4 weeks in the case of a very rapid onset of action medication and 8 - 12 weeks with slower onset of action medication.

We do not know at this time whether patients who are treated with anti-suicidality medications will need long-term treatment or how many will go into remission and at what rate they may relapse following initial recovery. Our current clinical experience suggests that this will vary by each phenotype of suicidality disorder. However, much additional work needs to be done on each of these phenotypes to properly address this question.

## Study Setting

The options here include either inpatient, outpatient, a brief period of inpatient hospitalization followed by a more extended outpatient treatment phase, partial hospitalization program, or intensive outpatient program. The setting will be largely driven by safety and ethical concerns. This in turn will be strongly associated with the severity of the suicidality being treated and

perhaps the phenotype of suicidality disorder. Clinician may be much more concerned about those with Impulse Attack Suicidality Disorder who are in a sever flare-up of impulse attacks than they would about those with less-severe, episodic Life Event Induced Suicidality Disorder. Because those with Impulse Attack Suicidality Disorder and those with very severe suicidality have long been excluded from clinical trials and because these presentations are perceived to be more serious, we can no longer ethically avoid both including such patients in clinical trials, and in seeking treatment for their life-threatening condition. An initial period of inpatient hospitalization may be appropriate in trials investigating this phenotype.

We expect that in the next several years effective new specific anti-suicidality medications will become available that will provide substantial therapeutic benefit. When the field has confidence that such treatments will work, it is likely that patients will express interest in participating in clinical investigations of neuroimaging and other diagnostic and neuroscientific procedures that will help us learn more about the neurochemical and pathophysiological basis for each of the suicidality disorders. For example, it is possible that 10-20ml of 10% solution of IV calcium gluconate, may be able to reliably reproduce, in controlled and safe hospital settings, a suicidal impulse attack in those with Impulse Attack Suicidality Disorder. This may permit the imaging and biomarker investigation of this disorder. If such patients respond within 30 minutes to such treatments as ketamine, following such a provocative challenge investigation, it will help them understand how their condition can be both switched on and switched off biologically. They will come to see that their suicidality is not their own fault, and as a result of such studies society may begin to change its perception of the nature of suicidality. We have spoken to informed suicidal people, who have expressed interest in participating in such investigations for exactly those reasons, as long as they had confidence that the protocol of the study would ensure their safety, that their condition would be immediately treated, and that they would have access to long-term treatment for their condition. The model for this already exists in the use of half molar solutions IV of sodium lactate or of 35% or higher CO<sub>2</sub> inhalations in the investigation of Panic Disorder in the 1980s. The second author recalls and was surprised that so many patients with Panic Disorder willingly volunteered for such studies after providing full informed consent and full awareness that they were likely to experience a terrifying panic attack occurring suddenly as a result. However the availability of alprazolam as a rapid and very effective antipanic medication provided a model for the safe conduct of such studies. This issue needs to be discussed and debated before any steps are taken to consider initiating such studies.

# Choice of Primary Efficacy Outcome Measures

The primary outcome measure should be a scale allowing dimensional assessments of suicidality phenomena as opposed to a scale that is capturing data in categories. We do not consider the C-SSRS<sup>4</sup> as a suitable candidate for such efficacy outcome assessments<sup>5</sup>. The S-STS CMCM, the

4

<sup>&</sup>lt;sup>4</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

SIBAT (Suicidal Ideation and Behavior Assessment Tool)<sup>6</sup>, and the ISST-Plus (InterSePT Scale for Suicidal Thinking - Plus)<sup>7</sup> are the best candidate scales for such efficacy outcome tracking at this time.

Such an efficacy outcome measure needs to not only be capable of assessing the full range of suicidality phenomena, but should also collect data that would provide regulatory agencies, the scientific community, and other clinicians information by which they can judge whether the effect seen with the new anti-suicidality medication can be considered to be clinically meaningful. This recommendation was suggested by the European Medicines Agency as a necessary requirement that needed to be met before they would consider approving any medication as effective and safe for the treatment of suicidality. We concur with this wise decision. In stark contrast to many other psychiatric disorders the treatment of suicidality disorders is a matter of life and death, even in the near-term. Therefore, approval of an anti-suicidality medication by a regulatory agency should meet a higher standard and provide clinicians prescribing such medications with more confidence that the medication was clinically meaningful and not just a small effect that demonstrated statistical significance over placebo in a large sample size. The S-STS CMCM is designed to provide data that helps anchor the clinically meaningfulness of the reduction in suicidality from the patients' and clinicians' perspective.

# Frequency of administration of S-STS CMCM

The S-STS CMCM should be administered at the screening visit, at the baseline visit, and at least weekly throughout the course of the study. In long-term studies, over 6 months, less frequent administration may be considered in those who have achieved substantial improvement in their suicidality.

#### Patient-rated versus clinician-rated

The S-STS CMCM is designed to be both patient-rated and clinician-rated. It can also be administered using a combination of patient-ratings and clinician-ratings. In practice, this hybrid approach, asks the patient to rate the first 10 pages. The clinician reviews all of the patient ratings, interviews the patient, and asks any additional clarifying questions. Then the clinician rates pages 12 and 13. Clinician ratings should take all sources of information into account.

Another rating option is to first have the patient self-rate the S-STS CMCM pages 1 - 10. Then the clinician, blind to the patient's prior ratings, interviews the patient and makes a clinician rating of pages 1 - 13. Before the patient leaves the site these ratings are compared and

<sup>&</sup>lt;sup>5</sup> Giddens, J. M., Sheehan, K. H., & Sheehan, D. V. (2014). The Columbia-Suicide Severity Rating Scale (C–SSRS): Has the "Gold Standard" Become a Liability?. *Innovations in clinical neuroscience*, *11*(9-10), 66. Available from: http://innovationscns.epubxp.com/i/425963/66

<sup>&</sup>lt;sup>6</sup> Alphs, L., Canuso, C., & Williamson, D. (2015). P. 1. k. 032 The Suicide Ideation and Behavior Assessment Tool: development of a novel measure of suicidal ideation and behavior and perceived risk of suicide. *European Neuropsychopharmacology*, 25, S371.

<sup>&</sup>lt;sup>7</sup> Meltzer, H. Y., Alphs, L., Green, A. I., Altamura, A. C., Anand, R., Bertoldi, A., ... & Potkin, S. (2003). Clozapine treatment for suicidality in schizophrenia: international suicide prevention trial (InterSePT). *Archives of general psychiatry*, *60*(1), 82-91.

discrepancies between the patient and clinician rating are discussed between them and a final combined and agreed upon rating is made. This is in the interest of safety. This reconciliation strategy as outlined above is most easily accomplished using the computerized version of the scale.

# Rater training

It is essential to ensure that both clinicians and patients are properly trained on the correct or rating of the scale. Consistent definition of terms and close adherence to the wording and spirit of the wording in each question is necessary to ensure good inter-rater reliability across investigators and sites. Adequate time needs to be allowed to do this training properly to help all clinicians understand in detail the phenomena they are assessing and the nature of suicidality. This cannot be done in less than an hour and in the interest of safety and efficiency should probably require more extensive training time at least for the first training for each investigator. Such training needs to be repeated at least annually for investigators using the scale in ongoing clinical trials.

The same training principles hold when the T-CASA is used to monitor suicidality events in clinical trials.

Diagnostic Evaluation of Suicidality Disorder Phenotype

We have developed a structured diagnostic interview called the Suicidality Disorders Module (Module Z) of the Mini International Neuropsychiatric Interview (MINI). The standard version of the MINI is used to screen many patients into clinical trials. It collects information on the symptom clusters for the most common psychiatric disorders in clinical practice. This permits a reproducible documentation of the principle comorbidities associated with the suicidality. This assists clinicians with psychiatric diagnosis and in making inclusion / exclusion decisions in their clinical trials. The MINI for Suicidality Disorders Studies Module Z operationalizes the diagnostic criteria for each of the suicidality disorder phenotypes and for their specifiers. This provides a way to reproducibly assign patients to one or another phenotype in the interest of studying relatively homogeneous samples of each phenotype in a clinical trial. It may also provide a reproducible system to assure regulatory agencies that phenotype designs (as outlined above) are being reproducibly implemented across sites in multi-center trials.

We provide a numeric coding system for each suicidality disorder phenotype and its associated specifiers along the lines used by DSM-5 and ICD-10 (although neither of these include any of the suicidality disorders identified in our classification).

## Homicidality in subjects with suicidality

Homicidality can be comorbid with suicidality. Some subjects with suicidality are suicidal because they are experiencing homicidality. Consequently, all subjects with suicidality entering clinical trials for the treatment of suicidality should be assessed for comorbid homicidality. The MINI has an optional homicidality module. In addition, we have a Sheehan-Homicidality Tracking

Scale (S-HTS) and we have a Homicide Plan Tracking Scale (HPTS) for those who have comorbid homicidality and suicidality.

Patients with comorbid homicidality need to be monitored more closely. Some of these individuals could get treatment emergent homicidality in the course of a clinical trial. We consider it prudent at this time to exclude such patients from clinical trials with anti-suicidality medications until appropriate protocols can be developed to ensure their safe inclusion.

# Genotyping and Other Biomarkers

There is recent data on genotypes and biomarkers that appear to be associated with suicidality. It would be valuable to collect such information at baseline on all subjects who agree to provide body fluid samples, or other biomarker data. This information may help genotypes or biomarkers that identify those most likely to respond or least likely to respond to the various anti-suicidality treatments. If used in conjunction with the phenotypes described in this book for the various phenotypic suicidality disorders this information could help improve and refine the classification of suicidality disorders and help better tailor anti-suicidality treatments to the correct patients in a personalized medicines paradigm that would improve treatment outcome for each individual subject.

Those seeking guidance on the current best selection of genotypes that may be worth studying in this regard should consult Niculescu et al<sup>8</sup>., Sokolowski et al.<sup>9</sup>, or Labonte and Turecki<sup>10</sup>.

Those seeking guidance on the current best selection of biomarkers that may be worth studying in this regard should consult the recent reviews of a range of biomarkers for suicidality in the Koslow, Ruiz and Nemeroff book, A Concise Guide to Understanding Suicidality<sup>11 12 13 14 15</sup>.

<sup>&</sup>lt;sup>8</sup> Niculescu, A. B., Levey, D. F., Phalen, P. L., Le-Niculescu, H., Dainton, H. D., Jain, N., ... & Salomon, D. R. (2015). Understanding and predicting suicidality using a combined genomic and clinical risk assessment approach. *Molecular psychiatry*, *20*(11), 1266-1285.

 <sup>&</sup>lt;sup>9</sup> Sokolowski M, Wasserman J, Wasserman D. Genome-wide association studies of suicidal behavior. Chapter 31 (pages 277-287) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.
 <sup>10</sup> Labonte B, Turecki G. Epigenetics. Chapter 32 (pages 288-306) in in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

Bailey CR, Greene AM, Neumeister A. The use of neuroimaging to investigate the pathophysiology of suicide.
 Chapter 33 (pages 307-316) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.
 Anango V, Bach H. Brain serotonin in suicides with psychological autopsy. Chapter 34 (pages 317-324) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

<sup>&</sup>lt;sup>13</sup> Chandley MJ, Ordway GA. The noradrenergic system in depression and suicide. Chapter 35 (pages 325-335) in A Concise Guide to Understanding Suicide:Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

# Statistical Analysis Plan

An anti-suicidality medication should demonstrate not only statistical separation from placebo or statistical superiority over standard of care or treatment as usual, but in addition should be able to demonstrate that the statistically significant effect seen is also clinically meaningful. Guidance on this is provided in the S-STS Scoring Instructions (see chapter 14.4). Essentially this involves showing a substantial impact on both the clinician and the patient judgment of risk and treatment needed sections of the S-STS CMCM.

An effective anti-suicidality medication should impact a broad range of suicidality phenomena. While impacting a broad range of suicidality phenomena, the treatment should not worsen any of these suicidality phenomena significantly. This may also be tracked with precision using the T-CASA event classification data collection method outlined in chapters 5 - 5.3.

For additional detailed scoring instructions on the S-STS CMCM see chapter 14.4.

We recommend the use of hierarchical linear modeling analyses like MMRM (Mixed Model Repeated Measures) or an ET Rank Analysis. The ET Rank Analysis is a non-parametric equivalent of the MMRM and does not require that the missing at random assumption needs to be met. A sensitivity analysis on these choices could be done using a Pattern Mixture Model analysis. A Pattern Mixture Model analysis formulates assumptions based on / regarding missing data in a transparent and clinically interpretable manner. Last observation carried forward (LOCF) analyses could be done. However, because the LOCF is a more punitive analysis that requires larger sample size to yield statistical significance compared to the MMRM or ET Rank Analysis we recommend against its use as a first choice analysis in suicidality treatment studies. Observed cases analyses and completer analyses should also be done as a cross-check on all of the above, but are considered secondary to the MMRM and the ET Rank Analysis.

#### Safety

In the interest of time and efficiency, some may wish to use the S-STS for the dual purpose of efficacy and safety assessment of suicidality. We recommend the concomitant use of the T-CASA system for those sponsors, regulatory agencies, and sites wishing to use an accurate and detailed assessment instrument to monitor suicidality events independent of the dimensional ratings captured on the S-STS.

# Study stopping rules

Pandey GN. Brain corticotropin releasing factor and the hypothalamic-pituitary-adrenal axis in suicide. Chapter 36 (pages 336-342) in A Concise Guide to Understanding Suicide: Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.
 Dwivedi Y. Receptor signaling in suicide. Chapter 37 (pages 343-356) in A Concise Guide to Understanding Suicide: Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

It is critically important to ensure that all clinical trials involving the investigation of potential anti-suicidality medications in suicidal subjects have a data safety monitoring board in place. Such trials should have in place study stopping rules that include thresholds for rescuing individual patients as well as thresholds for temporarily or permanently stopping those trials. One possible model that provides some guidance on this is in the Study Stopping Rules for the S-STS (see chapter 14.4). The sponsor should conduct interim analyses for futility and the results of these analyses should be made available to the data safety monitoring board.

# Data safety monitoring boards

Data safety monitoring boards (DSMB) in suicidality studies should meet more frequently and have access to data in real time or as close to real time as reasonably possible to properly monitor and make decisions about the wisdom and safety in allowing such studies to continue or not and in allowing subjects to remain in the study or not. The DSMB should review un-blinded safety and efficacy data throughout the trial.

The data safety monitoring boards, as is usually the case, may have an obligation to communicate with regulatory agencies more frequently than is usually the case in standard CNS clinical trials.

# Concomitant treatments

Adequate time should be allowed to permit stabilization on concomitant medications, on the dose of these medications, and on any other psychotherapeutic treatments that patients may be taking prior to starting a trial with an anti-suicidality medication. The reason is to reduce the influence of these concomitant medications and other associated treatments on the assessment of suicidality. Four weeks is a reasonable period of time to permit stabilization on the current dose of any concomitant medication. Eight weeks is a reasonable period of time to permit stabilization on a concomitant psychotherapeutic or behavior treatment.

#### Secondary Outcome Measures

We recommend minimizing the use of too many additional scales in suicidality studies. This reduces the burden on both the patient and the clinician, improved adherence to the study medication, and in retaining patients in the trial. It is also more likely to achieve the goal of having both the patient and the clinician devote adequate amount of time and care in the proper implementation on the central focus of the study, which is the assessment and monitoring of both suicidality phenomena and the tracking of suicidality events. We hope that reducing this burden this may improve safety.

# 11

# Stages of Recovery

# **Reduction in Symptoms**

Severity, Frequency, Symptom Duration and Time Spent Per Day

The first change most suicidal patients notice in response to treatment is a reduction in suicidal symptoms. This change involves a reduction in the severity, the frequency, the symptom duration, and/or the time spent each day experiencing suicidality. One subject explained this reduction as follows:

Less and less of my day was wasted experiencing the suicidality and getting myself refocused. I could now focus on other things for longer periods of time without the suicidality interfering. When the suicidality did happen it was less severe and easier for me to manage. It didn't have as devastating an impact on me as it had in the past.

"Sputtering Decline" Profile

Suicidality reduction often follows what we call a "sputtering decline". One individual with IASD reported that the phenomena resolved in the following order: 1<sup>st</sup> the suicidality, 2<sup>nd</sup> the hopelessness, 3<sup>rd</sup> the depressed mood, 4<sup>th</sup> the suicidal planning, and 5<sup>th</sup> the depersonalization. This resolution, however, came in a kind of repeating wave pattern, with each phenomenon partially resolving, as described in detail in the next paragraph.

In the 1<sup>st</sup> wave I felt a reduction in suicidality followed by a reduction in hopelessness.

In the 2<sup>nd</sup> wave, I experienced a further reduction in suicidality followed in turn by a further reduction in hopelessness.

This pattern was the same in the 3<sup>rd</sup> wave except that I also felt a new reduction in depressed mood washing over me.

The 4<sup>th</sup> wave brought a further lessening in my suicidality followed by a further reduction in my hopelessness, followed by another decline in my depressed mood, and this was then followed by a reduction in my suicidal planning.

In the 5<sup>th</sup> wave I felt a further reduction in my suicidality followed by a further reduction in my hopelessness, followed by a further reduction in my depressed mood, followed by a further reduction in my suicidal planning, and this was then followed by a reduction in my sense of depersonalization.

This pattern continued until a wave occurred without the suicidality, but with a further reduction in hopelessness, followed by a further reduction in depressed mood, followed by a further reduction in suicidal planning, and this was then followed by a further reduction in depersonalization.

This pattern continued until a wave occurred without the hopelessness, but with a further reduction in depressed mood, followed by a further reduction in suicidal planning, and this was then followed by a further reduction in depersonalization.

This pattern continued until a wave occurred without the depressed mood, but with a further reduction in suicidal planning, and this was then followed by a further reduction in depersonalization. This pattern continued until an eventual wave occurred without the suicidal planning, but with a further reduction in her depersonalization until the depersonalization resolved.

We suspect that different disorders will have a different "sputtering decline" profile than the example above. Subjects at different stages of a disorder may also have different "sputtering decline" profiles. Future studies need to investigate the sputtering decline profiles associated with each suicidality disorder.

# Internal Struggle

# Anxiety / Doubt / Fear

You might think that a reduction in symptoms would be a cause for elation, but for those who have struggled with suicidality for years, the loss of symptoms can paradoxically bring new anxiety, doubt, and fear. Will the symptoms come back?

The more chronically suicidal may have had periods where they got their hopes up about their suicidality ending only to have it return again. These patients may try to ignore the current change - fearing it is only temporary. Some may continue to live their lives with the expectation that the symptoms will return after each partial improvement. One such individual described this experience as, "This week is only a fluke. My symptoms will get bad again soon."

Even after a period of weeks or months, some will continue to wonder when their suicidality will return. This is likely a coping mechanism - a way to feel more prepared to cope if the suicidality does return and needs to be addressed as part of treatment.

# Cautious Optimism

Almost all patients have moments when they question whether the changes will last. They may waver between the doubt they previously experienced and a new cautious optimism. One subject reported this feeling as the thought, "My symptoms have been better for a while, I wonder how much longer this will last."

## Acceptance

In this stage individuals begin to *accept* the idea that the symptoms of suicidality will not return. Subjects will still waver but between cautious optimism and acceptance. One subject reported this acceptance as thinking, "If my symptoms have been better for all this time, maybe this will last for the long-term."

We suspect some subjects will waver between the anxiety / fear / doubt, the cautious optimism, and the state of acceptance many times before settling in one of these stages for a long period of time.

## **Expanding Horizons**

# Depression

When suicidality is the primary *source* of depression (i.e. in cases where the depression started as a result or consequence of suicidality) the depression tapers and ends in response to successful treatment of suicidality with a specific anti-suicidality medication. With the reduction in the suicidality driver, there is no longer a reason to be depressed. The patient may still

experience depression in response to life events, but depression experienced as a direct result of suicidality ends.

# Hopelessness

When suicidality is the primary *source* of hopelessness (i.e. in cases where the hopelessness started as a result or consequence of suicidality) the hopelessness tapers and ends in response to successful treatment of suicidality with a specific anti-suicidality medication. With the reduction in the suicidality driver, there is no longer a reason to feel hopeless. Though some subjects may continue to experience hopelessness due to other factors of their life (e.g. overall quality of life or psychosocial stressors), the hopelessness experienced as a direct result of the suicidality ends in response to the anti-suicidality treatment.

# Quality of Life

Compounding features and functional impairment generally decrease in response to treatment. One subject reported a short decrease in her willingness to "stay safe" in response to an antisuicidality treatment. This occurred in the context of an increased willingness to go out and explore the world and improve her quality of life, instead of "staying safe" and cloistered at home. Although it may appear paradoxical she and her doctor interpreted this as a positive development. This decrease lasted a couple of weeks after the end of the suicidality. For one subject, the overall quality of life did improve in response to anti-suicidality treatment, even further than the treating clinician expected. The subject reported this was because the reduction of the suicidality allowed the subject to see the other problems in her life as being less of an impact than they were when she was suicidal. In other words, the subject's perspective on things that negatively impacted the quality of her life changed in response to the anti-suicidality treatment. Things that had previously been a major impact on the quality of her life seemed less significant once she responded to treatment. Over time, months, without suicidality the subject's scores on the overall quality of life question slowly reached "0", even when some triggering psychosocial events were occurring in this subject's life. Apart from these two values, the scores on the other Discan Metrics of the S-STS CMCM slowly decreased to a score of "0" in response to treatment.

Some clinicians may expect the patient-rated need for treatment on the S-STS CMCM to also return to "0". However, the way that measure is set up a "0" suggests that patient expects they will never need any care for their condition. Most suicidal subjects responding to this question seem unlikely to assume they will never need any care and will flatline at a score of "1" (indicating they require outpatient visits as needed in the event the suicidality returns). For one subject at a later stage of the disorder it took more than a year without any symptoms of suicidality for her to even consider rating this value as a "0".

Treatment Lessens the Impact on Suicidality of the Factors that Previously Increased Suicidality

After responding to treatment, the impact the factors have on a subject's suicidality tends to lessen until all of the factors either do not apply for that subject or they have no impact on the subject's suicidality because the subject is no longer suicidal.

# Adjustment to the New Self

Less Stigma (Both Self Imposed and Imposed by Others)

In response to effective treatment, individuals will experience a lower level of stigma. Others impose some of this stigma, but some is self-imposed. One subject explained this reduction in stigma as follows:

It has been very difficult for me to accept the change in my perception of my suicidality. I find myself going back to the idea that there are things I can't or shouldn't even attempt to do simply because of my suicidality. From time to time, I also find myself going back to the mindset that I should have been able to control my suicidality and feeling frustrated with myself for not being able to do so. Loved ones have also become more open to talking about my suicidality now that it is less severe. I sometimes think this is because the less severe suicidality is the less scary it is for them.

Less Isolation (Both Self Imposed and Imposed by Others)

Patients are likely to experience a lower level of social isolation. Some of this isolation was self-imposed. It was also imposed by others, by society, by culture, and by religious beliefs. One subject explained this lessening of social isolation:

Since my suicidality has lessened, I am more at ease in social settings. It seems as though the part of my brain that was constantly focused on when my suicidality would be bad again and how to cope with a flare-up in symptoms is now freed up. That makes it easier for me to interact with people around me. I think I am more personable and more likeable now. I know that those around me have picked up on this and are more welcoming to interactions with me.

I recently visited friends I had not seen in years. I have to say I was terrified they would not accept me or want to be around me after knowing the depths of my suicidality. It was really hard for me not to cancel. My mind kept going over every possible negative scenario. In the end, I had a wonderful time. I wish I had pushed myself to reach out to them sooner because they were so much more welcoming than I had expected. I look forward to spending more time with them.

Feeling Free to Make and Pursue Dreams and Long-term Goals

In response to the reduction in symptoms, patients may begin to feel that they can pursue goals and dreams that once seemed impossible or pointless. One individual told us that he had never saved for retirement because he never expected to live long enough to retire. After successful treatment he saw a point to saving. He could now imagine retiring - a goal he previously did not even consider. Others may start working towards fulfilling dreams - travelling to Europe, getting involved in a relationship, developing hobbies or skills, or completing a higher degree.

Let's Not Go Back Down That Rabbit Hole Again

Some individuals recovering from suicidality will try to distance themselves from the severity of their prior symptoms. One person reported feeling overwhelmed if she thought about how severe her suicidality has been. She said it made her "scared because of the real possibility that I could have died." She preferred to not think about this possibility:

I was afraid to look back and think about how I used to feel or what symptoms I had during the symptomatic stages of my suicidality disorder. I didn't want to go down the 'rabbit hole' of processing it. I actually delayed emotionally processing the change in my symptoms until a time when I felt my schedule would allow me to be overly emotional for a longer stretch of time.

Some may find weekends are a good time for this. Others may prefer to wait until they have a set of consecutive days when they do not have many work, social, and / or family responsibilities.

Another way of thinking about this is putting off grieving the life I would have had if my suicidality had not been present or had not been as severe.

I lost out on living the life that my friends and peers were allowed to live and now that I am not consistently fighting just to keep myself alive, I have to reconcile the life I would have had with the life I did have. I must come to terms with how the suicidality influenced my life for the negative, but also for the positive. Sometimes acknowledging the positive has been more difficult for me than focusing on the negative.

Higher Expectations of Self

Gains may feel fragile but patients may begin to have higher expectations of themselves. This change may occur gradually over time, as the individual feels better and more confident in the reduction of their suicidality. One individual experiencing these higher expectations reported:

I expect the suicidality to return, so I don't want to waste the good days. I need to push myself even when I am tired or exhausted, to make the most productive use of my time while I still feel good.

# Moving On

Shifting Goals to More Ambitious Targets

Eventually individuals recovering from suicidality will begin to move on. Part of this involves a shifting of goals to more ambitious targets. This can be considered as a further progression of feeling free to make and pursue dreams and long-term goals.

While the suicidality is likely to stay with them, as a part of the person's life, at some point they will reconcile this part of their past and move beyond it.

One subject just reaching this stage reported:

When I had transient improvement I would begin to hope that things were going to work out. When the next phase of worsening occurred, I was devastated. It ended my hopes and made managing the suicidality even harder than if I had never had any improvement in the first place. This is one of the reasons why I didn't really want a treatment to be effective. I didn't want to have my hopes lifted only to find that the relief was temporary.

Even after 6 months without symptoms, I still have moments when I expect the symptoms to return. I expect they will probably return at the worst possible time. To cope with these moments, I find myself setting new more ambitious targets for recovery. These new targets delay the acceptance that the treatment was actually going to be effective for the long-term (a "make hay while the sun shines" experience). This allowed me to cautiously return to some of my previous life ambitions. This kept me grounded in the idea that the symptoms may in fact return (which would make it somewhat easier to cope with if the symptoms do return).

The "Moving On" stage may be one of the longest for some subjects because of this need to be cautious with their optimism.

# Case Studies: Observations Based on Data Mining

- 12. 1 Is the Suicide Event Count Important?
- 12.2 Does citalopram increase the frequency of up-switches of impulsive suicidality in a subject with Impulse Attack Suicidality Disorder? A case study
- 12.3 Study of Magnesium in the Treatment of Impulse Attack Suicidality Disorder
- 12.4 Analysis of A Dataset Collected Using the Tampa Classification Algorithm for Suicidality Assessment (T-CASA): A Case Study
- 12.5 Do suicidal phenomena have a linear or a non-linear relationship with one another?
- 12.6 What is a Patient Rated Scale Really?

# 12.1

# Is the Suicide Event Count Important?

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

A revised version of this case study was published in:

Giddens JM, Sheehan DV. Is a count of suicidal ideation and behavior events useful in assessing global severity of suicidality? a case study. Innov Clin Neurosci. 2014;11(9–10):179–181. http://innovationscns.epubxp.com/i/425963/178

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

#### Abstract

# Objective

While regulatory agencies and suicidality scales show interest in counting events of suicidality, the predictive value and clinical utility of such information remains unclear. This single case study investigates the value of counting the number of events of suicidality and of another simpler and more clinically useful alternative.

#### Methods

One suicidal subject documented suicidality global severity, the number of events of suicidality, and the amount of time spent experiencing suicidality on a daily basis for 366 consecutive days.

## Results

There is a much stronger relationship between the time spent in suicidality and global severity of suicidality than there is between the suicidality event count and global severity of suicidality.

## Conclusion

In assessing and monitoring the global severity of suicidality, capturing information on time spent in suicidality may be a more useful and accurate way of collaterally assessing suicidality than tracking the count of suicidality events, especially at the severe end of the spectrum. The limitations of this study are that it is a single case report, the case may be an outlier, and the findings may not be generalizable to other cases of suicidality. This finding needs to be investigated in a larger sample, in other types of suicidality disorders and in other disorders associated with increased suicidality.

#### Introduction

Suicidality assessment scales and regulatory agency documents reflect more interest in assessing the count of suicidality events as an index of suicidality severity than alternatives<sup>1 2</sup>. The data supporting the value of suicidality event count is impressionistic and based largely on precedent and clinical lore. The purpose of this paper is to explore its value and that of another simple alternative.

## Methods

A 30-year-old female who experienced suicidality almost daily for more than twenty years collected data on suicide event count and global severity of suicidality over 366 consecutive days.

Her first psychiatric diagnosis at age 12 was Major Depressive Disorder (DSM III-R³). Four years later her diagnosis changed to Bipolar 2 Disorder (DSM IV-TR⁴). In 2010 these diagnoses were replaced by Pervasive Developmental Disorder - Not Otherwise Specified (PDD-NOS)(DSM IV-TR⁵). Her presentation meets criteria for Asperger Syndrome in ICD-10⁶. She is very organized, has a very high level of attention to detail and is highly intelligent by IQ. She reports that her symptoms previously interpreted as hypomania were more closely related to stress from and / or difficulties with communication, being distracted by various stimuli, and periods of excessive focus on topics of interest. All of these are common characteristics found in persons with Pervasive Developmental Disorder and Asperger Syndrome.

She rated the severity of her suicidality daily using a 0 - 4 global severity scale, where 0 = Not at all, 1 = Mild, 2 = Moderate, 3 = Severe, and 4 = Extreme. Suicidality was defined as the suicidal phenomena captured by page 1 of the 11/12/13 version of the *Sheehan-Suicidality Tracking Scale*<sup>7</sup>, with the exception of non-suicidal self-injury. She captured these scores every morning for the prior day (12:00 am through 11:59 pm) in a spreadsheet.

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm

<sup>&</sup>lt;sup>1</sup> C-SSRS Posner K., Brown GK, Stanley B, Brent DA, Yershova KV, et.al.: The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. Am J Psychiatry 2011; 168:1266–1277.

<sup>&</sup>lt;sup>2</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance*, issued in August 2012. Revision 1 (10302 dft.doc 08/06/12). Available at:

<sup>&</sup>lt;sup>3</sup> American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R). 3<sup>rd</sup> edition revised. Washington, DC: American Psychiatric Association; 1987.

<sup>&</sup>lt;sup>4</sup> American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). 4th ed. Washington, DC: American Psychiatric Association; 2000.
<sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> World Health Organization. (1992). *The ICD-10 classification of mental and behavioural disorders: clinical descriptions and diagnostic guidelines*. Geneva: World Health Organization.

<sup>&</sup>lt;sup>7</sup> Sheehan DV, Giddens JM, Sheehan IS. Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Innov Clin Neurosci. 2014;11(9–10):93–140. Available from <a href="http://innovationscns.epubxp.com/i/425963/92">http://innovationscns.epubxp.com/i/425963/92</a>

She concurrently documented her suicidality events for the prior day every morning for a total of 31,183 events of suicidality over 366 days in a spreadsheet. This documentation included the coding category for each event category in the US Food and Drug Administration (FDA) 2012 draft guidance on the prospective assessment of suicidal ideation and behavior (FDA-CASA 2012)<sup>8</sup>, the amount of time spent experiencing the event, and the number of times the event occurred in the prior day.

She tracked the global suicidality severity prior to tracking any other details of her suicidality out of concern that if she thought about all the details of her suicidality from the prior day she might exaggerate her global severity score. She feared that an inflated global suicidality severity score could increase her level of hopelessness and depressed mood which she feared would make a suicide attempt more likely.

#### Results

Figure 12.1.1 shows a scatter plot of the relationship between the number of events of suicidality (the event count) daily and the daily global severity of suicidality scores. This relationship was very weak. The linear trend line provided the best fit with an  $R^2$  of 0.0314.

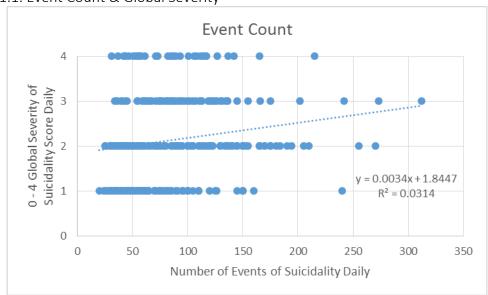


Figure 12.1.1. Event Count & Global Severity

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm

<sup>&</sup>lt;sup>8</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance*, issued in August 2012. Revision 1 (10302 dft.doc 08/06/12). Available at:

Figure 12.1.2 shows a scatter plot of the relationship between the number of minutes spent (the time spent) experiencing suicidality daily and the daily global severity of suicidality scores. This relationship was much stronger. The logarithmic trend line provided the best fit with an  $R^2$  of 0.6209. These findings suggest the time spent experiencing suicidality is a much stronger reflection of global suicidality severity than the event count for this subject.

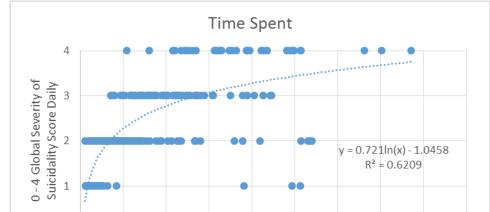


Figure 12.1.2. Time Spent & Global Severity

0 0

100

200

300

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

400

Total Number of Minutes Experiencing Suicidality Daily

500

900

Figure 12.1.3 shows the relationship between the median number of events of suicidality (the event count) for each global severity score. Figure 12.1.4 shows the relationship between the median number of minutes spent (the time spent) experiencing suicidality for each global severity score. The distribution of the data was not normal for either. For this reason we used the median scores, rather than the means.

Median Event Count

A glopal Severity of A glopal S

Figure 12.1.3. Median Event Count for Each Global Severity Score

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

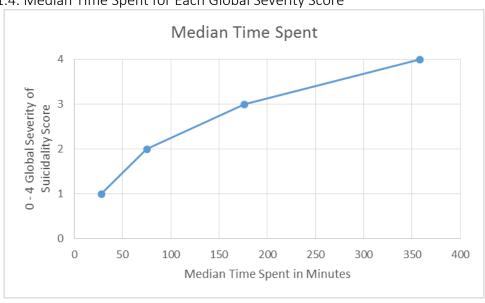


Figure 12.1.4. Median Time Spent for Each Global Severity Score

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Table 12.1.1 shows the relationship between global severity of suicidality score (global severity), the time spent experiencing suicidality (time spent), and the number of suicidal events (event count). The results show no significant relationship between number of events and global severity of suicidality (0.17) or between the time spent experiencing suicidality and the number of events (0.14). However there is a strong relationship between total time spent in suicidality and the global severity of suicidality rating (0.68).

Table 12.1.1. Correlation Matrix of Time Spent, Event Count and Global Severity of Suicidality

	Time Spent	<b>Global Severity</b>	<b>Event Count</b>
Time Spent	1		
Global Severity	0.68070953	1	
Event Count	0.140768218	0.177115946	1

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.1.5 shows a comparison of 2 days of tracking with the same number of events of suicidality (55 events). Although the number of events of suicidality was the same for both days, the number of minutes spent experiencing suicidality each day and the global severity of suicidality score were substantially different for both days. On day 4, indicated in blue, the subject recorded a total of 481 minutes or 8 hours and 1 minute of suicidality. On day 43, indicated in orange, the subject recorded a total of just over 18 minutes of suicidality.

Figure 12.1.5. Two Days with Same Event Count, but Substantial Difference in Time Spent

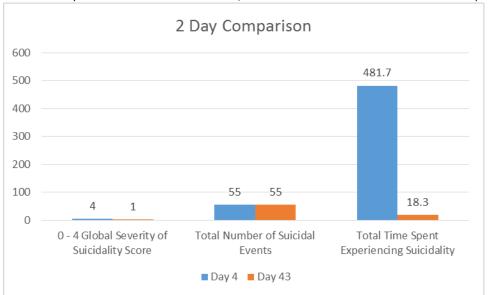


Figure 12.1.6 shows a comparison of two days when the subject experienced 4 events of FDA-CASA 2012 Passive suicidal ideation: wish to be dead. The 4 events lasted a total of 80 minutes on day 273, shown in blue. The 4 events only lasted a total of less than half a minute on day 366, shown in orange.

Figure 12.1.6. Two Days with Same Passive Ideation Event Count, but with a Difference in Time Spent

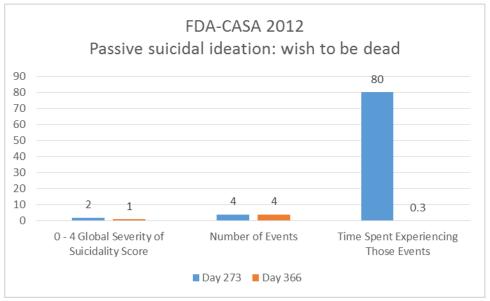
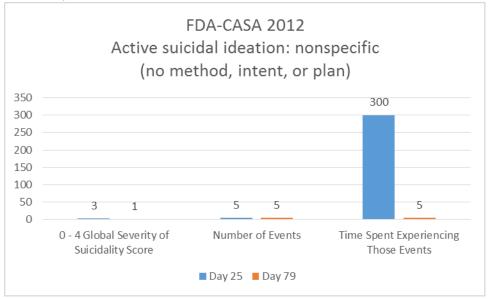


Figure 12.1.7 shows a comparison of two days when the subject experienced 5 events of FDA-CASA 2012 Active suicidal ideation: nonspecific (no method, intent, or plan). The 5 events lasted a total of 300 minutes (5 hours) on day 25, shown in blue. The 5 events lasted a total of 5 minutes on day 79, shown in orange.

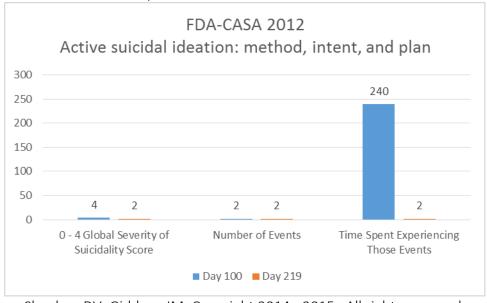
Figure 12.1.7. Two Days with Same Active Ideation: Nonspecific Event Count, but with a Massive Difference in Time Spent



Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.1.8 shows a comparison of two days when the subject experienced 2 events of FDA-CASA 2012 Active suicidal ideation: method, intent, and plan. The 2 events lasted a total of 240 minutes or 4 hours on day 100, shown in blue. The 2 events lasted a total of only 2 minutes on day 219, shown in orange.

Figure 12.1.8. Two Days with Same Active Ideation: Method, Intent, and Plan Event Count, but with a Major Difference in Time Spent



The subject did not experience enough of the other FDA-CASA 2012 suicidality categories during this time to allow for other similar comparisons.

#### Discussion

The subject interpreted the relationship in Figure 12.1.1 (between global severity and time spent experiencing suicidality) as weak because the impact from different events varies widely. Some events of suicidality had much less impact on her than other events. For example, a passing thought "I wish I was dead" lasting five seconds, had much less impact on her than being completely overwhelmed a high level of suicidal ideation, method, plan and intent to act. These observations prompted the creation of Figures 12.1.5 through 12.1.8.

The subject identified some of the outliers to the right of the trend line in Figure 12.1.2 as the result of engaging in many behaviors that fit the definition of FDA-CASA 2012 Preparatory acts toward imminent suicidal behaviors, although she did not have active suicidal ideation or intent at the time<sup>9</sup>. For example, the subject decided that she wanted to complete a particular quilt prior to making a suicide attempt. Days later, if she sewed pieces for the quilt without having any awareness of suicidality while doing so and only later makes the connection, this counts as a preparatory behavior since it puts her closer to proceeding with a suicide attempt. Since this behavior technically fits the definition of a Preparatory act toward imminent suicidal behaviors she included this time spent sewing in the time spent experiencing suicidality, though such an event had no impact on her rating of the global severity of suicidality. This is one reason why her global severity of suicidality is as low as 1 with a time spent of 513 minutes or as low as 2 with a time spent of 539 minutes.

The subject identified some of the outliers to the left of the trend line in Figure 12.1.2 as results from days she was less able to cope with her suicidality. There were some instances of days of more severe suicidality followed by days of less severe suicidality. On such days of lesser suicidality she often had more difficulty coping because her ability to resist suicidality was

<sup>9</sup> There is a lack of consistency between the title of this FDA-CASA 2012 coding category and the definition. Although the title states the behavior in question is connected to an imminent suicidal behavior, the definition of this category does not require such a connection. This allows for behaviors, such as the subject's time spent sewing, to be classified within this category simply because the subject at one time thought about completing the behavior prior to a suicide attempt.

An argument could be made that the definition should be amended to not include such behaviors. However, including these behaviors can help with patient safety. Consider a patient that experienced a severe episode of suicidality three months ago. During this time he decided he wanted to see his mother again before making an attempt. He has experienced no suicidality in the past month, but his mother happened to stop by yesterday to see him. If the patient finds himself suicidal again three weeks from now, he may not feel the need to see his mother an additional time prior to making an attempt. If preparatory behaviors were required to be engaged in with some intent or suicidal ideation, a clinician may not have any knowledge of the patient's visit with his mother (due to this event not meeting the definition of the category) and the clinician may consider the patient at a lower likelihood of an attempt. With the knowledge of the visit the clinician is not likely to factor the patient's desire to see his mother again into their assessment and will have a clearer understanding of the current factors playing a role in the patient's suicidality.

depleted from the earlier days of severe suicidality. This is one reason her time spent may be as low as 71 minutes with a global severity of suicidality at 3 or as low as 109 minutes with a global severity of 4.

The subject interpreted the reduction in the number of suicidal events per day at severity level 4 in Figure 12.1.3 as the result of the number of suicidal events decreasing while the time spent in each suicidal event increased.

Why was there such a discrepancy between the time spent in suicidality on the days shown in Figure 12.1.5 when the count of the number of events of suicidality was the same? On day 43 (Figure 12.1.5), there were 55 shorter periods of suicidality. On day 4 (Figure 12.1.5) there were 54 shorter period of suicidality, but there was also one very long period of suicidal ideation and time spent planning for an attempt. This illustrates why the event count alone does not give an adequate perspective of the patient's suicidality and why time spent in suicidality may be a better metric for this purpose.

On some days the global severity and the event count were the same, but the time spent was different. How is that possible? On day 8 (not highlighted in any figure), there was a brief period of intense suicidality, but the time spent in total suicidality for the day was short. On day 325 (not highlighted in any figure), the time spent in suicidality was very prolonged, but the intensity was more moderate. The compound effect of time spent with intensity for each of these days and the subject's ability to cope on these days resulted in the global severity of suicidality score being the same for both days – a score of 2.

Figures 12.1.6, 12.1.7, and 12.1.8 illustrate that you cannot rely only on the number of events within most suicidal ideation or preparatory behavior categories (FDA-CASA 2012) as a substitute for capturing time spent in suicidality and in assessing global severity of suicidality. This is further reinforced by the findings in the Table 12.1.1 correlation matrix, showing no significant relationship between number of suicidality events and global severity of suicidality or the time spent experiencing suicidality. However there is a strong relationship between total time spent in suicidality and the global severity of suicidality rating.

The limitations of this study are that it is a single case report, the case may be an outlier, and the findings may not be generalizable to other cases of suicidality beyond the diagnosis of Asperger's syndrome. This finding needs to be investigated in a larger sample, in other types of suicidality disorders and in other disorders associated with increased suicidality.

# Conclusion

In assessing and monitoring the global severity of suicidality, capturing information on time spent in suicidality may be a more useful and accurate way of collaterally assessing suicidality than tracking the count of suicidality events, especially at the severe end of the spectrum.

12.2

Does citalopram increase the frequency of up-switches of impulsive suicidality in a subject with Impulse Attack Suicidality Disorder? - A case study

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

# Introduction

The relationship between antidepressant medications and increased suicidality is not understood. In 1991 the United States Food and Drug Administration's (FDA) psychopharmacologic drugs advisory committee concluded there was no clear evidence of an increased risk of suicide with an antidepressant, fluoxetine<sup>1</sup>. Additional data compiled as more antidepressant medication trials were conducted and was reviewed by several groups that found no increased risk of completed suicide<sup>2 3 4</sup>. A 2003 analysis of pediatric trials of paroxetine suggested antidepressants may have contributed to suicidal ideation and suicide attempts in children and adolescents. The FDA requested additional data on all trials of antidepressants in children and adolescents. In 2004 analysis finding a relative risk for suicidal ideation or behavior of 1.95 (95% CI 1.28 o 2.98) in the treatment group compared to the placebo was presented to two FDA committees<sup>5</sup>. The committees recommended the FDA add a boxed warning to all antidepressant labels and recommended further analysis on data from adult trials of antidepressants. In 2009 Stone et al. analyzed data from adult trials by age<sup>6</sup>. In the discussion they reported that antidepressants seem "moderately protective for adults aged 25-64 and more strongly protective in those aged 65 and older" for "suicidality" (presumably for all suicidality in all indications in aggregate, although this is not explicitly stated). In the abstract they state that antidepressants seem "to be neutral for suicidal behavior, but possibly protective for suicidal ideation in adults aged 25-64". In addition, they found antidepressants increased risk among adults under age 25 compared to those taking placebo, similar to the suicide risk seen in children and adolescents.

The boxed warnings were updated with this age specific information. The boxed warning for Celexa<sup>7</sup> now reads:

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Celexa or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber.

<sup>&</sup>lt;sup>1</sup> Psychopharmacological Drugs Advisory Committee. United States Food and Drug Administration. Department of Health and Human Services Public Health Service. 1991. [Meeting Transcript]. Accessed September 22, 2015. Retrieved from http://www.fda.gov/ohrms/dockets/ac/prozac/2443T1.PDF

<sup>&</sup>lt;sup>2</sup> Khan, A., Warner, H. A., & Brown, W. A. (2000). Symptom reduction and suicide risk in patients treated with placebo in antidepressant clinical trials: an analysis of the Food and Drug Administration database. *Archives of General Psychiatry*, *57*(4), 311-317.

<sup>&</sup>lt;sup>3</sup> Storosum, J. G., van Zwieten, B. J., van den Brink, W., Gersons, B. P., & Broekmans, A. W. (2001). Suicide risk in placebo-controlled studies of major depression. *American Journal of Psychiatry*, *158*(8), 1271-1275.

<sup>&</sup>lt;sup>4</sup> Hammad, T. A., Laughren, T. P., & Racoosin, J. A. (2006). Suicide rates in short-term randomized controlled trials of newer antidepressants. *Journal of clinical psychopharmacology*, 26(2), 203-207.

<sup>&</sup>lt;sup>5</sup> Hammad TA, Laughren T, Racoosin J. Suicidality in Pediatric Patients Treated With Antidepressant Drugs. *Arch Gen Psychiatry*. 2006;63(3):332-339. doi:10.1001/archpsyc.63.3.332.

<sup>&</sup>lt;sup>6</sup> Stone, M., Laughren, T., Jones, M. L., Levenson, M., Holland, P. C., Hughes, A., ... & Rochester, G. (2009). Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. *Bmj*, 339.

<sup>&</sup>lt;sup>7</sup> Celexa. Prescribing information. Accessed June 20, 2015. Retrieved from

 $http://www.access data.fda.gov/drugs atf da\_docs/label/2009/020822s037,021046s015lbl.pdf$ 

The purpose of this case report is to offer one explanation for the reports of increased suicidality in subjects taking antidepressants.

# Methods

A 29-year-old female subject who experienced suicidality almost daily for over 20 years prospectively collected a self-report data series using the Suicidality Modifiers Scale (SMS)<sup>8</sup> and the Sheehan - Suicidality Tracking Scale (S-STS)<sup>9</sup>. The data was collected using the computerized versions of the scales<sup>10</sup>. Question 1 in the Impulsivity section of the 11/11/11 version of the SMS is used. The 11/11/11 version of S-STS contained 11 questions on suicidality and 1 question on non-suicidal self-injury<sup>11</sup>. Question 1 on the SMS is laid out as seen in Figure 12.2.1. The S-STS uses the same response option anchors as shown in Figure 12.2.1. Data was collected at various intervals ranging between 0 and 5 days (mean 3.78 days) for a total of 66 data collection points.

Figure 12.2.1: Suicidality Modifiers Scale Impulsivity Question  ${\bf 1}$ 

Over the past (timeframe):

Topic

Not at all | A little | Moderately | Very | Extremely

1. How strong was the impulse (urgent need) to plan or to act in any suicidal way?

Sheehan DV Copyright 2005 - 2015. All rights reserved.

The subject was first diagnosed with Major Depressive Disorder<sup>12</sup> at age 12. At age 16 this diagnosis was changed to Bipolar II Disorder<sup>13</sup>. At age 27 the diagnosis was instead changed to Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)<sup>14</sup> because many of the symptoms that were used to meet criteria for Bipolar II Disorder were more appropriately attributed to her PDD. The subject meets ICD-10 criteria for Asperger Syndrome<sup>15</sup> and meets criteria for Impulse Attack Suicidality Disorder (IASD)<sup>16</sup>.

The subject reported having first taken a selective serotonin reuptake inhibitor (SSRI) at age 12 and having been on at least 10 different antidepressants since then. It is important to note that the *subject's age at the time of data collection* (29) *is outside the age range of the boxed warnings for increased risk of suicidality* (under age 25) *on all antidepressants*.

<sup>&</sup>lt;sup>8</sup> Giddens JM, Sheehan DV. *The Complexity of Assessing Overall Severity of Suicidality: A Case Study*. Innov Clin Neurosci. 2014;11(9–10):164–171. Available from: http://innovationscns.epubxp.com/i/425963/164

<sup>&</sup>lt;sup>9</sup> Sheehan DV, Giddens JM, Sheehan IS. *Status Update on the Sheehan Suicidality Tracking Scale (S-STS) 2014*. Innov Clin Neurosci. 2014;11(9–10):93–140. Availavle from: <a href="http://innovationscns.epubxp.com/i/425963/92">http://innovationscns.epubxp.com/i/425963/92</a>

<sup>&</sup>lt;sup>10</sup> Dolphin Electronic Data Capture (eMINI Professional Version 2.1.1 / R131112.1 Database Version 2.26) [Software]. (1994 - 2012). Retrieved from http://medical-outcomes.com/

<sup>&</sup>lt;sup>11</sup> Sheehan DV, Alphs L, Mao L, et al. *Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 Draft Guidance suicidality categories*. Innov Clin Neurosci. 2014;11(9–10):32–46. Available from: <a href="http://innovationscns.epubxp.com/i/425963/32">http://innovationscns.epubxp.com/i/425963/32</a>

<sup>&</sup>lt;sup>12</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)*. 3rd edition revised. Washington, DC: American Psychiatric Association; 1987.

<sup>&</sup>lt;sup>13</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

<sup>&</sup>lt;sup>14</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

<sup>&</sup>lt;sup>15</sup> World Health Organization. (1992). *ICD-10 Classifications of Mental and Behavioural Disorder: Clinical Descriptions and Diagnostic Guidelines*. Geneva. World Health Organization.

<sup>&</sup>lt;sup>16</sup> Sheehan, DV and Giddens, JM. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: http://www.HarmResearch.org

Data was collected as indicated above for a total of 248 days. On day 62 the subject began to take 5mg citalopram daily due to an increase in her depression following the loss of a loved one. The subject reported she "insisted on starting with a very low dose" because she had experienced changes to her suicidality during prior treatments with antidepressants, including 2 prior periods of treatment with citalopram. Citalopram was chosen because it previously had less suicidality inducing effects on her than any antidepressant she had used. After 49 days at 5mg daily, the subject became so concerned about the increased rate of up-switches in suicidality that she began taking the 5mg dose every other day. This dose was continued for 27 days until she changed the dose to 5mg for 2 days and then skipped the third day. The subject reported that the reduction in dose / dose frequency did not appear to reduce the rate of up-switches in suicidality. Consequently she discontinued the citalopram after an additional 40 days. She took the citalopram over the span of a total of 116 days.

The values for Question 1 of the Impulsivity section of the SMS were exported from the Dolphin Software <sup>17</sup>. The classification of the suicidal phenomena into the Columbia-Classification Algorithm of Suicide Assessment (C-CASA)<sup>18</sup> categories in the 2010 FDA draft guidance document <sup>19</sup>, which we refer to as C-CASA 2010, and into the categories in the 2012 FDA draft guidance document <sup>20</sup>, which we refer to as FDA-CASA 2012, were also exported from the software. The exported data maps to each of the C-CASA 2010 and FDA-CASA 2012 categories and provides the corresponding output for each timeframe of data collection. This allowed us to address the question of whether either of these classifications would have picked up a treatment emergent signal of suicidality. For some of the categories the exported data also includes a count of the number of times the category occurred during each timeframe of data collection. In addition, there is an additional category related to the FDA-CASA 2012 which outputs the number of times *any* active suicidal ideation occurred. Figure 12.2.1 shows all of these categories. The values exported for the occurrence of the C-CASA 2010 and FDA-CASA 2012 categories were either "No", this category did not occur, or "Yes", this category did occur. These values were transformed as follows: "Yes" to "1" and "No" to "0". The values for each of these categories were plotted in a line graph together with the values (0 - 4) for Question 1 of the Impulsivity section of the SMS.

<sup>&</sup>lt;sup>17</sup> Dolphin Electronic Data Capture (eMINI Professional Version 2.1.1 / R131112.1 Database Version 2.26) [Software]. (1994 - 2012). Retrieved from http://medical-outcomes.com/

<sup>&</sup>lt;sup>18</sup> Posner, K., Oquendo, M., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *American Journal of Psychiatry*, *164*(7), 1035-1043.

<sup>&</sup>lt;sup>19</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance,* issued in September 2010.

<sup>&</sup>lt;sup>20</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance*, issued in August 2012. Revision 1 (10302 dft.doc 08/06/12). Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm

Figure 12.2.1: Categories

	C-CASA 2010 Categories		FDA-CASA 2012 Categories
	Completed Suicide	1	Passive Suicidal Ideation: Wish to be Dead
2	Suicide Attempt	2	Active Suicidal Ideation: Nonspecific (No Method, Intent, or Plan)
3	Preparatory Acts Toward Imminent Suicidal Behavior	3	Active Suicidal Ideation: Method, but No Intent or Plan
4	Suicidal Ideation	4	Active Suicidal Ideation: Method and Intent, but No Plan
5	Self-Injurious Behavior Intent Unknown	5	Active Suicidal Ideation: Method, Intent, and Plan
6	Fatal Event: Not Enough Information	6	Completed Suicide
7	Self-Injurious Behavior Without Suicidal Intent	7	Suicide Attempt
8	Other (Accident, Psychiatric, Medical)	8	• Interrupted Suicide Attempt
9	Nonfatal Event: Not Enough Information	9	Aborted Suicide Attempt
	Other Category	10	Preparatory Acts Toward Imminent Suicidal Behaviors
	Active Suicidal Ideation	11	Self-Injurious Behavior Without Suicidal Intent

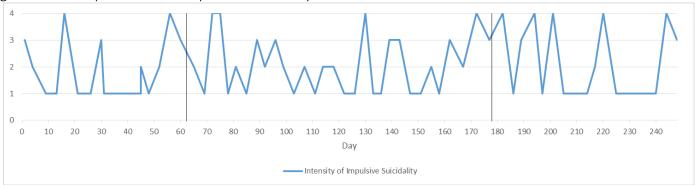
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

# **Impulsivity Results**

# Results 1

Figure 12.2.2 shows the intensity of impulsive suicidality score for the different timeframes. The left vertical black line at day 62 identifies the start date of citalopram. The right black vertical line at day 178 identifies when the citalopram was discontinued. Figure 12.2.2 accordingly shows the two citalopram-free timeframes with the timeframe on citalopram between them.





The left vertical axis captures the Intensity of Impulsive Suicidality on a 0 to 4 intensity rating. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

## Discussion 1

In the time on the citalogram there were a total of 11 up-switches in suicidal impulsivity in 116 days while there were only 9 up-switches in impulsivity during the 132 days while not taking the citalogram. (We define up-

switch as a directional increase in the intensity of suicidal impulsivity score from the SMS.) This means there was a 39% increase in up-switches in impulsive suicidality<sup>21</sup> while taking the citalogram.

If suicidal subjects are already struggling to keep themselves safe, the increased frequency of the impulsive suicidality due to an antidepressant can further exhaust the subject by giving them less time between the experiences of impulsive suicidality to recover and make it more difficult for them to stay safe. The subject of this case study reported, "this is what I have been trying to explain to clinicians since I was 12, but most of them refused to accept this was true. Even after the boxed warnings were added to the antidepressants clinicians told me this 'can't be happening' and that I was 'making this up for attention'. One clinician even went as far as citing a published study<sup>22</sup> that showed researchers couldn't find data to support the idea that antidepressants cause an increase in suicidality. The problem with that study is that the researchers didn't have a data set which included the concept of impulsive suicidality. Their data sets were so limited that they would not have captured such changes in a patient's suicidality."

## C-CASA 2010 Results

## Results 2

Both the C-CASA 2010 and the FDA-CASA 2012 only require documentation of the category if the patient meets criteria for the category. There are no specific instructions with either of these classification systems in the FDA draft guidance documents<sup>23</sup> <sup>24</sup> that the number of times each category occurred must be documented. Therefore, figures 12.2.3, 12.2.4, 12.2.5, 12.2.7, 12.2.9, 12.2.10, 12.2.11, 12.2.13, and 12.2.14 show whether each of the C-CASA 2010 categories occurred during the timeframes of data collection, and the intensity of impulsive suicidality scores during the same timeframes. A value of "0" shows that category did not occur during the timeframe while a value of "1" shows the category did occur during the timeframe. Three categories did occur during the timeframe of data collection. To be thorough, figures 12.2.6, 12.2.8, and 12.2.12 show the number of times each of these categories occurred.

<sup>&</sup>lt;sup>21</sup> The term "impulsive suicidality" is used here instead of the phrase Unexpected Suicidal Impulse Attacks (USIA) (as it is used elsewhere in the book) because the criteria for the USIA's was not created at the time of data collection. However, the subject believes, "most of the events captured by the tracking of SMS Impulsivity Question 1 were likely USIAs".

<sup>&</sup>lt;sup>22</sup> Beasley, C. M., et al. (1991). Fluoxetine and suicide: a meta-analysis of controlled trials of treatment for depression. <u>BMJ</u>: British <u>Medical Journal</u> 303(6804): 685-692.

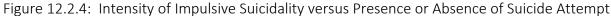
<sup>&</sup>lt;sup>23</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance,* issued in September 2010.

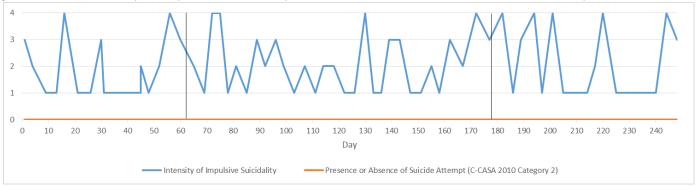
<sup>&</sup>lt;sup>24</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance*, issued in August 2012. Revision 1 (10302 dft.doc 08/06/12). Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm

Day Presence or Absence of Completed Suicide (C-CASA 2010 Category 1) Intensity of Impulsive Suicidality

Figure 12.2.3: Intensity of Impulsive Suicidality versus Presence or Absence of Completed Suicide

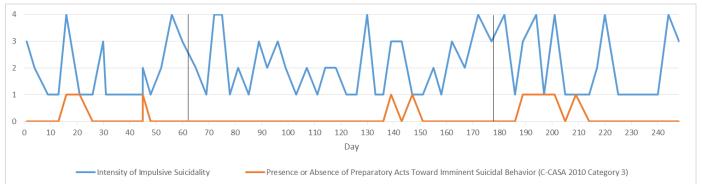
The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of completed suicide as either 0 = did not occur or 1 = did occur. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.





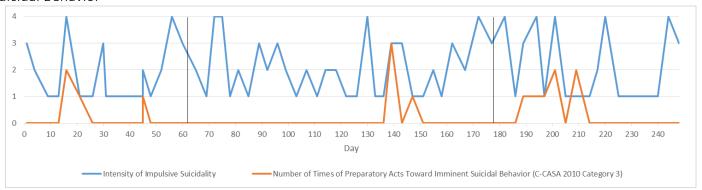
The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of suicide attempt as either 0 = did not occur or 1 = did occur. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.5: Intensity of Impulsive Suicidality versus Presence or Absence of Preparatory Acts Toward Imminent Suicidal Behavior



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of preparatory acts toward imminent suicidal behavior as either 0 = did not occur or 1 = did occur.

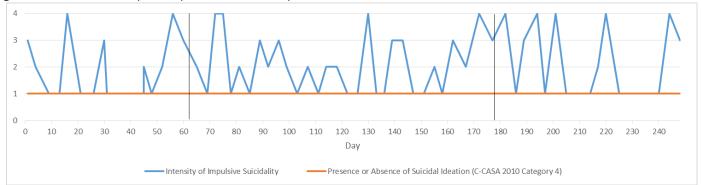
Figure 12.2.6: Intensity of Impulsive Suicidality versus Number of Times of Preparatory Acts Toward Imminent Suicidal Behavior



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the number of times preparatory acts toward imminent suicidal behavior occurred.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

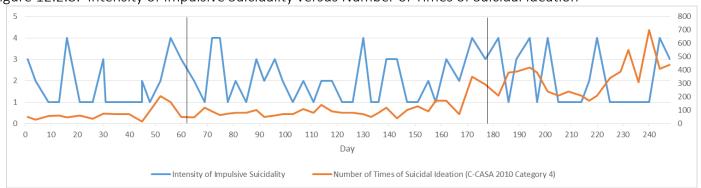
Figure 12.2.7: Intensity of Impulsive Suicidality versus Presence or Absence of Suicidal Ideation



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of suicidal ideation as either 0 = did not occur or 1 = did occur.

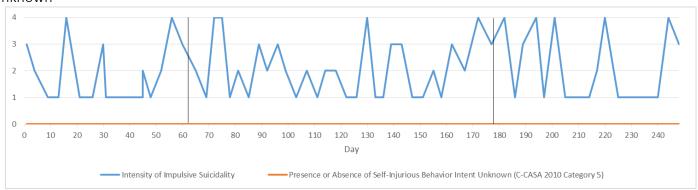
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.8: Intensity of Impulsive Suicidality versus Number of Times of Suicidal Ideation



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The right vertical axis captures the number of times suicidal ideation occurred.

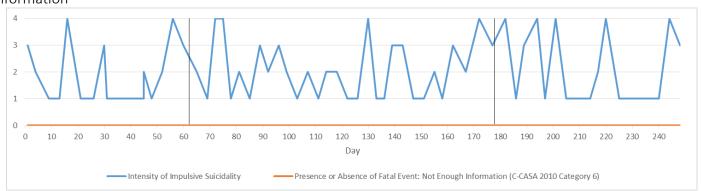
Figure 12.2.9: Intensity of Impulsive Suicidality versus Presence or Absence of Self-Injurious Behavior Intent Unknown



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of self-injurious behavior intent unknown as either 0 = did not occur or 1 = did occur.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

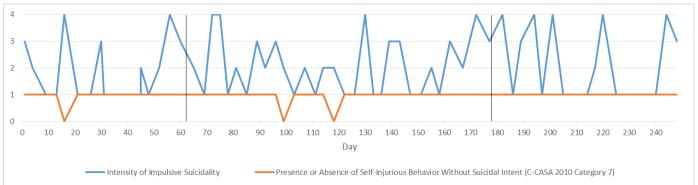
Figure 12.2.10: Intensity of Impulsive Suicidality versus Presence or Absence of Fatal Event: Not Enough Information



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of fatal event: not enough information as either 0 = did not occur or 1 = did occur.

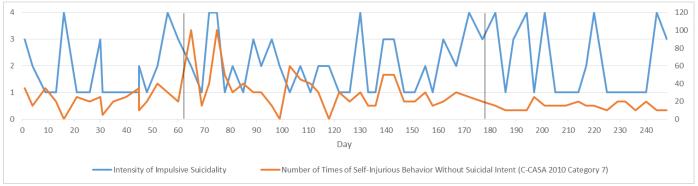
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.11: Intensity of Impulsive Suicidality versus Presence or Absence of Self-Injurious Behavior Without Suicidal Intent



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of self-injurious behavior without suicidal intent as either 0 = did not occur or 1 = did occur.

Figure 12.2.12: Intensity of Impulsive Suicidality versus Number of Times of Self-Injurious Behavior Without Suicidal Intent



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The right vertical axis captures the number of times self-injurious behavior without suicidal intent occurred.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

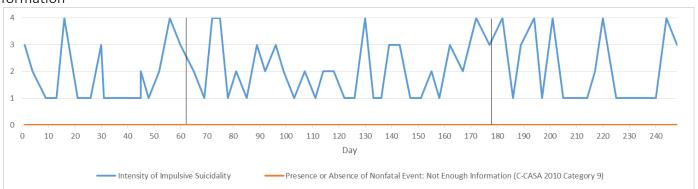
Figure 12.2.13: Intensity of Impulsive Suicidality versus Presence or Absence of Other (Accident, Psychiatric, Medical) (No Deliberate Self-Harm)



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of other (accident, psychiatric, medical) (no deliberate self-harm) as either 0 = did not occur or 1 = did occur.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.14: Intensity of Impulsive Suicidality versus Presence or Absence of Nonfatal Event: Not Enough Information



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of nonfatal event: not enough information as either 0 = did not occur or 1 = did occur.

# Discussion 2

Figures 12.2.3, 12.2.4, 12.2.8, 12.2.9, 12.2.10, 12.2.13, and 12.2.14 show that the presence or absence of events in C-CASA 2010 categories 1, 2, 4, 5, 6, 8, and 9 did not change at any time during the time frame under investigation. These C-CASA 2010 categories captured *no signal* of the *increased frequency* of the up-switches *of impulsive suicidality*.

#### Results 3

Figure 12.2.5 shows more timeframes containing Preparatory Acts Toward Imminent Suicidal Behaviors during the time the subject was not taking citalopram (during 8 timeframes of data collection) compared to the time the subject was taking the citalopram (during 2 timeframes of data collection). Note that on there are 2 distinct timeframes of data collection between days 16 and 21, there are 4 timeframes of data collection between days 189 and 201, and there is one timeframe of data collection for days 45, 139, 147, and 209, for a total of 10 timeframes of data collection with preparatory behaviors. Figure 12.2.6 shows more preparatory behaviors during the time the subject was not taking the citalopram (12 behaviors) compared to the time the subject was on the citalopram (4 behaviors).

## Discussion 3

The subject reported "the preparatory behaviors after stopping the citalopram were a result of being completely exhausted from fighting the impulsivity for so long while taking the citalopram and not having enough time to recover from the more frequent impulsivity during the time on the citalopram." The subject felt that "the [preparatory behaviors] after stopping the citalopram wouldn't have happened if I hadn't been so worn down from impulsive suicidality while on the citalopram that I began to think killing myself was the only way to make the impulsive suicidality stop."

If the subject's reporting is correct that the preparatory behaviors that happened after stopping the citalopram were a result of the increase in frequency of the impulsive suicidality, then it is likely there would have been fewer preparatory behaviors if the subject had not taken the citalopram.

Regulatory agencies could have interpreted the reduced number of preparatory acts towards imminent suicidal behavior on citalopram, compared to the number while not on citalopram, as a positive outcome in favor of citalopram. However from the patient's perspective she felt at *greater suicidal risk* because of the significant increase in up-switches of impulsive suicidality.

# Results 4

Figure 12.2.7 shows that events of suicidal ideation occurred in all of the timeframes of data collection. Figure 12.2.8 shows more events of suicidal ideation after the subject stopped taking the citalogram.

#### Discussion 4

We asked the subject about this increase in suicidal ideation. Her response was "After experiencing the frequent impulsive suicidality for a period of time, I found myself fearing the next event of impulsivity and fearing what the rest of my life would be like if I continued to experience this [impulsive suicidality]. Sometimes I would willfully think about suicide as an escape from my suicidality. I told myself that since current treatments actually made me feel worse and many clinicians didn't even believe that this happened, I might as well kill myself to prevent myself from going through this again. I began to willfully think about and plan for a suicide

attempt around [the end of this data set] and thought about it frequently in hopes of more thoroughly convincing myself that killing myself was my best option."

# Results 5

Figure 12.2.11 shows 1 fewer episode of Self-Injurious Behavior, No Suicidal Intent during the time the subject was taking citalopram (2 timeframes of data collection *without* self-injury) compared to the time the subject was off the citalopram (1 timeframe of data collection *without* self-injury). Figure 12.2.12 shows more events of self-injury without suicidal intent during the time the subject was taking the citalopram (1030 total events) compared to the time the subject was not taking the citalopram (630 total events). In other words, there was a mean of 8.9 events of self-injury each day the subject was taking the citalopram compared to 4.8 events during the days she was not taking the citalopram. This is an increase of 86% in the count of events of self-injurious behavior without suicidal intent while the subject was taking the citalopram.

Because of this significant increase in the events of suicidality, we looked at the seriousness of the non-suicidal self-injury as captured by question 9 of the S-STS. The mean level of seriousness while the subject was *not taking* the citalopram was 1.43 on a 0 to 4 point scale (with a range of 0 to 3). The mean level of seriousness while the subject was *taking* the citalopram was 1.16 (with a range of 0 to 3). This is a reduction in the mean level of seriousness of non-suicidal self-injury of 23% while the subject was taking the citalopram.

# Discussion 5

Although there was a significant increase in the number of events of self-injurious behavior without suicidal intent, there were more timeframes without self-injury and the seriousness of the self-injury were less while the subject was taking citalopram. Since this seemed puzzling, we asked the subject for any insight. She explained, "Just after starting the citalopram I noticed the increased frequency in the impulsive suicidality and used the non-suicidal self-injury to cope with these experiences. I was careful to keep the seriousness of the self-injury at a very mild level to prevent myself from accidently seriously harming myself, which might have been interpreted by a clinician as a suicide attempt. My demoralization escalated after the midpoint of the time I was on the citalopram. The medication that everyone thinks should stop my suicidality was making it worse. At some point towards the end of the course of citalopram I lost hope and decided my only way to make this suicidality stop was to kill myself. I knew the self-injury was providing relief so I made a conscious decision not to self-injure as much or as seriously as I normally would have done in hopes the emotions would build inside me and I would actually succeed in killing myself this time."

Regulatory agencies could have interpreted the reduced number of timeframes of data collection with non-suicidal self-injurious behavior on citalopram (93.5% of timeframes), compared to the number while not on citalopram (97.1% of timeframes), as a positive outcome in favor of citalopram (a 3.8% decrease in timeframes). However, the number of events of self-injury show a significant increase (86%) while the subject was taking the citalopram. If researchers / clinicians / regulatory agencies only focus on the presence or absence of a C-CASA 2010 category and not the number of times it occurs, they are likely to completely miss this significant increase in self-injurious behavior events.

# Results 6

Figures 12.2.3, 12.2.4, 12.2.5, 12.2.7, 12.2.8, 12.2.9, 12.2.10, 12.2.11, 12.2.13, and 12.2.14 do not show a significant increase in the presence or absence of the C-CASA 2010 categories while the subject was taking the citalopram. If anything, it shows a reduction in both preparatory behaviors (Figure 12.2.5) and non-suicidal self-

injury (Figure 12.2.8) while the subject was taking citalopram. Most categories show no change in their presence or absence over the entire timeframe of data collection.

# Discussion 6

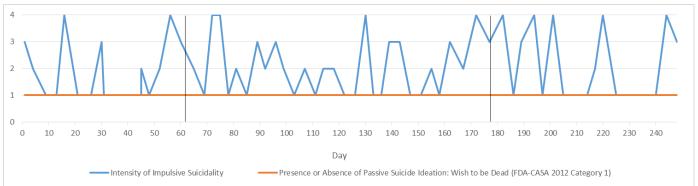
If the presence or absence of a C-CASA 2010 category is used to assess whether any adverse events of suicidality are happening, then the increased frequency of up-switches of impulsive suicidality are *completely missed* by anyone reviewing the data. Even if we look at the number of times these categories occurred, the categories in the C-CASA 2010 *fail to detect* the signal of the increased frequency of up-switches in impulsive suicidality.

# FDA-CASA 2012 Results

## Results 7

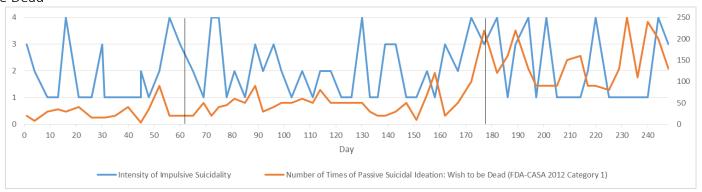
Figures 12.2.15, 12.2.17, 12.2.18, 12.2.19, 12.2.20, 12.2.21, 12.2.22, 12.2.23, 12.2.24, 12.2.25, and 12.2.27 show which of the FDA-CASA 2012 categories occurred (or not), and the intensity scores of impulsive suicidality during the timeframes of data collection. A value of "0" means that category did not occur during the timeframe. A value of "1" means the category did occur during the timeframe. Four FDA-CASA 2012 categories did occur during the timeframe of data collection. One of the categories, FDA-CASA 2012 category 5 (active suicidal ideation: method, intent, and plan), was not compatible with the active suicidal ideation number of times captured by the S-STS. Therefore, no data is available for the number of times that category 5 occurred, even though it was present across the entire period of data collection. Figures 12.2.16, 12.2.26, and 12.2.28 show the number of times each of the other categories occurred.

Figure 12.2.15: Intensity of Impulsive Suicidality versus Presence or Absence of Passive Suicidal Ideation: Wish to be Dead



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of passive suicidal ideation: wish to be dead as either 0 = did not occur or 1 = did occur.

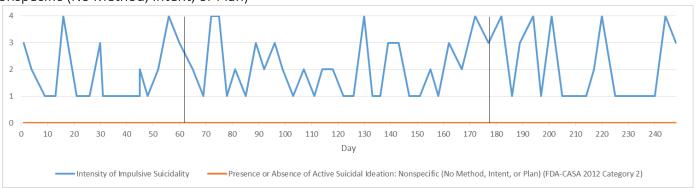
Figure 12.2.16: Intensity of Impulsive Suicidality versus Number of Times of Passive Suicidal Ideation: Wish to be Dead



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The right vertical axis captures the number of times passive suicidal ideation: wish to be dead occurred.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

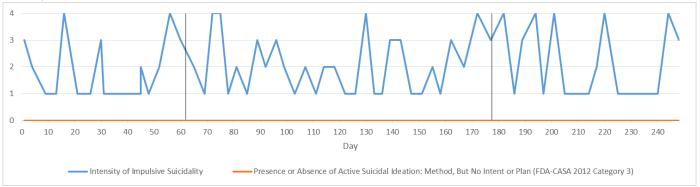
Figure 12.2.17: Intensity of Impulsive Suicidality versus Presence or Absence of Active Suicidal Ideation: Nonspecific (No Method, Intent, or Plan)



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of active suicidal ideation: nonspecific (no method, intent, or plan) as either 0 = did not occur or 1 = did occur.

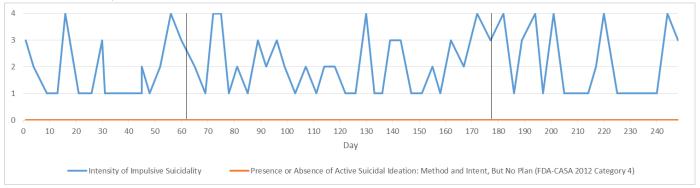
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.18: Intensity of Impulsive Suicidality versus Presence or Absence of Active Suicidal Ideation: Method, But No Intent or Plan



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of active suicidal ideation: method, but no intent or plan as either 0 = did not occur or 1 = did occur.

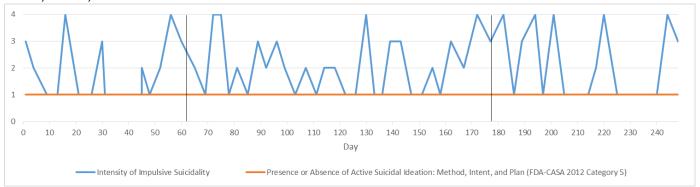
Figure 12.2.19: Intensity of Impulsive Suicidality versus Presence or Absence of Active Suicidal Ideation: Method and Intent. But No Plan



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of active suicidal ideation: method and intent, but no plan as either 0 = did not occur or 1 = did occur.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

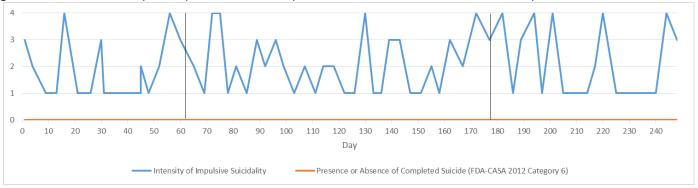
Figure 12.2.20: Intensity of Impulsive Suicidality versus Presence or Absence of Active Suicidal Ideation: Method, Intent, and Plan



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of active suicidal ideation: method, intent, and plan as either 0 = did not occur or 1 = did occur.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.21: Intensity of Impulsive Suicidality versus Presence or Absence of Completed Suicide

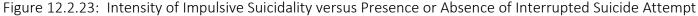


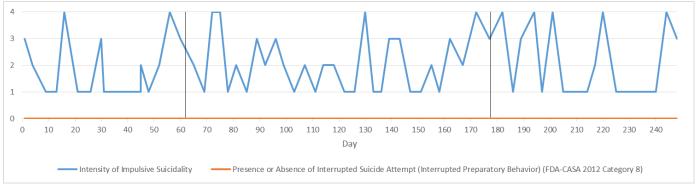
The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of completed suicide as either 0 = did not occur or 1 = did occur. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Day Presence or Absence of Suicide Attempt (FDA-CASA 2012 Category 7) Intensity of Impulsive Suicidality

Figure 12.2.22: Intensity of Impulsive Suicidality versus Presence or Absence of Suicide Attempt

The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of suicide attempt as either 0 = did not occur or 1 = did occur. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

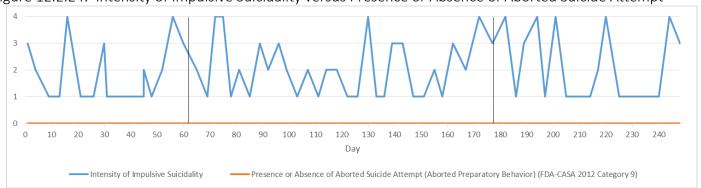




The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of interrupted suicide attempt (interrupted preparatory behavior) as either 0 = did not occur or 1 = did occur.

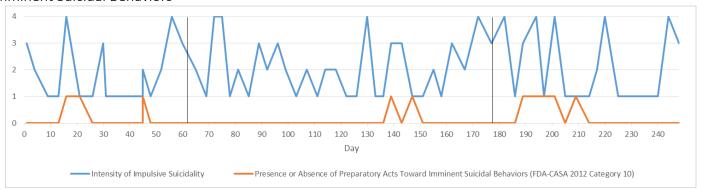
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.24: Intensity of Impulsive Suicidality versus Presence or Absence of Aborted Suicide Attempt



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of aborted suicide attempt (aborted preparatory behavior) as either 0 = did not occur or 1 = did occur.

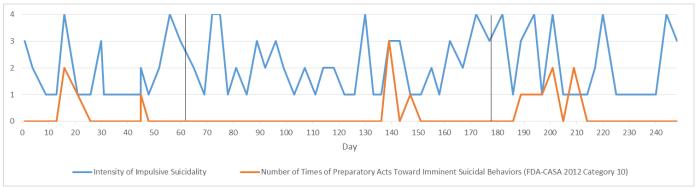
Figure 12.2.25: Intensity of Impulsive Suicidality versus Presence or Absence of Preparatory Acts Toward Imminent Suicidal Behaviors



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of preparatory acts toward imminent suicidal behaviors as either 0 = 0 did not occur or 1 = 0 did occur.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

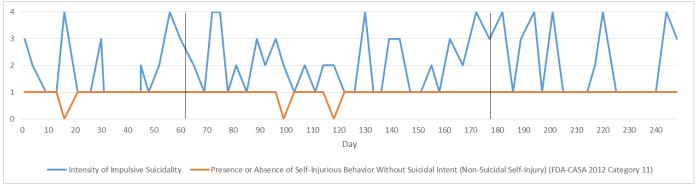
Figure 12.2.26: Intensity of Impulsive Suicidality versus Number of Times of Preparatory Acts Toward Imminent Suicidal Behaviors



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the number of times preparatory acts toward imminent suicidal behaviors occurred.

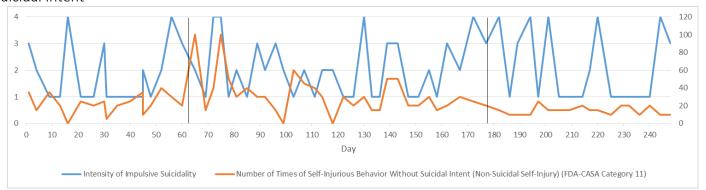
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.2.27: Intensity of Impulsive Suicidality versus Presence or Absence of Self-Injurious Behavior Without Suicidal Intent



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The left vertical axis also captures the presence or absence of self-injurious behavior without suicidal intent (non-suicidal self-injury) as either 0 = did not occur or 1 = did occur.

Figure 12.2.28: Intensity of Impulsive Suicidality versus Number of Times of Self-Injurious Behavior Without Suicidal Intent



The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The right vertical axis captures the number of times self-injurious behavior without suicidal intent (non-suicidal self-injury) occurred.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Discussion 7

Figures 12.2.15, 12.2.17, 12.2.18, 12.2.19, 12.2.20, 12.2.21, 12.2.22, 12.2.23, and 12.2.24 show that the presence or absence of events in FDA-CASA 2012 categories 1, 2, 3, 4, 5, 6, 7, 8, and 9 did not change at any time during the time frame under investigation. These FDA-CASA 2012 categories captured *no signal* of the increased frequency of the up-switches *of impulsive suicidality*. These results are consistent with Results 2 above.

# Results 8

Figure 12.2.16 shows a significant increase in the number of times the subject experienced passive suicidal ideation towards the end of the time she was taking citalogram and in the time after taking the citalogram.

# Discussion 8

The subject explained this increase in passive suicidal ideation as follows: "after I reduced the dose of the citalopram, and while I was off the citalopram, the events of [passive] suicidal ideation seemed to last a shorter period of time than they did earlier while I was taking the citalopram. This allowed more events of passive [suicidal] ideation to occur. Many of these events were passing thoughts that lasted only a few seconds."

The only way to know if there was a net increase or net decrease in this passive suicidal ideation category would be to have a measure of the time spent experiencing passive suicidal ideation. This is possible by documenting each event and the amount of time spent in each event, as is done when using the Tampa - Classification Algorithm for Suicidality Assessment (T-CASA)<sup>25</sup>. The T-CASA was created as a result of this subject's insight into the need to have a more detailed system for collecting event data, in order to investigate if the overall time spent experiencing a phenomenon, such as passive suicidal ideation, changed in response to a treatment.

<sup>&</sup>lt;sup>25</sup> Sheehan, DV and Giddens, JM. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: http://www.HarmResearch.org

# Results 9

Figure 12.2.25 shows more episodes of Preparatory Acts Toward Imminent Suicidal Behaviors during the time the subject was not taking citalopram (during 8 timeframes of data collection) compared to the time the subject was off the citalopram (during 2 timeframes of data collection). Note that on there are 2 distinct timeframes of data collection between days 16 and 21, there are 4 timeframes of data collection between days 189 and 201, and there is one timeframe of data collection for days 45, 139, 147, and 209, for a total of 10 timeframes of data collection with preparatory behaviors. Figure 12.2.26 shows more preparatory behaviors during the time the subject was not taking the citalopram (12 behaviors) compared to the time the subject was on the citalopram (4 behaviors).

# Discussion 9

These results are consistent with results 3 above. This category in the FDA-CASA 2012 is similar to the preparatory behavior category in the C-CASA 2010.

# Results 10

Figure 12.2.26 shows 1 fewer episode of Self-Injurious Behavior Without Suicidal Intent during the time the subject was taking citalopram (2 timeframes of data collection without self-injury), compared to the time the subject was off the citalopram (1 timeframe of data collection without self-injury). Figure 12.2.27 shows more events of self-injury without suicidal intent during the time the subject was taking the citalopram (1030 total events) compared to the time the subject was not taking the citalopram (630 total events). In other words, there was a mean of 8.9 events of self-injury each day the subject was taking the citalopram compared to 4.8 events during the days she was not taking the citalopram. This is an increase of 86% in the count of events of self-injurious behavior without suicidal intent, while the subject was taking the citalopram.

Because of this significant increase in the events of suicidality, we looked at the seriousness of the non-suicidal self-injury, as captured by question 9 of the S-STS. The mean level of seriousness while the subject was not taking the citalopram was 1.43 on a 0 to 4 point scale (with a range of 0 to 3). The mean level of seriousness while the subject was taking the citalopram was 1.16 (with a range of 0 to 3). This is a reduction in the mean level of seriousness of non-suicidal self-injury of 23% while the subject was taking the citalopram.

# Discussion 10

These results are consistent with results 5 above. This category in the FDA-CASA 2012, is the same as the self-injurious behavior without suicidal intent category, in the C-CASA 2010.

# Results 11

Figures 12.2.15, 12.2.17, 12.2.18, 12.2.19, 12.2.20, 12.2.21, 12.2.22, 12.2.23, and 12.2.24 do not show a significant increase in the presence or absence of the C-CASA 2010 categories while the subject was taking the citalopram. It shows a reduction in both preparatory behaviors (Figure 12.2.26) and non-suicidal self-injury (Figure 12.2.28) while the subject was taking the citalopram. Most categories show no change in their presence or absence over the entire timeframe of data collection.

# Discussion 11

If the occurrence of an FDA-CASA 2012 category is used to assess the presence of any adverse events of suicidality, the increased frequency of up-switches of impulsive suicidality are completely missed by anyone reviewing the data. Even if we examine the number of times these categories occurred, the categories in the FDA-CASA 2012 fail to detect the signal of the increased frequency of up-switches in impulsive suicidality.

# Active Suicidal Ideation Number of Times

# Result 12

Figure 12.2.29 shows the number of times any active suicidal ideation occurred and the intensity of impulsive suicidality during the timeframes of data collection. This value is not directly related to any of the C-CASA 2010 or FDA-CASA 2012 categories. However, since we were unable to calculate the number of times the 4 categories of active suicidal ideation in the FDA-CASA 2012 occurred, it seemed prudent to explore the total active suicidal ideation event count, to assess whether this value showed a signal of the up-switches in impulsive suicidality.

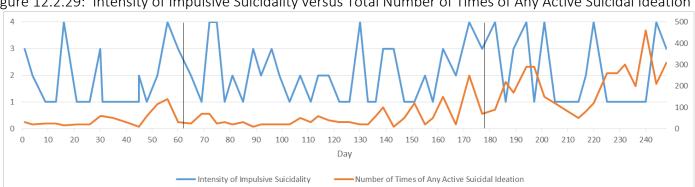


Figure 12.2.29: Intensity of Impulsive Suicidality versus Total Number of Times of Any Active Suicidal Ideation

The left vertical axis captures the intensity of impulsive suicidality on a 0 to 4 intensity rating. The right vertical axis captures the number of times any active suicidal ideation occurred.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Discussion 12

Figure 12.2.29 shows a significant increase in the number of times the subject experienced active suicidal ideation towards the end of the time she took citalogram and after stopping the citalogram.

The subject explained this increase in the total number of times of active suicidal ideation as follows: "there are 2 reasons for this increase. First, the autonomous events of active suicidal ideation lasted for shorter periods of time as I was coming off the citalogram and after stopping the citalogram. Second, there was some level of willfulness on my part, in this active suicidal ideation. The increased frequency of the [up-switches in] impulsive suicidality while taking the citalopram caused me to become more hopeless about my future. As this increased frequency of up-switches in impulsive suicidality persisted, I decided that killing myself was the only way to make the suicidality stop. I had hoped that I would make a suicide attempt [toward the end of the data collection] and I knew that I had to slowly work to convince myself to actually go through with the attempt, otherwise it would be less likely to happen. I would purposely spend time thinking about killing myself as preparation to the planned [suicide] attempt."

# Result 13

Figures 12.2.3 through 12.2.29 show the signal of the increased frequency of the up-switches of impulsive suicidality were not captured by any of these values, by any of these C-CASA 2010 categories, or by any of these FDA-CASA 2012 categories.

#### Discussion 13

In response to the failure of these categories to capture this increased frequency of up-switches of impulsive suicidality, a question was added to the most recent version of the S-STS (see chapters 14.1 and 14.2). Question 11 on this version of the S-STS reads "How seriously did you feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?". Just under this question there are boxes to check if the patient experienced this "sooner rather than later" feeling as 'provoked' and / or 'largely unprovoked' and if the patient felt this as a need to 'kill themself' and / or to 'plan to kill themself'. The language in this question was selected because it is broader than the language used in SMS Impulsivity question 1. The focus of the SMS question was to capture incidents of what we now refer to as Unexpected Suicidal Impulse Attacks (USIAs) (see chapter 6.1 for USIA criteria and chapter 6.2 for an overview of the experience of an USIA). Meanwhile, the use of the phrase "sooner rather than later" in the S-STS question captures a wider range of experiences. The follow-up questions about the presence or absence of provocation provides additional information that may help clarify whether someone is reporting a USIA, or if the impulsive suicidality is the immediate consequence of a triggering life event.

# Results 14

The newest version of the S-STS that contains question 11 quoted above was used by this same subject for tracking for 87 consecutive weeks. Concurrently she tracked the SMS for the same weekly timeframes. Figure 12.2.30 shows the relationship between the *seriousness* of impulsive suicidality (question 11 from the S-STS) and the intensity of the impulsive suicidality (Impulsivity question 1 from the SMS) values. The correlation coefficient for these values is 0.916.

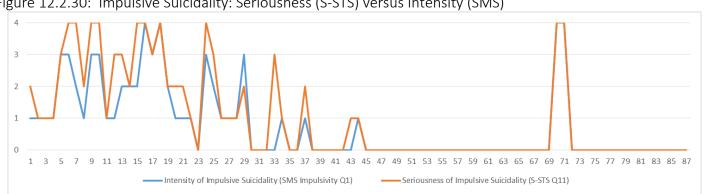


Figure 12.2.30: Impulsive Suicidality: Seriousness (S-STS) versus Intensity (SMS)

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

## Discussion 14

Figure 12.2.30 shows that there was only one occasion (week 29) when the seriousness score for impulsive suicidality (from the S-STS), in orange, was lower than the intensity score for impulsive suicidality (from the SMS), in blue. For all other timeframes of data collection (98.9%) the seriousness score was the same as or higher than the *intensity* score for the impulsive suicidality.

The subject explained as follows: "the [seriousness] question on the S-STS allowed me to capture a wider range of experiences than the [intensity] question on the SMS. In addition, there were times when the impulsive suicidality occurred at a lower intensity, but I rated the seriousness higher because I was less able to cope with the impulsive suicidality during those times. My reduced ability to cope with [the impulsive suicidality] concerned me and made those experiences seem more serious."

#### Limitations

The limitations of this study are that it is a case report on only one subject. The results may not be generalizable to other cases of suicidality. The symptom presentation in this subject met criteria for only one of the suicidality disorders, Impulse Attack Suicidality Disorder (IASD), and these results may not be generalizable to other suicidality disorders.

# **Implications**

The C-CASA 2010 and FDA-CASA 2012 do not capture up-swings in impulsive suicidality with precision in a way that identifies this negative adverse event. As we have previously commented elsewhere <sup>26</sup> <sup>27</sup>, the C-CASA 2010 and the FDA-CASA 2012 (in 2010 and 2012 draft guidance documents, respectively) are insensitive or not sufficiently sensitive in detecting this dangerous treatment emergent suicidality signal. This is a serious type II error in these systems, in that it fails to detect an effect that is present. Using a more sensitive signal detector may pick up this signal of treatment emergent suicidality in smaller sample sizes, at an earlier stage of drug development, with much less expense to drug development, while minimizing risk to patients. This current flaw in the C-CASA 2010 and FDA-CASA 2012 systems need to be rectified urgently.

If a patient taking an SSRI kills themself, how can we legally defend the clinician, the institution, the researcher, or the pharmaceutical company, if they are sued because the classification system they have used to determine if treatment emergent suicidality occurs, does not capture up-swings in impulsive suicidality?

What is an IRB member or a data safety monitoring board member, or a journal article reviewer or a grant reviewer to do if they are aware of these flaws in these classification systems used to monitor treatment emergent suicidality and they have to adjudicate approval for use for funding or for publication? The field of suicidality assessment cannot scientifically move forward until these issues are resolved. How best to do this remains unresolved.

We leave the reader with these unanswered questions and dilemmas. We have a responsibility to our suicidal patients to fix these problems and to resolve these dilemmas because they pose potential threats to public health, to research on the safety of medications, and the search for effective medication treatments for suicidality.

<sup>&</sup>lt;sup>26</sup> Giddens JM, Sheehan KH, Sheehan DV. *The Columbia–Suicide Severity Rating Scale (C-SSRS): Has the "Gold Standard" become a liability?* Innov Clin Neurosci. 2014;11(9–10):66–80. Available from: <a href="http://innovationscns.epubxp.com/i/425963/66">http://innovationscns.epubxp.com/i/425963/66</a>

<sup>&</sup>lt;sup>27</sup> Sheehan DV, Giddens JM, Sheehan KH. *Current assessment and classification of suicidal phenomena using the FDA 2012 Draft Guidance document on suicide assessment: a critical review*. Innov Clin Neurosci. 2014;11(9–10):54–65. Available from: <a href="http://innovationscns.epubxp.com/i/425963/54">http://innovationscns.epubxp.com/i/425963/54</a>

# Conclusion

The data is consistent with the observation that the SSRI citalopram is associated with more frequent upswitches in impulsive suicidality, when compared to timeframes during which the subject was not taking citalopram.

The C-CASA 2010 or FDA-CASA 2012 categories fail to detect such up-switches in impulsive suicidality from citalopram.

It is possible that the increased signal of suicidal ideation and behavior seen in those under the age of 25 may be due, at least in part, from these "up-switches in impulsive suicidality". It is possible that the increased signal of suicidal ideation and behavior previously reported in those under the age of 25 is not restricted to people under the age of 25, but will continue to occur in some vulnerable individuals as they age beyond the age of 25. We need to study larger, more age-diverse samples to understand the extent of this up-switch in impulsive suicidality induction by antidepressants and other medications, using a measure more sensitive in detecting such a signal.

# 12.3

Study of Magnesium in the Treatment of Impulse Attack Suicidality Disorder

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

#### Introduction

Although suicide is the 10<sup>th</sup> leading cause of death in the United States¹ and the 15<sup>th</sup> leading cause of death worldwide², there are no medications approved for the treatment of suicidality with the exception of clozapine which is indicated for "reducing suicidal behavior in patients with schizophrenia or schizoaffective disorder"³. Pharmaceutical companies and academic clinical researchers and institutional review boards have been understandably hesitant to engage in clinical research on anti-suicidality medications. Until recently, it was assumed that suicidality was a natural complication of depression and that treating depression with antidepressants or mood stabilizers would result in a resolution of the suicidality. Unfortunately this is not always the case. Medical research needs to more directly and specifically seek and develop specific anti-suicidality medications even if they have no antidepressant or mood stabilizing properties. Among the few options available used to treat suicidality in clinical practice (clozapine and lithium) and more recently the exploration of ketamine there are no choices available that appear to be relatively safe for long-term use. We offer the case below as another possible inexpensive treatment option that may help some other cases of suicidality and merits more thorough investigation.

Our purpose in developing rating scales that would be capable of sensitively detecting an efficacy signal with an anti-suicidality medication and in developing classifications for suicidality phenomena, suicidality events, and suicidality disorders was to provide instruments that would be much more capable of finding anti-suicidality treatments and in identifying genetic and other biomarkers of suicidality with greater precision.

We adopted a phenomenological approach recommended in the late 19<sup>th</sup> century by Louis Agassiz, a pioneer scientist and mentor of many great scientists at the time. Agassiz stressed to his students the importance of persistent, meticulous observations of natural phenomena over time. He actively discouraged his students from discussing their observations with others, and of consulting any published research or observations by others of the same phenomena over extended periods of time. The purpose of these latter recommendations was to preclude the possibility that the students would be distracted or influenced by the authority of others writings and observations. This practice he cautioned could blind them to relying on the accuracy of their own observations. Only after all of their observations of months or years were complete were they permitted to share these with others and consult other publications about similar biological phenomena. He wanted them to learn that science was in essence the making of very precise observations of natural phenomena and the relationships between these phenomena. He explained that the above strategy coupled with patience on the part of the scientists would

http://www.who.int/mental health/prevention/suicide/suicideprevent/en/

<sup>&</sup>lt;sup>1</sup> Suicide: Facts at a Glance. (2015, September 3). Retrieved September 15, 2015, from http://www.cdc.gov/violenceprevention/pub/suicide\_datasheet.html

<sup>&</sup>lt;sup>2</sup> Suicide data. (n.d.). Retrieved May 15, 2015, from

<sup>&</sup>lt;sup>3</sup> Novartis Pharmaceuticals Corporation. (2014). HIGHLIGHTS OF PRESCRIBING INFORMATION: CLOZARIL® (clozapine) tablets, for oral use. East Hanover, NJ. Retrieved from

maximize the chance of a large body of data telling its own story without the data being molded to adapt to or to confirm or disconfirm any existing theory or prevailing view<sup>4</sup>. We adopted a similar approach in the collection and the organization of the data reported throughout this book and specifically in the collection of observations used to generate the information in the case report below.

# Method

A 29-year-old female subject who experienced suicidality almost daily for over 20 years prospectively collected a self-report data series for 1,163 days (or 166 weeks or 3.19 years). The subject concurrently used both the 10 question (11/11/11) and the 14 question (1/4/14) versions of the Sheehan - Suicidality Tracking Scale (S-STS)<sup>5</sup> on a weekly basis. The week ran from 12:00am (midnight) Monday morning through 11:59:59pm Sunday night. The data for the 10-question version was collected for a total of 166 weeks using the computerized version of the S-STS<sup>7</sup>. The data for the 14-question version of the S-STS was captured in a spreadsheet the subject created. The 14-question version of the S-STS was used for weeks 67 - 166 of data collection (a total of 100 weeks). Both versions of the S-STS use a 0 to 4 (5 point) Likert scale with the following response option anchors: 0 = Not at all, 1 = A little, 2 = Moderately, 3 = Very, 4 = Extremely. Question 11 from the 14-question version of the S-STS asks "How seriously did you feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?".

The subject concurrently tracked the Suicide Plan Tracking Scale (SPTS)<sup>8</sup> on a weekly basis (Monday morning through Sunday night) for weeks 39 - 166 of data collection (a total of 128 weeks) in a spreadsheet she created. The SPTS is a 20-question scale about suicidal planning that uses a 0 to 4 (5-point) Likert scale with three sets of response option anchors. Seventeen questions use 0 = Not at all, 1 = A little, 2 = Partially, 3 = Mostly, and 4 = Totally as descriptive anchors; two questions use 0 = None, 1 = A little, 2 = Partial, 3 = A lot, and 4 = Complete as descriptive anchors; and one question has a No / Yes response option.

The subject concurrently tracked the Tampa - Classification Algorithm for Suicidality Assessment (T-CASA)<sup>9</sup> on a daily basis for days 60 - 1163 of data collection. The time the subject experienced

<sup>&</sup>lt;sup>4</sup> Cooper, Lane (1917). <u>Louis Agassiz as a Teacher: Illustrative Extracts on his Method of Instruction</u>. Ithaca: The Comstock Publishing Company.

<sup>&</sup>lt;sup>5</sup> Sheehan DV, Alphs L, Mao L, et al. *Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 Draft Guidance suicidality categories*. Innov Clin Neurosci. 2014;11(9–10):32–46.

<sup>&</sup>lt;sup>6</sup> Sheehan DV, Giddens JM, Sheehan IS. *Status Update on the Sheehan Suicidality Tracking Scale (S-STS) 2014*. Innov Clin Neurosci. 2014;11(9–10):93–140.

<sup>&</sup>lt;sup>7</sup> Dolphin Electronic Data Capture (eMINI Professional Version 2.1.1 / R131112.1 Database Version 2.26) [Software]. (1994 - 2012). Retrieved from http://medical-outcomes.com/

<sup>&</sup>lt;sup>8</sup> Sheehan, D. V. and Giddens, J. M. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: <a href="http://www.harmresearch.org">http://www.harmresearch.org</a>

<sup>&</sup>lt;sup>9</sup> Sheehan, D. V. and Giddens, J. M. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: <a href="http://www.harmresearch.org">http://www.harmresearch.org</a>

suicidality (time spent) each day was summed. The time spent in suicidality each week was summed for the same weekly timeframes as used for the S-STS and SPTS data collection.

The subject was first diagnosed with Major Depressive Disorder<sup>10</sup> at age 12. At age 16 this diagnosis was changed to Bipolar II Disorder<sup>11</sup>. At age 27 the diagnosis was instead changed to Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS)<sup>12</sup> because many of the symptoms that were used to meet criteria for Bipolar II Disorder were more appropriately attributed to her PDD. The subject meets ICD-10 criteria for Asperger Syndrome<sup>13</sup> and meets criteria for Impulse Attack Suicidality Disorder (IASD)<sup>14</sup>.

The subject was previously treated with 11 different antidepressants, some of them multiple times, using adequate doses and for adequate durations to provide antidepressant effects in most typical cases with Major Depressive Disorder. None of these treatments provided any relief for her symptoms of depression or suicidality. Indeed, she consistently reported with every one of them that they increased her up-switches in impulsive suicidality identical to that described in chapter 12.2. The subject was also treated on 4 occasions. On the last three of three of these occasions she was treated by different experienced psychopharmacologists al of whom monitored her 12 hour trough lithium levels and tracked it in a therapeutic range of 0.8 - 1.2 mEq/L over several months. The lithium provided no relief for her suicidality during any of these trials.

On day 516 the subject began taking 250mg magnesium (Mg) as magnesium oxide on a daily basis to help prevent migraine headaches. The subject saw multiple claims online suggesting magnesium can prevent migraine headaches. She found a study that supported this idea <sup>15</sup>. She found information stating that magnesium oxide is one of the more bioavailable versions of magnesium <sup>16</sup> and decided to purchase some magnesium oxide. The subject found one version of magnesium as magnesium oxide at her local grocery store: Nature Made 250mg Magnesium as magnesium oxide. Please note, that neither the subject nor the authors, have ever received any funding, consulting fees, or income from the manufacturer or sale of the magnesium oxide used in this case, nor from any corporate entity that they know to be directly involved in the

<sup>&</sup>lt;sup>10</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)*. 3rd edition revised. Washington, DC: American Psychiatric Association; 1987.

<sup>&</sup>lt;sup>11</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

<sup>&</sup>lt;sup>12</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

<sup>&</sup>lt;sup>13</sup> World Health Organization. (1992). *ICD-10 Classifications of Mental and Behavioural Disorder: Clinical Descriptions and Diagnostic Guidelines*. Geneva. World Health Organization.

<sup>&</sup>lt;sup>14</sup> Sheehan, D. V. and Giddens, J. M. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: <a href="http://www.harmresearch.org">http://www.harmresearch.org</a>

<sup>&</sup>lt;sup>15</sup> Peikert, A., Wilimzig, C., & Köhne-Volland, R. (1996). Prophylaxis of migraine with oral magnesium: results from a prospective, multi-center, placebo-controlled and double-blind randomized study. *Cephalalgia*, *16*(4), 257-263.

<sup>&</sup>lt;sup>16</sup> Magnesium - Health Professional Fact Sheet. (2013, November 4). National Institutes of Health: Office of Dietary Supplements. Retrieved October 22, 2015, from https://ods.od.nih.gov/factsheets/Magnesium-HealthProfessional/

manufacture or marketing of magnesium oxide or any formulation of magnesium. For consistency, the subject continued to take this version of magnesium throughout the course of data collection.

# Results

Shortly after starting the 250mg daily of magnesium, the second author (DS) noticed a significant change in the subject and began to inquire about the change. The subject and second author reviewed the recent data collection and found the time spent in suicidality had decreased significantly. Since the subject continued to improve, the authors began to investigate the cause of the change. The magnesium was identified as the only change in medication.

After 3 weeks of continued improvement the subject stopped taking the magnesium for 3 weeks to test if the magnesium was the cause of the change. The subject's suicidality increased in these weeks. The time spent in suicidality increased by 59.7% and the 14-question S-STS total score increased by 24%. Report the raw values (means) each. The subject then began the magnesium at 500mg daily (125mg in am + 375mg at dinner).

Figure 12.3.1 shows the change in the S-STS total score for both the 10 and the 14-question scales. The right vertical axis reflects the average daily dose of magnesium in milligrams. In tandem with the increased dose of magnesium, there was a corresponding drop in the total S-STS score over the following weeks. Figure 12.3.2 captures data collected on the 10-question S-STS over the prior 66 weeks, since the subject did not use the 14-question S-STS prior to week 67. The data in Figure 12.3.2 illustrates that the level of suicidality present immediately before starting the magnesium was not a transient flare-up at that time, but had been present at this level of severity over the prior 66 weeks. Indeed, by history, the subject indicated that the suicidality had been present persistently for over 20 years. During those 20 years the subject was only able to identify 8 periods during which she did not experience suicidality on a daily basis. The range of these 8 suicidality-free periods was 3-5 days. The level of severity of suicidality captured in the figures below prior to taking the magnesium reflects the general level of severity of her suicidality over the prior 20 years as best she can recall.



Figure 12.3.1: Change in S-STS vs. Dose of Magnesium



Figure 12.3.2: Change in 10 Question S-STS vs. Dose of Magnesium

The subject kept track of the duration of therapeutic anti-suicidality action of each dose. She reported that each dose appeared to have some anti-suicidality effect lasting 6 - 7.5 hours, after which point she had a significant increase in suicidal ideation. As a result the dose was increased to 250mg in the am + 125mg at lunch + 250mg at dinner. This lunchtime dose attenuated the prior mid-afternoon flare up of suicidal ideation.

However, since the suicidality was still present, especially in the very early am hours, the dinner dose was decreased to 125mg and 125mg was taken at bedtime. This resulted in a further decrease in the early morning suicidality. However, since some suicidality remained, the total daily was increased up to 750mg daily (125mg in the am + 125mg at lunch + 250mg at dinner + 250mg at bedtime). This resulted in yet a further reduction in overall suicidality. The dose was increased to 875mg daily (250mg in the am + 125mg at lunch + 250mg at dinner + 250mg at bedtime). The overall suicidality reduced further, but was still present. The dose was then increased to 1000mg daily (250mg in the am + 250mg at lunch + 250mg at dinner + 250mg at bedtime).

Because of increasing diarrhea, as the dose of magnesium increased, the daily dose of magnesium was then decreased to 500mg daily. We explored various strategies to minimize the diarrhea, none of which were entirely helpful. One of these strategies, the introduction of calcium antacids for both an upset stomach and diarrhea, caused a further worsening of the suicidality. We investigated the effect of various decreases and increases of the magnesium dose on the diarrhea at that stage. Since the reduction and changes in the magnesium dose did not alleviate the diarrhea, the dose was increased back up to 1000mg a day.

At week 107 there was a small spike in suicidality after 4 weeks of being asymptomatic. On investigating this spike, the authors realized that there had been a substantial increase in the subject's consumption of dairy products immediately preceding and during that spike. It was at this juncture that the subject realized that the common denominator of the increased consumption of dairy products and the spike associated with the antacids was the increased intake of calcium. Calcium is known to interfere with the absorption of magnesium in the upper

GI tract, leaving more magnesium in the lumen of the gut in the lower GI tract. They hypothesized that this increased quantity of magnesium in the lower GI tract might have been contributing to the episodes of diarrhea.

To test this hypothesis, they reduced the subject's total daily intake of calcium to 30% of the total recommended daily intake. This resulted in an immediate cessation of the diarrhea and a complete cessation of all suicidality. This combination of 1000mg per day of magnesium distributed as outlined above combined with the reduction of calcium intake daily to 30% of the recommended daily intake ended the diarrhea and maintained the anti-suicidality effect over the next 5.5 months.

On approaching the 6-month mark free of symptoms, the subject wondered if this might be a placebo effect. Although this was the longest period of complete remission of symptoms the subject had in over 20 years, it is entirely possible this was a spontaneous remission that had nothing to do with the magnesium and low calcium diet. To test this hypothesis, the subject decided that she wanted to stop the magnesium while keeping the calcium intake at 30% of the recommended daily intake.

Within 48-hours the second author noticed a significant physical and psychological deterioration, at a level he had not seen since prior to her starting the magnesium. That evening the subject had an unexpected suicidal impulse attack (USIA). Although the second author urged the subject to restart the magnesium immediately, the subject wanted to remain off the magnesium for at least 1 full week to see if this surge in suicidality was merely a transient surge that would settle down of its own accord without having to restart the magnesium.

With each day the suicidality further deteriorated. At the end of a week the subject herself realized that this flare up was a rather serious flare-up of her suicidality and agreed to restart the magnesium immediately. The magnesium was restarted at a dose of 875mg daily for two days and then increased to 1000mg daily distributed as before. On the 4th day the flare up of suicidality gradually subsided. On day 5 she was asymptomatic. On day 10 there was a small transient spike in suicidality, after which all the suicidality cleared completely. She remained on the 1000mg of magnesium daily and the reduced calcium intake for the next 7 months. During that time there was no suicidality at all as measured by the S-STS, the SPTS, or the T-CASA. At the time of this writing the subject remains free of all suicidality.

Figure 12.3.3 summarizes all of the above commentary in graphic form.

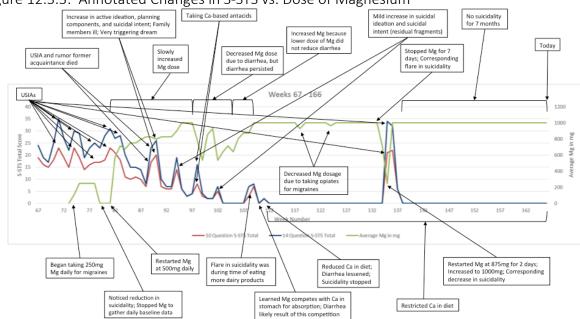


Figure 12.3.3: Annotated Changes in S-STS vs. Dose of Magnesium

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.3.4 shows the change over time in the 14-question S-STS total score, in the total time spent in suicidality, and in the magnesium dose. Figure 12.3.5 shows the change over time in the Suicide Plan Tracking Scale (SPTS) total score and in the magnesium dose. Figure 12.3.6 the change over time in the impulsivity question of the S-STS (question 11) and in the magnesium dose.

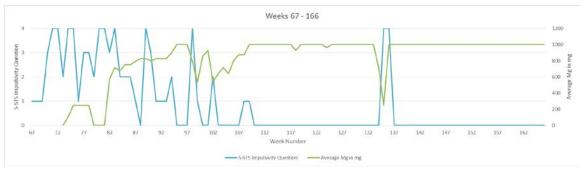




Figure 12.3.5: Change in SPTS vs. Dose of Magnesium



Figure 12.3.6: Change in S-STS Impulsivity Question vs. Dose of Magnesium



Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

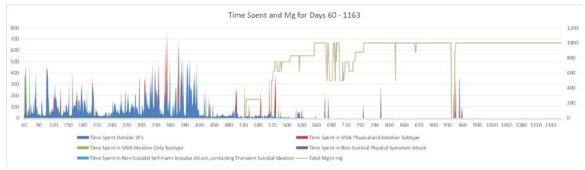
Figures 12.3.1, 12.3.2, 12.3.3, 12.3.4, 12.3.5, and 12.3.6 show that the trajectory of improvement in each of these scale scores was different over time. The 14-question S-STS was more sensitive than the 10-question scale in detecting the seriousness of suicidality. The time spent in suicidality (Figure 12.3.4) illustrates that this measure was the most sensitive in first detecting the efficacy signal. The magnitude of its drop was more rapid and complete than data captured by the other measures. The SPTS took longer to change in a meaningful way than the other outcome measures. The subject commented, "having a suicide plan in place made it easier for me to resist acting upon the impulse to kill myself because my mind was not trying to piece together the parts of a plan. I held onto the previously made plan because I expected my suicidality to return and wanted to be prepared for its return. It was only after the suicidality symptoms were resolved for an extended period that I felt safe enough to deconstruct my prior suicide plan."

Figure 12.3.6 in combination with Figure 12.3.4 shows that while the unexpected suicidal impulse attacks continued intermittently and were serious, they lasted a shorter period of time and were less intense. Figure 12.3.6 shows that when the magnesium was stopped after an asymptomatic 5.5-month timeframe, the unexpected suicidal impulse attacks were extremely severe when they recurred.

At week 61 in Figure 12.3.2 there was a drop in the overall suicidality reflected in the 10-question S-STS total score. On close scrutiny, the subject noticed that the only variable that changed during that time compared to the preceding month was her ingestion of two cups of peppermint tea for nausea. During the immediate timeframe thereafter, she continued to have this small reduction in suicidality. Then she began significantly increasing her consumption of spinach on a daily basis over approximately a month. Two weeks into this month, she increased her intake of peppermint tea from 2 to 6 cups daily because she liked the taste of the tea. After an additional two weeks, she stopped the above routine consumption of the peppermint tea and spinach. Since this reduction in suicidality was out of the ordinary, we wondered why. One explanation is that both peppermint and spinach have high magnesium content. Taken with the subsequent reduction in suicidality when she took the 250mg dose of magnesium for migraine, it is reasonable to hypothesize that her suicidality was magnesium-sensitive.

Figure 12.3.7 graphically displays the data on time spent in suicidality as recorded daily (in contrast to weekly in Figure 12.3.4 above) and the total daily dose of magnesium for days 60 through 1,163. Figures 12.3.8, 12.3.9, 12.3.10, 12.3.11, and 12.3.12 break this data up into displays that permit a closer inspection of each of the 5 timeframes within Figure 12.3.7. Figure 12.3.13 graphically summarizes all of the data from days 60 through 1,163 with annotations.

Figure 12.3.7: Time Spent in Different Subtypes of Suicidality Over Time vs. Pre and Post Magnesium



Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.3.8: Time Spent in Different Subtypes of Suicidality Over Time Pre Magnesium

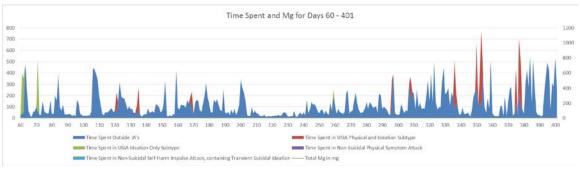


Figure 12.3.9: Time Spent in Different Subtypes of Suicidality Over Time in Early Phase of Increased Magnesium Intake

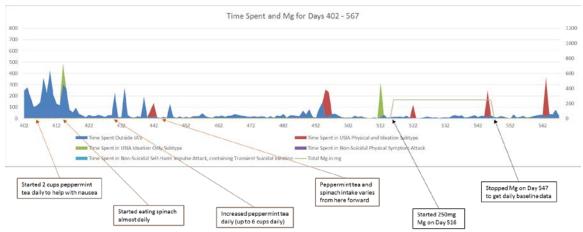


Figure 12.3.10: Time Spent in Different Subtypes of Suicidality Over Time During Escalation of Magnesium Dose

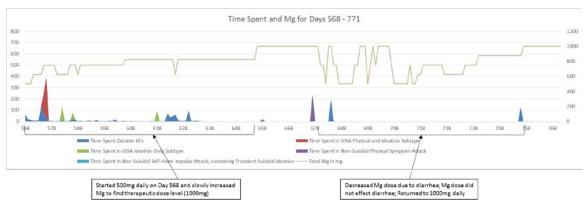


Figure 12.3.11: Time Spent in Different Subtypes of Suicidality Over Time During Optimal Magnesium Dose

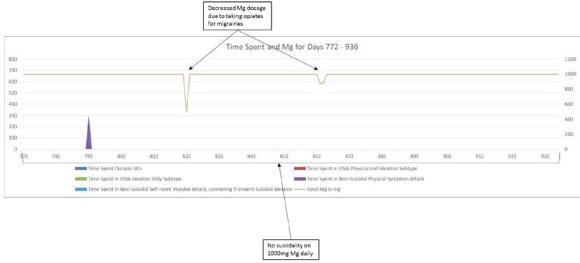
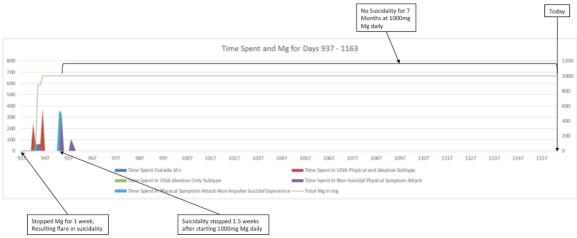


Figure 12.3.12: Time Spent in Different Subtypes of Suicidality Over Time Following Discontinuation and Subsequent Restarting of Magnesium at Optimal Dose



Decreased Mg dosage No Suicidality for 7 Today due to taking opiates for migraines Months at 1000mg Time Spent and Mg for Days 60 - 1163 1200 600 300 400 200 Time Spent in USIA Ideation Only Subty Decreased Mg dose due to diarrhea Started 2 cups peppermint tea daily to help with nause Peppermint tea and Stopped Mg for 1 week Resulting flare in suicid Stopped Mg on Day 547 spinach intake varie from here forward Mg dose did not effect diarrhea; Returned to 1000mg daily Started eating spinach Increased peppermintte daily (up to 6 cups daily) Started 250mg Mg on Day 516 Started 500mg daily on Day 568 and slowly increased No suicidality on Suicidality stopped 1.5 weeks Mg to find therapeutic dose level (1000mg) after starting 1000mg Mg daily

Figure 12.3.13: Annotated Changes in Time Spent vs. Dose of Magnesium

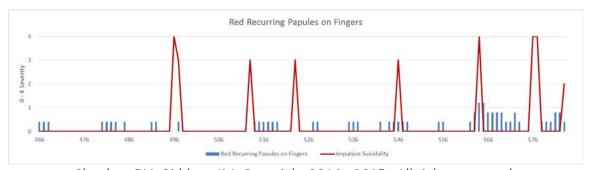
Red Recurring Papule Lesions on Fingers Associated with Unexpected Suicidal Impulse Attacks

During the course of the above data collection the subject reported intermittent outbreaks of red recurring papules on her fingers and hands. Figure 12.3.14 is a photograph of these lesions. These lesions did not occur elsewhere. Careful scrutiny of the data (shown in Figure 12.3.15) revealed that these lesions consistently antedated the acute flare-ups of unexpected suicidal impulse attacks by 30 days (± 4 days). Figure 12.3.16 is a phase adjustment of the data in Figure 12.3.15 generated by moving the USIA data back in time 30 days from when it occurred. This phase shifting of the data most clearly illustrates the consistent coincidence of the outbreaks of the lesions with the onset of unexpected suicidal impulse attacks 30 days later. Figure 12.3.17 is a further extension of the data shown in Figure 12.3.16 showing that even though the eruption of these lesions persisted after the magnesium treatment, that these eruptions were no longer associated with unexpected suicidal impulse attacks. A dermatologist who looked at the photograph of these lesions (Figure 12.3.14) offered a differential diagnosis of dyshydrotic eczema, urticarial, periodic vasculitis, and eryhtmea multiforme and recommended a skin biopsy as the best way to differentiate between these alternatives. The subject was hesitant to have the skin biopsied at this time especially since the flare-ups of these lesions were transient in nature. This association suggests a possible role of either inflammatory or immunological link between the antecedent skin lesions and unexpected suicidal impulse attacks.

Figure 12.3.14: Red Recurring Papule Lesions on Lateral Side of Left Index Finger



Figure 12.3.15: Red Recurring Papule Lesions on Fingers in Relation to Unexpected Suicide Impulse Attacks



Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.3.16: Red Recurring Papule Lesions on Fingers in Relation to Unexpected Suicide Impulse Attacks with Phase Adjustment by 30 Days

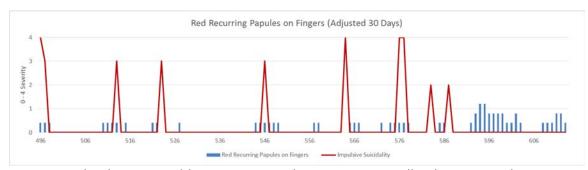
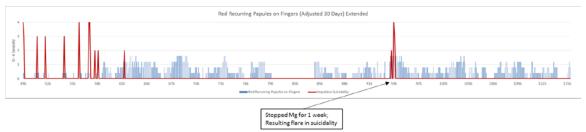


Figure 12.3.17: Red Recurring Papule Lesions on Fingers in Relation to Unexpected Suicide Impulse Attacks with Phase Adjustment by 30 Days Pre and Post Magnesium



#### **Adverse Events**

The escalation in dose of magnesium was associated with an increase in diarrhea when the recommended daily intake went above 500mg a day. As discussed above we subsequently learned that in this subject this was calcium intake dependent. The reduction of calcium intake to 30% or less of the total recommended daily intake provided relief of the diarrhea in doses up to 1000mg per day.

High levels of Vitamin C intake, for example drinking a lot of orange juice, was associated with associated diarrhea. The subject experienced this adverse event. When she stopped drinking the orange juice the diarrhea stopped. In the years prior to using the magnesium for the suicidality she never had diarrhea from the consumption of orange juice. During the time she was taking magnesium for suicidality she was careful to only take orange juice that did not contain calcium. However, in spite of this precaution, diarrhea did occur. We suspect that the increased intake of vitamin C displaced magnesium from the upper to the lower GI tract causing the diarrhea.

The rapidity and magnitude of the suicidality when the magnesium was stopped after an asymptomatic 5.5-month period leave us concerned that a severe rebound in suicidality may occur if the magnesium is abruptly stopped. This merits further investigation. The subject recalled that several years earlier, prior to any of the above data collection, she experienced a similar rebound of suicidality. After 11 ECT treatments administered 3 times weekly with ketamine used as the anesthesia, she responded to treatment. From ECT #11 onwards the ECT was administered at weekly intervals. Four days after ECT #11 she had a 10 days of at least daily unexpected suicidal impulse attacks (USIAs). We note that both ketamine and magnesium are antagonists or modulators at the NMDA receptor complex.

After several months of daily intake of 1000mg of magnesium and a low calcium diet, the subject began to experience more frequent headaches / common migraines. We note that this phase of increased headaches began after a night when the subject ate very little with the dinner dose of magnesium and did not sleep that night. Whether this event was incidental or related to the

subsequent cascade of headaches remains unclear. We recommend that those taking a high magnesium / low calcium intake be monitored closely for headaches in the event that this is an adverse event associated with the chronic use of this regimen.

# Possible Mechanism of Action

The mechanism of action of magnesium in reducing suicidality in the above case is unknown at this time. However, in the chapter on mechanism of action of magnesium (chapter 13) we offer a hypothesis for a mechanism of action that may be associated with this anti-suicidality property. In essence, it is possible that magnesium is exerted its anti-suicidality effect on this subject by modulating the activity of the voltage-gated calcium channel within the NMDA receptor complex.

In addition, magnesium occupies a neighboring position to lithium in the periodic table of the elements. An extensive body of data suggests lithium has anti-suicidality properties<sup>17</sup>. Calcium is also a very close neighbor of both lithium and magnesium in the periodic table of elements (see chapter 13).

Approximately 1 year after first noting the anti-suicidality benefit of magnesium in this subject we found a citation from Eby and Eby<sup>18</sup> which mentioned a case of a subject with bipolar depression whose mood disorder and associated suicidality significantly improved on a high dose of magnesium. This lent further support to our above observations.

Approximately 1 year after first noting the anti-suicidality benefit of magnesium in this subject we found a secondary source that discussed observations made by a French scientist L. Robinet, who found an inverse relationship between suicide rates and the concentration of magnesium in the soil across many regions of France. We have been unable to locate this publication at the time of this writing.

# **Implications**

The above case provides information on dose and dose distribution of magnesium and of the importance of calcium restriction in the management of this subject's Impulse Attack Suicidality Disorder. It suggests that this treatment regimen has an onset of action within days and may be fully effective within one week at the above doses. It further suggests that this benefit was maintained over the following year. When the treatment was stopped abruptly there was an occurrence of suicidality within 2 days and this recurrence persisted and even worsened over the following week of being off of magnesium.

<sup>&</sup>lt;sup>17</sup> Tondo, L., & Baldessarini, R. (2011, February 10). Can Suicide Be Prevented? Retrieved November 9, 2015, from http://www.psychiatrictimes.com/bipolar-disorder/can-suicide-be-prevented

<sup>&</sup>lt;sup>18</sup> Eby, G. A., & Eby, K. L. (2006). Rapid recovery from major depression using magnesium treatment. *Medical hypotheses*, *67*(2), 362-370.

This subject with a specific suicidality disorder (IASD) consistently got an increase in up-switches of suicidality in response to several different antidepressants (as seen in chapter 12.2) and had no anti-suicidality benefit. The same subject did not have any improvement in suicidality from properly ministered clinical trials of lithium of adequate therapeutic doses. Yet she had an impressive therapeutic benefit from the high magnesium / low calcium regimen described above. In light of these facts, this suggests that anti-suicidality treatments need to be investigated one phenotype at a time, rather than using a trans-nosological approach. Expecting that new anti-suicidality medications will provide a trans-nosological benefit for suicidality we think is akin to expecting that an SSRI will be effective for all nosological varieties of depressed mood (i.e. Bipolar Depression, Major Depressive Disorder, Cyclothymia, Cocaine Withdrawal Depression, and depression in Schizoaffective Disorder). The history of psychopharmacology suggests that the chance of early success is higher if the treatments are studied one disorder / phenotype at a time. It is likely that genotyping and the use of other biomarkers in conjunction with the phenotypes described in chapter 6.1 may improve our ability to predict treatment and failure to anti-suicidality medications, just as this approach has been found effective in many other therapeutic areas. Even if an anti-suicidality medication is effective across several suicidality disorders / phenotypes, it is unlikely that any anti-suicidality medication will be effective across all types. For example, we expect that the high magnesium / low calcium regimen described above will be much more likely to be effected in IASD and much less likely to be effective in Life Event Induced Suicidality Disorder.

Magnesium toxicity is traditionally treated with 10-20ml of 10% intravenous solution of calcium gluconate<sup>19</sup>. In chronically suicidal subjects, especially those with Impulse Attack Suicidality Disorder and whose suicidality is magnesium-sensitive, it may be possible to reliably reproduce their unexpected suicidal impulse attacks in safe, controlled settings. This would permit CNS imaging studies and changes in state biomarkers and altered gene expression in such individuals leading to a better understanding of their suicidality disorder. This model is similar to the one used to investigate the pathophysiology of panic disorder using lactate infusions and carbon dioxide. This strategy of course raises troubling ethical issues and would be very controversial, but in theory might address some unanswered questions. Suicidal subjects with whom we have spoken and have been denied access to clinical trials because of their suicidality have stated that they would volunteer for such studies because it would reinforce to them that their condition for which they had been long blamed had in fact a biological basis. However, extraordinary safety measures would need to be in place before such studies could ever be considered. Several suicidal said that this would give them hope that this would lead to a better understanding to the pathophysiology of suicidality and to discovering safe and effective treatments for their suicidality disorder.

Whether magnesium may serve as an augmenting agent or a competing agent for any possible anti-suicidality properties of ketamine, nitrous oxide, lithium, clozapine, antidepressants, atypical

<sup>19</sup> Fassler, C. A., Rodriguez, R. M., Badesch, D. B., Stone, W. J., & Marini, J. J. (1985). Magnesium toxicity as a cause of hypotension and hypoventilation: occurrence in patients with normal renal function. *Archives of internal medicine*, *145*(9), 1604-1606.

antipsychotics, or anticonvulsant mood stabilizers remains unclear at this time, but needs to be investigated further.

It is not known at this time whether magnesium may block the suicidality inducing properties of antidepressants, atypical antipsychotics, or anticonvulsant mood stabilizers especially in those under the age of 25, but this needs to be investigated further.

This subject reported that when she occasionally needed to take an opiate for a severe migraine that the magnesium appeared to augment the therapeutic effect of the opiate and therefore that she could get by with a lower dose of the opiate than she had needed for prior migraines.

This subject also reported that since taking the magnesium that there was significant potentiation of the sedating side effects of diphenhydramine, which she used occasionally for allergies. The basis for this amplification of side effects of both opiates and diphenhydramine merits further investigation.

It is possible, but unknown at this time, if other molecules that bind to the receptor binding site in voltage gated calcium channels of the NMDA receptor complex, medications with magnesium-like effects, medications with a mechanism of action like magnesium, formulations of magnesium other than magnesium oxide, or magnesium delivered via other delivery systems (like controlled release formulations, patch, co-crystal formulations) could provide a similar antisuicidality effect for some subjects. A co-crystal formulation of magnesium should be developed using a similar methodology of composition design to that used for the development of lithium co-crystal formulations<sup>20</sup>, with appropriate modifications adapted for magnesium. However, these possibilities need to be investigated further.

At this time, magnesium alone appears to have no abuse liability, no withdrawal syndrome, no apparent dissociative effects, no psychosis inducing effects, and minimal known adverse events with the possible exception of diarrhea, headache, and rebound of pre-existing suicidality on abrupt cessation of a high dose. If this holds true, even at the higher dose used in the above case, then it may provide a safer therapeutic option for some cases of suicidality than options currently used. However, this needs to be very carefully investigated.

If the above results can be replicated in either Impulse Attack Suicidality Disorder or in another suicidality disorder, then there is a rationale to investigate the possible anti-suicidality efficacy of etoxadrol, dexoxadrol, trichlorophenylmethyliodosalicyl (TCP), memantine, AMPA and Kainate receptor antagonists and the enantiomers of all of these.

We suspect that some cases of "treatment-resistant depression", "treatment-resistant Bipolar Disorder", and "treatment-resistant Borderline Personality Disorder" may have primary suicidality disorders which, when treated by anti-suicidality medications, will result in a

<sup>&</sup>lt;sup>20</sup> Zaworotko, M. J., Shytle, R. D., Ong, T. T., Kavuru, P., Cantwell, R. N., Nguyen, T., & Smith, A. J. (2012). *U.S. Patent Application* 14/007,023.

resolution of the secondary depressions associated with the suicidality disorders outlined in chapter 6.1. Only by investigating the efficacy of the high magnesium / low calcium regimen outlined above in rigorously designed scientific studies can these questions be resolved. Magnesium should also be studied for the treatment of suicidality associated with an Autistic Spectrum Disorder, especially for those who have unexpected suicidal impulse attacks.

There is a widespread belief that all suicidality is merely a complication of psychosocial events. The fact that some medications (i.e. varenicline, reserpine, and antidepressants, anticonvulsants, and atypical antipsychotics) are associated with a worsening of suicidality in some individuals, while other medications (i.e. clozapine, lithium, ketamine, and possibly magnesium) appear to be associated with a reduction in suicidality provides further support for the hypothesis that there may be a biological basis for suicidality.

Personal communication from a psychiatrist colleague in Brazil reports to us that some common surgical procedures, referred to as the vertical banded gastroplasty (VBG) and Roux-en-Y gastric bypass (RGB) by Capella<sup>21</sup> used to treat morbid obesity, Binge Eating Disorder, and Bulimia Nervosa are associated with a significant increased risk of suicidality, mood disorder, and mood instability post operatively. In most of the patient he saw the patients never had such severe suicidality or mood disturbance prior to this surgery. The relationship between these procedures and magnesium malabsorption and consequent magnesium deficiency needs to be investigated and closely monitored by regulatory agencies.

# Limitations

The limitations of this study are that it is a case report on only one subject. The results may not be generalizable to other cases of suicidality. The symptom presentation in this subject met criteria for only one of the suicidality disorders, Impulse Attack Suicidality Disorder (IASD), and these results may not be generalizable to other suicidality disorders.

Please note that the high magnesium / low calcium regimen described above is not approved by the United States Food and Drug Administration, nor by the European Medicines Agency, nor by the regulatory agency of Australia and New Zealand. Before such a treatment regimen can be recommended it must undergo proper regulatory scrutiny to investigate its safety and efficacy in a scientifically rigorous manner.

# Conclusion

The above case suggests that magnesium oxide in doses between 500mg and 1000mg per day in divided doses coupled with a restricted intake of calcium (<30% of recommended daily intake) may be worthy of further exploration as an anti-suicidality treatment regimen for some suicidal individuals.

<sup>21</sup> Capella, J. F., & Capella, R. F. (2002). An assessment of vertical banded gastroplasty-Roux-en-Y gastric bypass for the treatment of morbid obesity. *The American journal of surgery, 183*(2), 117-123.

# 12.4

Analysis of A Dataset Collected Using the Tampa - Classification Algorithm for Suicidality Assessment (T-CASA): A Case Study

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

# Introduction

For regulatory agencies and data safety monitoring boards to discharge their responsibilities in clinical trials for the purpose of monitoring suicidality, it is necessary to have an adequate and precise classification system and collection method for suicidality events. The C-CASA¹ and by extension the FDA-CASA 2012² appear to have generated a classification system of suicidal phenomena that attempted at the same time to both classify the phenomena and to classify and count events made up of various collections of these phenomena. As we see it, attempting to address both the classification of events and the classification of phenomena that make up the events into a single system and to permit data to be collected in a timely way using this system were in conflict with each other. Inevitably this led to the use of a Guttman Scaling or "staircase" model in the interest of data collection efficiency. Unfortunately, it also led to both type I and type II errors and deviated from standards recommended by the United Nations' *Best Practice Guidelines for Developing International Statistical Classifications*³.

In an attempt to rectify the situation and to collect data in a systematic and time efficient manner on events of suicidality we explored several alternative methods. The approach that lent itself best as a trade off between time efficiency of data collection and very precise data collection on the events themselves is reflected in the Tampa-Classification Algorithm for Suicidality Assessment (T-CASA) system.

Unlike the FDA-CASA 2012 and the C-CASA, the T-CASA uses a true algorithmic approach. The T-CASA system uses a series of variables to collect details on suicidality events. The data from this system may be best analyzed using neural networking, which may allow non-linear, dynamic analysis of the data and thereby reflect reality more accurately. However, there are other ways to analyze data collected using the T-CASA.

# How to Analyze T-CASA Data

Analyze the active treatment group and the placebo treatment and / or the treatment as usual (TAU) / standard of care (SOC) group separately in the following manner. Compare the patterns in each of these treatment groups with each other.

This works best if the following analysis is run by each separate suicidality disorder (phenotype) and / or by each one of the separate genetic markers (genotype) for suicidality and / or by each one of the separate biomarkers for suicidality, at a time. If one of these groups shows a signal or pattern of worsening or improvement, the follow up analysis should investigate subsets within each of these where this effect is greatest or least.

1. When the dataset is separated based upon treatment arm and / or phenotype / genotype / biomarker, at least 4 of the columns in the T-CASA *must* be analyzed. These columns are column 1 (Hierarchy of Experiences), column 3 (Willfulness), column 5 (Action Event), and column 6 (Associated With). All of the data must be sorted for each category in each of these columns, which totals 55 unique categories that must be reviewed.

<sup>&</sup>lt;sup>1</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, *164*(7), 1035-1043.

<sup>&</sup>lt;sup>2</sup> United States Food and Drug Administration, United States Department of Health and Human Services. Guidance for Industry: Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance. [October 1, 2014]. <a href="http://www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf">http://www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf</a> August 2012. Revision 1.

<sup>&</sup>lt;sup>3</sup> United Nations. *Best Practice Guidelines for Developing International Statistical Classifications*. UN Department of Economic and Social Affairs Statistics Division. Report from Expert Group Meeting on International Statistical Classifications. New York, NY: May 13–15, 2013.

- 2. When sorted, the event count and the time spent each day in each of these categories are plotted, each on their own line chart. This results in a total of 110 plots.
- 3. When plotted, inspect the data for each of these plots to determine if the pattern shows a worsening, an improvement, or no change. Determine if the pattern of the data shows phenomena emerging later, at an increased frequency or duration than was present earlier in treatment. Determine if there is any pattern in the data of the plot that raises concern.
  - A. Add a trendline to each plot.
  - B. Add an R<sup>2</sup> value to each plot.
  - C. Find the best fit for each trendline to the data.
  - D. Use the R<sup>2</sup> value as a guide to finding the trendline that best fits the data and accommodates the greatest amount of variance of the data set.
  - E. If the best fit is a polynomial trendline change the order to find the minimum order that accommodates the maximum  $R^2$  value.
- 4. If the pattern of data shows any worsening, improvement, or no change, <u>or</u> it shows any phenomena emerging later at an increased frequency or duration than was present earlier in treatment <u>or</u> it shows anything that raises concern <u>or</u> if the trendline is moving up instead of down (showing an increase in suicidality), clinicians at the sites must investigate the causes of these changes. (An overall sample is not likely to change in response to life events [except in the case of multifamily tragedies such as a tsunami or terrorist event], but this must be investigated to determine if such events are the cause of the increase in suicidality or if this is more likely explained by the study medication or for those on placebo, a lack of active treatment.)
- 5. The pattern of change in each plot in the treatment group must then be compared to the pattern of change in the placebo / TAU / SOC group to determine if there is a difference in suicidality experienced by either of these groups. If any of the changes listed in 4 above are noticed, then clinicians at the sites must investigate the causes of these changes.

# Additional Analysis

You can perform additional levels of granular analysis using the above methodology down to the individual or to any small subgroup level. Such individual granular analysis can be done if a subject reports a change in their suicidality in response to treatment. If a subject reports treatment emergent suicidality, but has difficulty identifying which suicidality phenomenon or phenomena changed, a clinician can use the T-CASA to identify which categories changed in response to treatment.

# Methods

Using the above methodology we analyzed a database of 23,840 suicidality events to uncover patterns in a chronically suicidal subject over 635 days (1.74 years). Part way through this process the subject started on a high magnesium oxide / low calcium dietary intake regimen. The analysis that follows investigates a timeframe during which the subject was suicidal on a daily basis, followed by an intermediary phase during which the optimal dose / dose distribution / calcium intake was tested, followed by an extended period without any suicidality. The dataset reflects a shift from very severe, persistent, chronic suicidality all the way through an extended asymptomatic phase. There are potentially 132 plots of data available. In the interest of clarity and space, we report the findings using plots that best illustrate the manner in which the T-CASA data can be used to identify interesting patterns in event data analysis.

# Results

To put the later figures in context, the first figure shows the overall amount of time the subject spent experiencing suicidality during the entire time of data collection. Figure 12.4.1 shows the total number of minutes the subject experienced suicidality each day. At the beginning of data collection the subject was suicidal on a daily basis. There is an intermediate phase during which the optimal dose / dose distribution / calcium intake was tested. The final phase is an extended period without any suicidality.

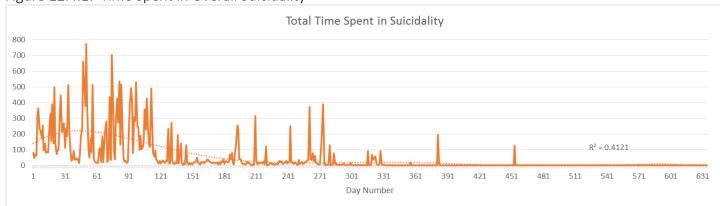


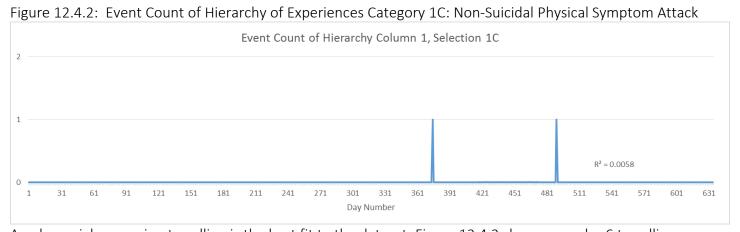
Figure 12.4.1: Time Spent in Overall Suicidality

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.1 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Does the pattern of data in any of the plots show any worsening?

#### Results 1

Figure 12.4.2 illustrates the number of times (event count) the subject experienced a Hierarchy of Experiences Category 1C: Non-Suicidal Physical Symptom Attack (NSPSA). Figure 12.4.3 illustrates the amount of time in minutes (time spent) the subject experienced Hierarchy of Experiences Category 1C: Non-Suicidal Physical Symptom Attack.



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.2 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Time Spent in Hierarchy Column 1, Selection 1C 400 350 250 150 100  $R^2 = 0.0061$ 50 271 331 421 451 Day Number

Figure 12.4.3: Time Spent in Hierarchy of Experiences Category 1C: Non-Suicidal Physical Symptom Attack

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.3 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

# Discussion 1

On days 375 and 490 the subject experienced an NSPSA (Figures 12.4.2 and 12.4.3). This phenomena was not experienced at any earlier point in data collection. The subject reported never previously experiencing an NSPSA in her lifetime. The subject reported the NSPSA experience was very similar to the USIA experience, but without the suicidal ideation and suicidal urge components. Because of the timing of this event in comparison to the USIA experiences in the following Figures 12.4.6 and 12.4.7, and due to the similarity of this experience to a USIA, we believe this is a further devolution of the USIA which presents without the suicidality phenomena. While this experience seems to be emerging in response to treatment, it appears to be a step on the road to recovery.

#### Results 2

Figure 12.4.4 illustrates the number of times the subject experienced an Action Event Category 6%: Completed Suicide (6) in the Medium Entertained (%). Figure 12.4.5 illustrates the amount of time in minutes the subject experienced Action Event Category 6%: Completed Suicide in the Medium Entertained.

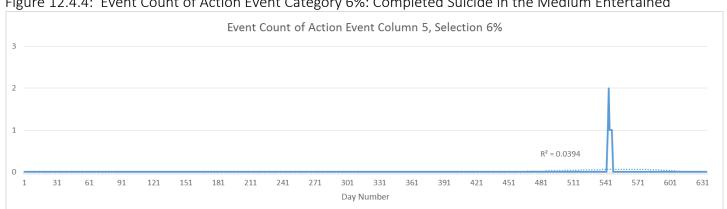


Figure 12.4.4: Event Count of Action Event Category 6%: Completed Suicide in the Medium Entertained

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.4 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Time Spent in Action Event Column 5, Selection 6%

150

100

R<sup>2</sup> = 0.0378

1 31 61 91 121 151 181 211 241 271 301 331 361 391 421 451 481 511 541 571 601 631

Day Number

Figure 12.4.5: Time Spent in Action Event Category 6%: Completed Suicide in the Medium Entertained

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.5 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

# Discussion 2

Figures 12.4.5 and 12.4.6 show an increase in Completed Suicide in the Medium Entertained. This relates to Hierarchy of Experiences Category 12: Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die (see following Figures 12.4.18 and 12.4.19). The subject reported this experience as, "I was watching TV and found myself hoping that a character would respond to a triggering life event by attempting to kill themself. When the subject of that TV show did not try to kill themself, I found an old episode of another TV show where a subject did kill themself and I watched that TV show. I found myself experiencing this interest in watching someone kill themself in a TV show or movie 1 to 3 hours each night for 4 consecutive days." She experienced this phenomenon on days 544 to 547. We asked the subject if something triggered this experience. She did not immediately identify a trigger, but did look through her notes and found she had been eating an increased amount of calcium in her diet 6 out of 7 days a week during the 2.5 weeks prior to her experiencing this phenomenon. It is possible the increased calcium intake precluded her body from absorbing the usual amounts of magnesium, which resulted in this increased interest in suicidal content in the media and desire for the suicidal subject to die.

In all plots where there is an increase in suicidality phenomena, it is prudent to explore the cause of the increase. There may be logical reasons for the increase in suicidality in some subjects, similar to the explanations above as many subjects have learned to attribute their suicidality to something in order to find an explanation for their experiences. There may not be any logical reasons for the increase in suicidality.

Does the pattern of data in any of the plots show any improvement?

# Results 3

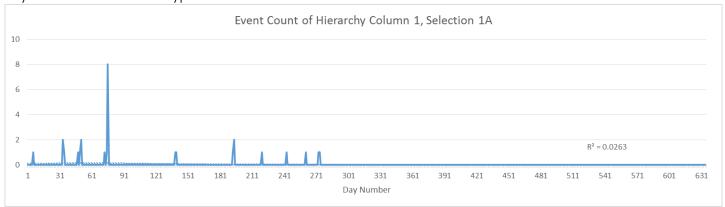
Figure 12.4.6 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 1A: Unexpected Suicidal Impulse Attack (USIA) Physical and Ideation Subtype. Figure 12.4.7 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 1A: Unexpected Suicidal Impulse Attack (USIA) Physical and Ideation Subtype.

Figure 12.4.8 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 13: Suicidal Experience Not Classified Above. Figure 12.4.9 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 13: Suicidal Experience Not Classified Above.

Figure 12.4.10 illustrates the number of times the subject experienced an Action Event Category 1#: Suicidal Ideation and / or Urge (1) in Reality (#). Figure 12.4.11 illustrates the amount of time in minutes the subject experienced Action Event Category 1#: Suicidal Ideation and / or Urge.

Figure 12.4.12 illustrates the number of times the subject experienced an Associated With Category G: Intent to Die in the Future. Figure 12.4.13 illustrates the amount of time in minutes the subject experienced Associated With Category G: Intent to Die in the Future.

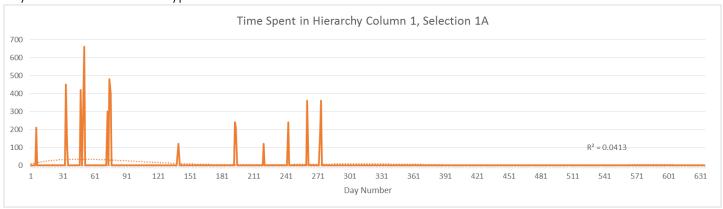
Figure 12.4.6: Event Count of Hierarchy of Experiences Category 1A: Unexpected Suicidal Impulse Attack (USIA) Physical and Ideation Subtype



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.6 shows an order 6 trendline.

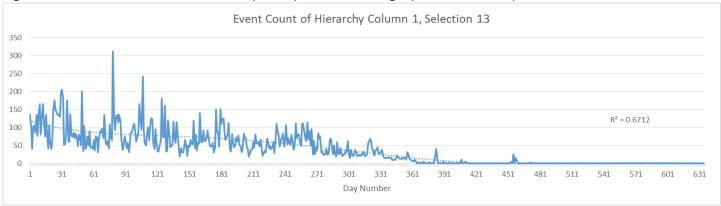
Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.7: Time Spent in Hierarchy of Experiences Category 1A: Unexpected Suicidal Impulse Attack (USIA) Physical and Ideation Subtype



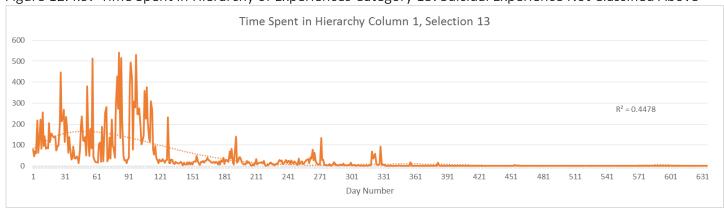
A polynomial regression trendline is the best fit to the dataset: Figure 12.4.7 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.8: Event Count of Hierarchy of Experiences Category 13: Suicidal Experience Not Classified Above



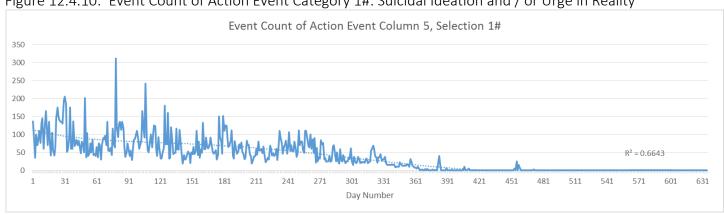
A polynomial regression trendline is the best fit to the dataset: Figure 12.4.8 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.9: Time Spent in Hierarchy of Experiences Category 13: Suicidal Experience Not Classified Above



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.9 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.10: Event Count of Action Event Category 1#: Suicidal Ideation and / or Urge in Reality



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.10 shows an order 5 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.11: Time Spent in Action Event Category 1#: Suicidal Ideation and / or Urge in Reality

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.11 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

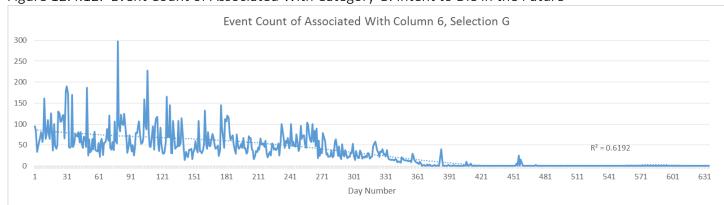


Figure 12.4.12: Event Count of Associated With Category G: Intent to Die in the Future

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.12 shows an order 5 trendline.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

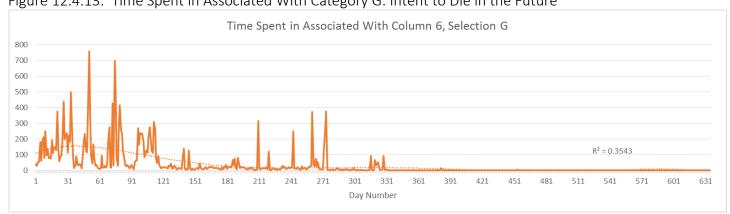


Figure 12.4.13: Time Spent in Associated With Category G: Intent to Die in the Future

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.13 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Discussion 3

An inspection of Figures 12.4.6, 12.4.7, 12.4.8, 12.4.9, 12.4.10, 12.4.11, and 12.4.12 clearly shows a decrease in each of these suicidal phenomena in response to treatment. The USIA Physical and Ideation Subtype (Figures 12.4.6 and 12.4.7) ceased before any of these other phenomena. This is likely because 3 of these phenomena were experienced in the same event. The subject reported "for a long time after many of the other symptoms subsided, I still experienced the intent to die in the future. I expected the reduction in overall suicidality to be a

short-term change. I kept thinking that I could always kill myself in the future when my suicidality became more severe again. It took a number of months for me to believe the reduction in my suicidality symptoms would last. Only then could I stop intending to kill myself at some point in the future." This type of event was coded as Suicidal Experience Not Classified Above (Hierarchy of Experiences Category 13 [Figures 12.4.8 and 12.4.9]), as a Suicidal Ideation and / or Urge in Reality (Action Event Category 1# [Figures 12.4.10 and 12.4.11]), and as the Intent to Die in the Future (Associated With Category G [Figures 12.4.12 and 12.4.13]). All of these coded categories occurred in the same event. The different coded categories allow us to simply investigate several different aspects of the same event.

Does the pattern of data in any of the plots show no change?

# Results 4

Figure 12.4.14 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 2: Hallucination Leading to Suicidality. Figure 12.4.15 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 2: Hallucination Leading to Suicidality.

Figure 12.4.16 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 3: Delusion Leading to Suicidality. Figure 12.4.17 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 3: Delusion Leading to Suicidality.

Event Count of Hierarchy Column 1, Selection 2  $R^2 = \#N/A$ 121 391 Day Number

Figure 12.4.14: Event Count of Hierarchy of Experiences Category 2: Hallucination Leading to Suicidality

A trendline cannot be created for this category because this category did not occur at all during data collection. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

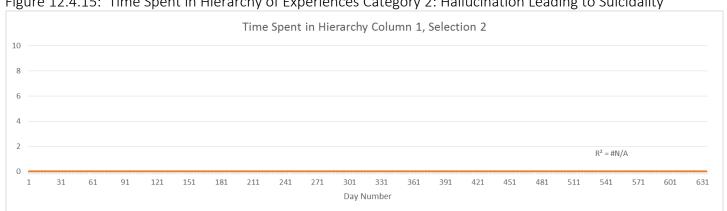
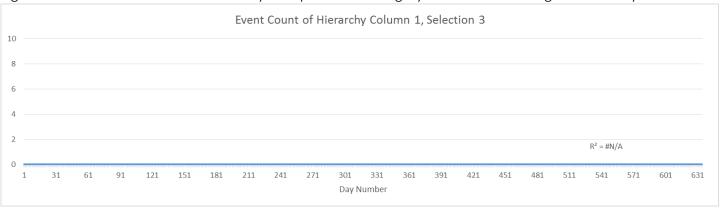


Figure 12.4.15: Time Spent in Hierarchy of Experiences Category 2: Hallucination Leading to Suicidality

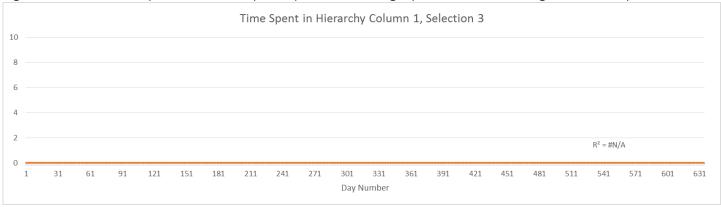
A trendline cannot be created for this category because this category did not occur at all during data collection. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.16: Event Count of Hierarchy of Experiences Category 3: Delusion Leading to Suicidality



A trendline cannot be created for this category because this category did not occur at all during data collection. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.17: Time Spent in Hierarchy of Experiences Category 3: Delusion Leading to Suicidality



A trendline cannot be created for this category because this category did not occur at all during data collection.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Discussion 4

There was no change in the subject's experience of a hallucination leading to suicidality (Figures 12.4.14 and 12.4.15) because the subject did not experience this phenomena at any point during data collection. Similarly, the subject did not experience a delusion leading to suicidality (Figures 12.4.16 and 12.4.17). The figures for both of these categories do not show any change in response to treatment.

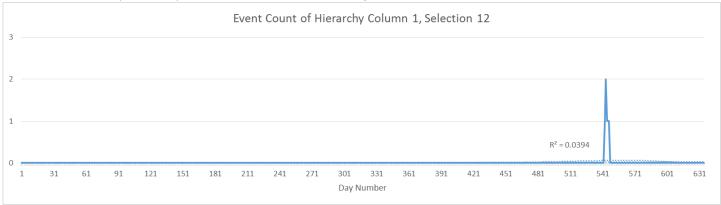
A treatment may be effective in reducing **some** suicidality phenomena, *but not all* suicidality phenomena. For example, if a subject regularly had (command) hallucinations leading to suicidality, and also had concurrent suicidality related to a life event, an antipsychotic medication may treat the command hallucinations leading to suicidality, while having no effect on the other life event related suicidality.

Does the pattern of data in any of the plots show any phenomena emerging at an increased frequency than was present earlier in treatment?

# Results 5

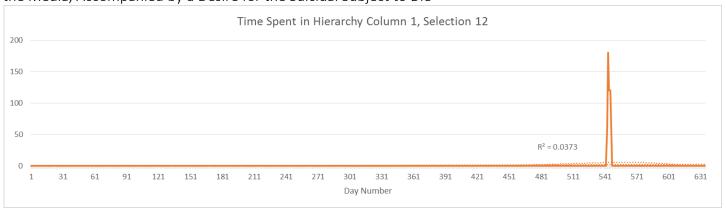
Figure 12.4.18 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 12: Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die. Figure 12.4.19 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 12: Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die.

Figure 12.4.18: Event Count of Hierarchy of Experiences Category 12: Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.18 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Figure 12.4.19: Time Spent in Hierarchy of Experiences Category 12: Increased Interest in Suicidal Content in the Media, Accompanied by a Desire for the Suicidal Subject to Die



A polynomial regression trendline is the best fit to the dataset: Figure 12.4.19 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

## Discussion 5

Figures 12.4.18 and 12.4.19 show a treatment emergent increased interest in suicidal content in the media, accompanied by a desire for the suicidal subject to die. This is consistent with Results 2 and Discussion 2 (Figures 12.4.5 and 12.4.6) above.

It is prudent to review all of the categories, even in subjects who have never experienced a particular phenomenon, because they could experience a never-before-experienced suicidal phenomenon in response to treatment. For example, the subject of this case study had a treatment emergent hallucination leading to suicidality, shortly after taking one dose of Lexapro for the first time as a teen. She never had a hallucination prior to that episode. However, two hours after taking a dose, "a knife suddenly appeared in front of me as I was driving on a busy road. I immediately felt the urge to use that knife to kill myself. When I reached for the knife and found it wasn't there, I immediately thought about turning my car into oncoming traffic." This experience is an example of a treatment emergent hallucination leading to suicidality that can be detected using the T-CASA.

## Results 6

Figure 12.4.20 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 11: Suicidality Related to a Life Event. Figure 12.4.21 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 11: Suicidality Related to a Life Event.

Event Count of Hierarchy Column 1, Selection 11

R<sup>2</sup> = 0.0094

Day Number

Figure 12.4.20: Event Count of Hierarchy of Experiences Category 11: Suicidality Related to a Life Event

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.20 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

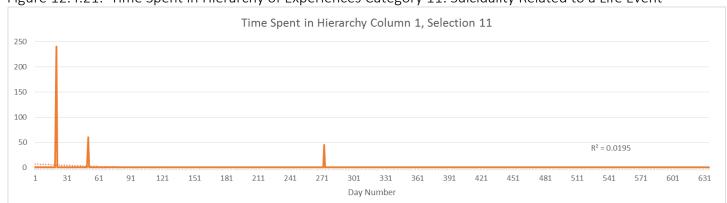


Figure 12.4.21: Time Spent in Hierarchy of Experiences Category 11: Suicidality Related to a Life Event

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.21 shows an order 6 trendline.

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

### Discussion 6

Figures 12.4.20 and 12.4.21 show an increase in event count of suicidality related to a life event. Although this value was only one event count higher than the prior highest count of events of suicidality related to a life event, it was still a 50% increase from the highest count of this type of event the subject had experienced in the timeframe of data collection. To investigate the cause of this increase, we asked the subject is anything in particular had happened on day 273. She reviewed her notes, "I made a mistake on a project I had been working on for months and almost lost the entire project. There were 3 *episodes* during the day where I became overwhelmed at the thought of losing all of that work and began to think about killing myself due to my carelessness. During the second *episode*, a family member needing first aid after accidently cutting themself interrupted me. The third *episode* occurred shortly after the family situation had resolved."

Does the pattern of data in any of the plots show any phenomena emerging at an increased duration than was present earlier in treatment?

#### Results 7

Figures 12.4.2 and 12.4.3 above show that the NSPSA experience emerged after the subject began to take the magnesium oxide and low calcium diet.

#### Discussion 7

Figure 12.4.3 shows the increase in time spent experiencing an NSPSA after the subject's suicidality had responded to treatment. This emergence is explained above in Results 1 and Discussion 1 above.

Does the pattern of data in any of the plots show anything that raises concern?

#### Results 8

Figure 12.4.22 illustrates the number of times the subject experienced a Hierarchy of Experiences Category 4: Dream of Suicidality. Figure 12.4.23 illustrates the amount of time in minutes the subject experienced Hierarchy of Experiences Category 4: Dream of Suicidality.

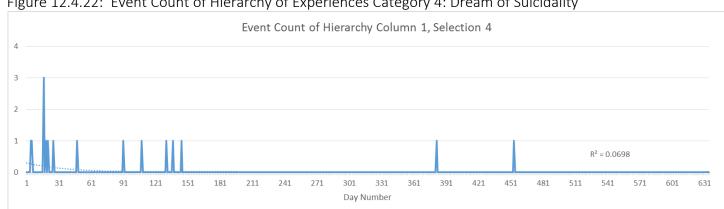


Figure 12.4.22: Event Count of Hierarchy of Experiences Category 4: Dream of Suicidality

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.22 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

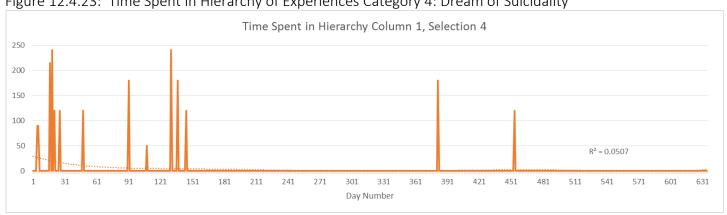


Figure 12.4.23: Time Spent in Hierarchy of Experiences Category 4: Dream of Suicidality

A polynomial regression trendline is the best fit to the dataset: Figure 12.4.23 shows an order 6 trendline. Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Discussion 8

Figures 12.4.22 and 12.4.23 show the re-emergence of suicidal dreams on Day 382 after more than 200 days without any suicidal dreams. The re-emergence of these suicidal dreams should be a concern to any clinician seeing this at the time, or to anyone later reviewing the data. When the subject was asked about this reemergence of suicidal dreams she said "I was still experiencing the diarrhea from the magnesium at this point. This was prior to understanding the need to limit the calcium intake. I had stopped taking the Vitamin B12 completely to test if it was the cause of the diarrhea. I'm a vegetarian and get very little B12 in my diet. Unfortunately the lack of B12 probably interfered with my ability to absorb the magnesium. The lower level of magnesium may have resulted in this increase in suicidality."

#### Results 9

Figures 12.4.18 and 12.4.19 above show a treatment emergent suicidal phenomenon - increased interest in suicidal content in the media, accompanied by a desire for the suicidal subject to die.

## Discussion 9

The emergence of any new suicidal phenomenon is always a concern. Although the explanation in Results 5 and Discussion 5 above appears to explain this suicidality, prudence would recommend heightened monitoring for suicidality after these events.

Is the trendline for any of the plots moving up instead of down?

#### Results 10

The trendline for Figures 12.4.4 and 12.4.5 above are moving up instead of down due to the treatment emergent NSPSA.

#### Discussion 10

The emergence of this new suicidal phenomenon warranted further investigation. In the case of suicidal phenomena this is usually a cause for increased concern. However, in this instance when the subject provided an explanation for the phenomenon it appeared to reflect a transitional phenomenon / devolution of suicidality on the path to recovery rather than the opposite (as described in Results 1 and Discussion 1 above).

## **Implications**

The current system for classification for suicidal events is not adequate to collect and examine data on treatment emergent suicidality events, nor on the impact of a medication on suicidal events. We provide an alternative system for collecting information on and analyzing suicidality event data that is less prone to type II error, is more revealing, and more precise. We hope that regulatory agencies and data safety monitoring boards and others who need to monitor suicidality with precision will find the ideas contained herein helpful.

### Limitations

The limitations of this study are that it is a case report on only one subject. The results may not be generalizable to other cases of suicidality. Similarly, this subject meets criteria for only one of the of the suicidality disorders, Impulse Attack Suicidality Disorder (IASD), and these results may not be generalizable to other suicidality disorders.

Another limitation of this study is that the subject did not experience all of the categories listed in the T-CASA columns analyzed in this study. For example, the subject did not experience a delusion leading to suicidality at any point during data collection.

A further limitation of this case study is that there is no placebo / TAU / SOC group(s) to compare with the data from this subject. In clinical trials, the data for each of these groups would be compared to one another, for each category, for both the event count and the time spent in the categories. The comparison between each of

these group's data would be used to determine if there is a difference between the treatment group and the placebo / TAU / SOC group(s).

The T-CASA is more time consuming for clinicians and patients in collecting suicidality event data. It is also more time consuming to analyze. The trade-off is much greater precision and accuracy and less likelihood of a type II error. However, we think that protecting every human life is worth this extra effort.

## Conclusion

The T-CASA is a system for collecting information on and analyzing suicidality event data. It is more precise and is less likely to fail in detecting the presence of treatment emergent suicidality or worsening of already present suicidality than other systems currently available. The T-CASA may provide those charged with monitoring suicidality in research and clinical settings with a more accurate and comprehensive approach to tracking suicidality events.

12.5

Do suicidal phenomena have a linear or a non-linear relationship with one another?

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

## Introduction

Clinicians, researchers, and the public assume the phenomenon of suicidality follow a linear progression from passive suicidal ideation to active suicidal ideation to a suicide plan to suicidal preparatory behaviors and on to a suicide attempt usually in response to escalating stress<sup>1</sup>. This linear progression assumes the prior step is completed before a higher step can be reached. For example, there is the assumption that a person cannot make a suicide attempt without making a plan for a suicide attempt. This assumption pervades much suicidality research in recent years and for traditional clinical assessment models for suicidality. An example of this is the linear progression / Guttman scaling inherent in the Columbia-Classification Algorithm for Suicide Assessment<sup>2</sup> and the Columbia - Suicide Severity Rating Scale<sup>3</sup>, which were both the recent 'gold standard' for suicide assessment in clinical trials in the United States<sup>4</sup>, and the classification categories in United States Food and Drug Administration (FDA) 2012 draft guidance document on the Assessment of Suicidal Ideation and Behavior in clinical trials<sup>5</sup>. All three of these systems use a Guttman scaling procedure that assumes the highest coded category is the most important and do not require the other phenomena experienced to be documented in order to know which of the other suicidal phenomena occurred or not.

## Methods

A 29-year-old female subject who experienced suicidality almost daily for over 20 years prospectively collected a self-report data series using the Sheehan - Suicidality Tracking Scale (S-STS)<sup>6</sup> (citation). The data was collected using the 11/11/11 computerized version of the scale<sup>7</sup> (cite eMINI) which contained 11 questions on suicidality and 1 question on non-suicidal self-injury<sup>8</sup> (cite UAB study for this version of S-STS). The S-STS uses the following response option anchors: 0 = Not at all, 1 = A little, 2 = Moderately, 3 = Very, 4 = Extremely. Data was collected weekly for a total of 145 weeks over the span of 1,015 days (2.78 years).

The subject was first diagnosed with Major Depressive Disorder<sup>9</sup> (DSM-III-R) at age 12. At age 16 this diagnosis was changed to Bipolar II Disorder<sup>10</sup> (DSM-IV-TR). At age 27 the diagnosis was instead changed to Pervasive

assessment-of-occurrence-in-clinical-trials September 2010.

<sup>&</sup>lt;sup>1</sup> Bonner, R. L. and Rich, A. R. (1988), A Prospective Investigation of Suicidal Ideation in College Students: A Test of a Model. Suicide and Life-Threat Behavi, 18: 245–258. doi: 10.1111/j.1943-278X.1988.tb00160.x

<sup>&</sup>lt;sup>2</sup> Posner, K., Oquendo, M. A., Gould, M., Stanley, B., & Davies, M. (2007). Columbia Classification Algorithm of Suicide Assessment (C-CASA): classification of suicidal events in the FDA's pediatric suicidal risk analysis of antidepressants. *The American journal of psychiatry*, *164*(7), 1035-1043.

<sup>&</sup>lt;sup>3</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

<sup>&</sup>lt;sup>4</sup> United States Food and Drug Administration, United States Department of Health and Human Services. Guidance for Industry: Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance. https://www.federalregister.gov/articles/2010/09/09/2010-22404/draft-guidance-for-industry-on-suicidality-prospective-

<sup>&</sup>lt;sup>5</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm. Accessed November 6, 2015.

<sup>&</sup>lt;sup>6</sup> Sheehan DV, Giddens JM, Sheehan IS. *Status Update on the Sheehan Suicidality Tracking Scale (S-STS) 2014*. Innov Clin Neurosci. 2014;11(9–10):93–140.

<sup>&</sup>lt;sup>7</sup> Dolphin Electronic Data Capture (eMINI Professional Version 2.1.1 / R131112.1 Database Version 2.26) [Software]. (1994 - 2012). Retrieved from http://medical-outcomes.com/

<sup>&</sup>lt;sup>8</sup> Sheehan DV, Alphs L, Mao L, et al. *Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 Draft Guidance suicidality categories*. Innov Clin Neurosci. 2014;11(9–10):32–46.

<sup>&</sup>lt;sup>9</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R)*. 3rd edition revised. Washington, DC: American Psychiatric Association; 1987.

<sup>&</sup>lt;sup>10</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

Developmental Disorder Not Otherwise Specified (PDD-NOS)<sup>11</sup> (DSM-IV-TR) because many of the symptoms that were used to meet criteria for Bipolar II Disorder were more appropriately attributed to her PDD. The subject meets ICD-10 criteria for Asperger Syndrome<sup>12</sup> and meets criteria for Impulse Attack Suicidality Disorder (IASD)<sup>13</sup>.

The values for each seriousness rating of each phenomenon on page 1 of the S-STS were plotted on a scatter plot with every other phenomenon. The trendline of these relationships and the R<sup>2</sup> value are shown on each scatter plot. There are a total of 45 figures showing the relationships between these 10 phenomena. Table 12.5.1 illustrates which relationship is shown in each figure in this chapter.

Table 12.5.1: Data Relationship Table

	Suicidal Passive Suicidal		Active Suicidal Suicide Method		Suicide Plan	Intent to Act on	Intent to Die	Suicidal Preparatory	Non-Suicidal	Suicide
	Accident	Ideation	Ideation	(method / means)	(where / when)	Suicidal Thoughts	by Suicide	Behavior	Self-Injury	Attempt
Suicidal Accident										
Passive Suicidal Ideation	Figure 12.5.1									
Active Suicidal Ideation	Figure 12.5.2	Figure 12.5.3			•					
Suicide Method (method / means)	Figure 12.5.4	Figure 12.5.5	Figure 12.5.6							
Suicide Plan (where / when)	Figure 12.5.7	Figure 12.5.8	Figure 12.5.9	Figure 12.5.10						
Intent to Act on Suicidal Thoughts	Figure 12.5.11	Figure 12.5.12	Figure 12.5.13	Figure 12.5.14	Figure 12.5.15					
Intent to Die by Suicide	Figure 12.5.16	Figure 12.5.17	Figure 12.5.18	Figure 12.5.19	Figure 12.5.20	Figure 12.5.21				
Suicidal Preparatory Behavior	Figure 12.5.22	Figure 12.5.23	Figure 12.5.24	Figure 12.5.25	Figure 12.5.26	Figure 12.5.27	Figure 12.5.28			
Non-Suicidal Self-Injury	Figure 12.5.29	Figure 12.5.30	Figure 12.5.31	Figure 12.5.32	Figure 12.5.33	Figure 12.5.34	Figure 12.5.35	Figure 12.5.36		
Suicide Attempt	Figure 12.5.37	Figure 12.5.38	Figure 12.5.39	Figure 12.5.40	Figure 12.5.41	Figure 12.5.42	Figure 12.5.43	Figure 12.5.44	Figure 12.5.45	

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

## Results

Figures 12.5.1 through 12.5.45 illustrate the relationship between the seriousness of two suicidal phenomenon as captured by the questions on the S-STS. For example, Figure 12.5.1 illustrates the relationship between the seriousness of the intent to die in a suicidal accident and passive suicidal ideation.

<sup>&</sup>lt;sup>11</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR)*. 4th ed. Washington, DC: American Psychiatric Association; 2000.

<sup>&</sup>lt;sup>12</sup> World Health Organization. (1992). *ICD-10 Classifications of Mental and Behavioural Disorder: Clinical Descriptions and Diagnostic Guidelines*. Geneva. World Health Organization.

<sup>&</sup>lt;sup>13</sup> Sheehan, D. V. and Giddens, J. M. 2015. *Suicidality: A Roadmap for Assessment and Treatment*. Available from: http://www.harmresearch.org

Figure 12.5.1: Seriousness of Intent to Die from Suicidal Accident and Passive Suicidal Ideation

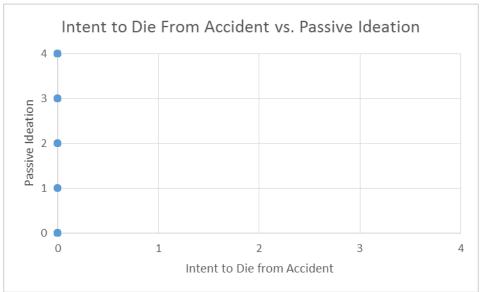


Figure 12.5.1 does not show a trendline or R<sup>2</sup> value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.2: Seriousness of Intent to Die from Suicidal Accident and Active Suicidal Ideation

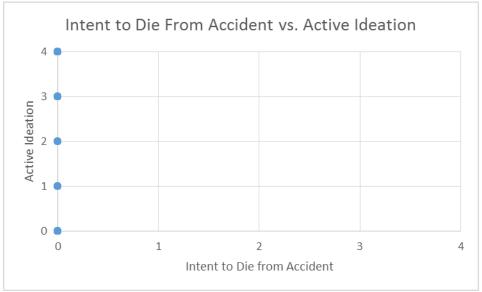
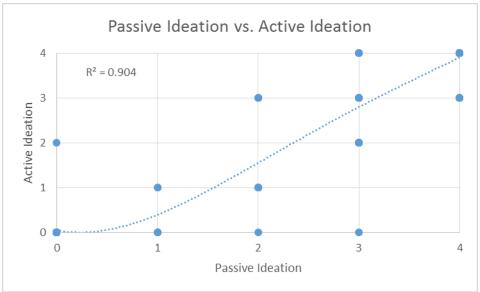


Figure 12.5.2 does not show a trendline or  $R^2$  value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.3: Seriousness of Passive Suicidal Ideation and Active Suicidal Ideation



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.3 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.4: Seriousness of Intent to Die from Suicidal Accident and Suicide Method in Mind

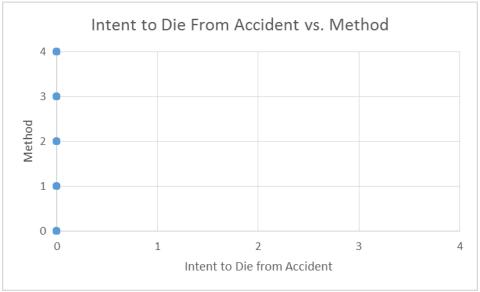
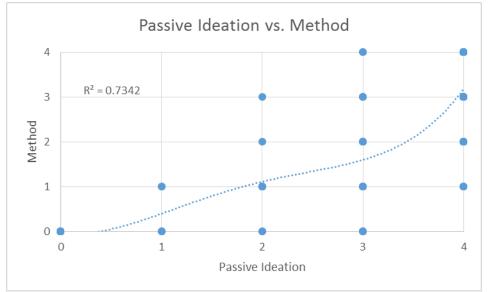


Figure 12.5.4 does not show a trendline or R<sup>2</sup> value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

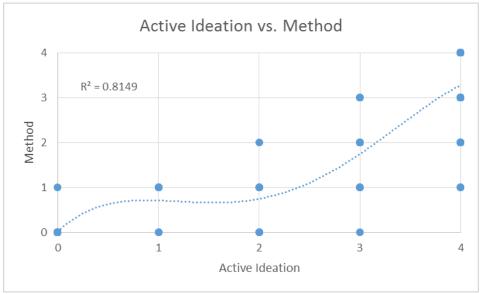
Figure 12.5.5: Seriousness of Passive Suicidal Ideation and Suicide Method in Mind



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.5 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

The apparent absence of the trendline between Passive Suicidal Ideation Score 0 and 0.4 reflects the polynomial trendline dipping below the zero line in a curved fashion. In Figures 12.5.8, 12.5.23, 12.5.24, 12.5.26, 12.5.27, 12.5.28, 12.5.44, and 12.5.45 below, the trendline also appears to be absent because it dips below zero and should be interpreted accordingly.

Figure 12.5.6: Seriousness of Active Suicidal Ideation and Suicide Method in Mind



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.6 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.7: Seriousness of Intent to Die from Suicidal Accident and Suicide Plan in Mind

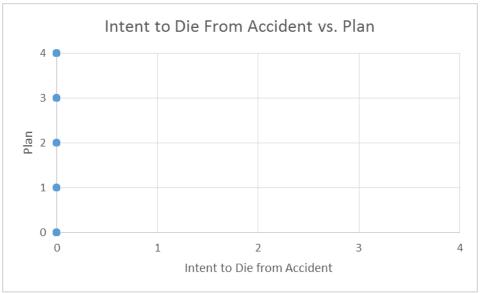
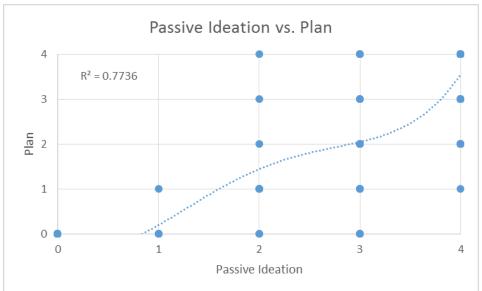


Figure 12.5.7 does not show a trendline or  $R^2$  value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

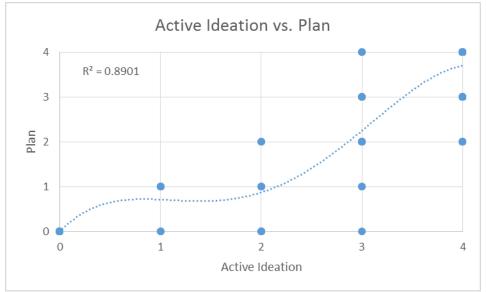
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.8: Seriousness of Passive Suicidal Ideation and Suicide Plan in Mind



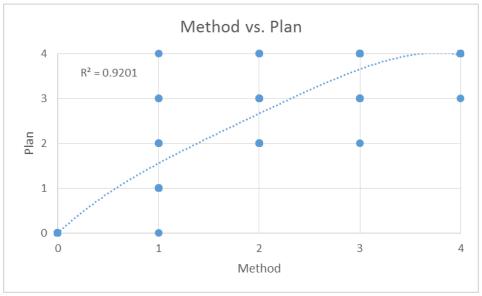
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.8 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.9: Seriousness of Active Suicidal Ideation and Suicide Plan in Mind



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.9 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.10: Seriousness of Suicide Method in Mind and Suicide Plan in Mind



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.10 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.11: Seriousness of Intent to Die from Suicidal Accident and Intent to Act on Suicidal Thoughts

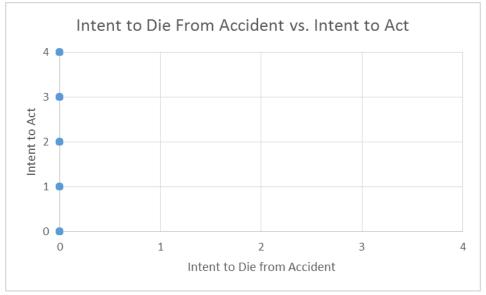
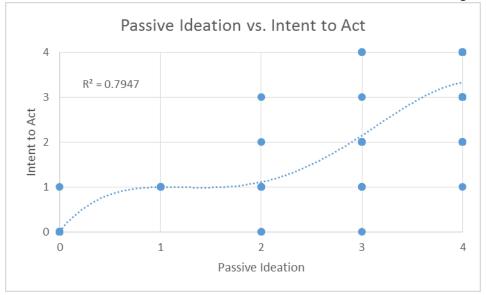


Figure 12.5.11 does not show a trendline or  $R^2$  value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

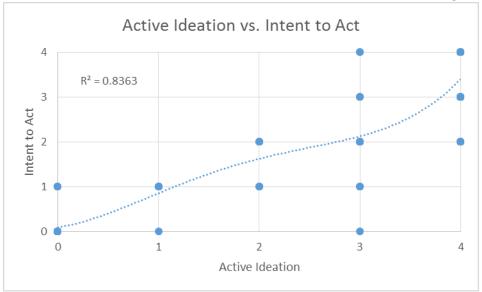
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.12: Seriousness of Passive Suicidal Ideation and Intent to Act on Suicidal Thoughts



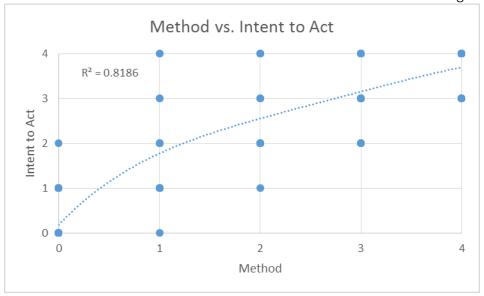
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.12 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.13: Seriousness of Active Suicidal Ideation and Intent to Act on Suicidal Thoughts



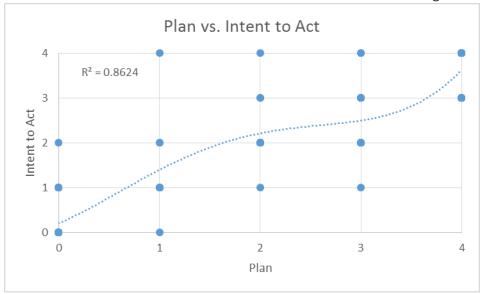
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.13 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.14: Seriousness of Suicide Method in Mind and Intent to Act on Suicidal Thoughts



A polynomial regression trendline is the best fit to the dataset: Figure 112.5.4 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.15: Seriousness of Suicide Plan in Mind and Intent to Act on Suicidal Thoughts



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.15 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.16: Seriousness of Intent to Die from Suicidal Accident and Intent to Die by Suicide

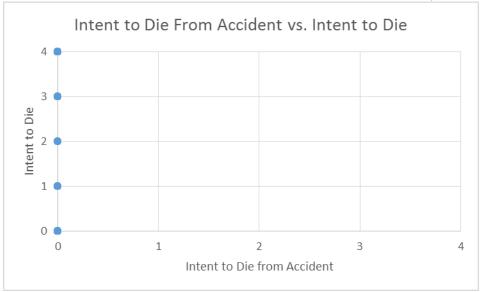
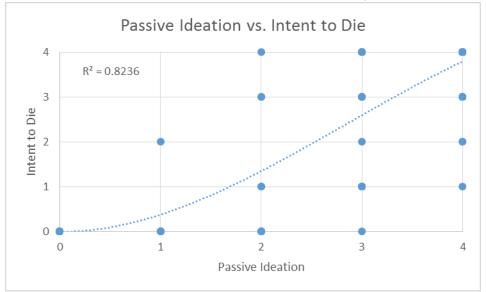


Figure 12.5.16 does not show a trendline or  $R^2$  value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

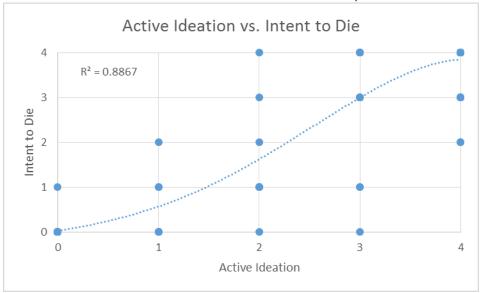
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.17: Seriousness of Passive Suicidal Ideation and Intent to Die by Suicide



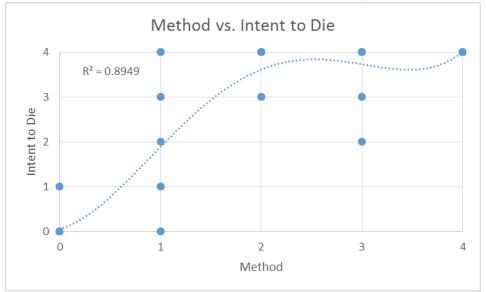
A polynomial regression trendline is the best fit to the dataset: Figure 112.5.7 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.18: Seriousness of Active Suicidal Ideation and Intent to Die by Suicide



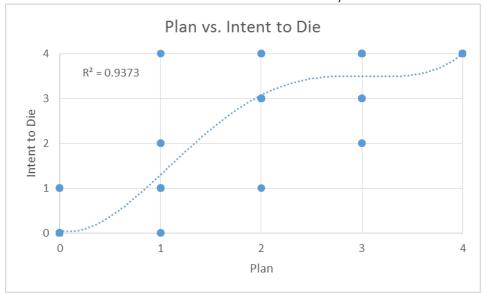
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.18 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.19: Seriousness of Suicide Method in Mind and Intent to Die by Suicide



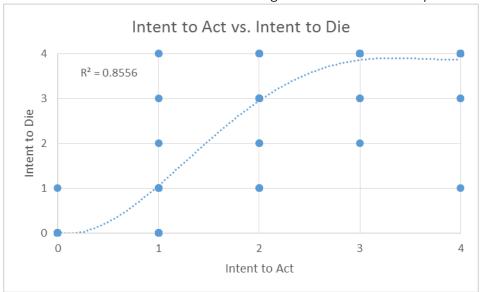
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.19 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.20: Seriousness of Suicide Plan in Mind and Intent to Die by Suicide



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.20 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.21: Seriousness of Intent to Act on Suicidal Thoughts and Intent to Die by Suicide



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.21 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.22: Seriousness of Intent to Die from Suicidal Accident and Suicidal Preparatory Behavior

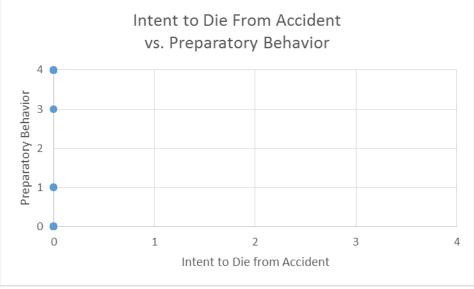
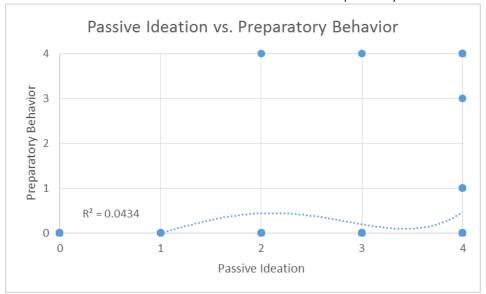


Figure 12.5.22 does not show a trendline or R<sup>2</sup> value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

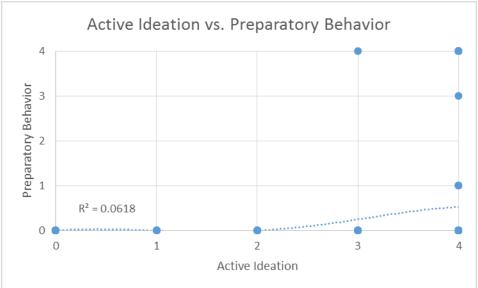
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.23: Seriousness of Passive Suicidal Ideation and Suicidal Preparatory Behavior



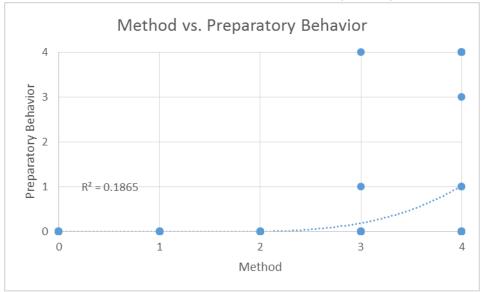
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.23 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.24: Seriousness of Active Suicidal Ideation and Suicidal Preparatory Behavior



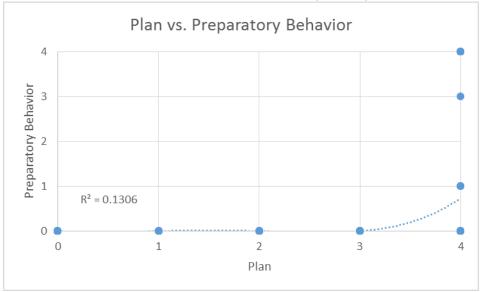
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.24 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.25: Seriousness of Suicide Method in Mind and Suicidal Preparatory Behavior



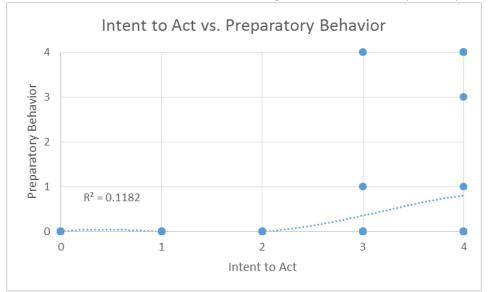
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.25 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.26: Seriousness of Suicide Plan in Mind and Suicidal Preparatory Behavior



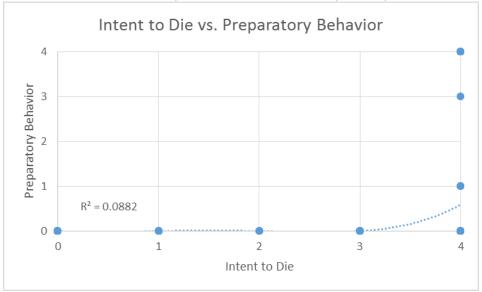
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.26 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.27: Seriousness of Intent to Act on Suicidal Thoughts and Suicidal Preparatory Behavior



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.27 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.28: Seriousness of Intent to Die by Suicide and Suicidal Preparatory Behavior



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.28 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.29: Seriousness of Intent to Die from Suicidal Accident and Non-Suicidal Self-Injury

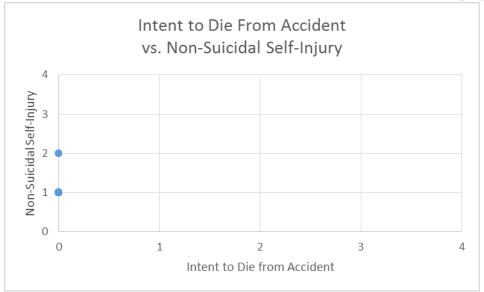
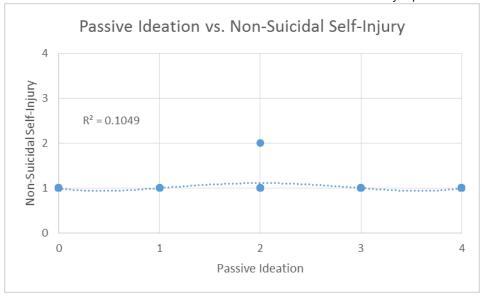


Figure 12.5.29 does not show a trendline or R<sup>2</sup> value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

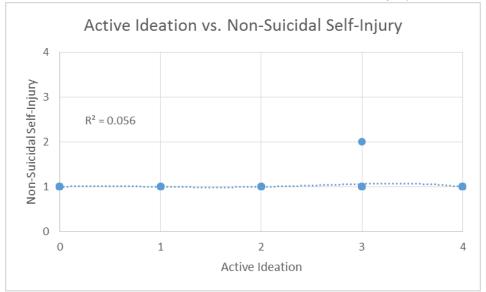
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.30: Seriousness of Passive Suicidal Ideation and Non-Suicidal Self-Injury



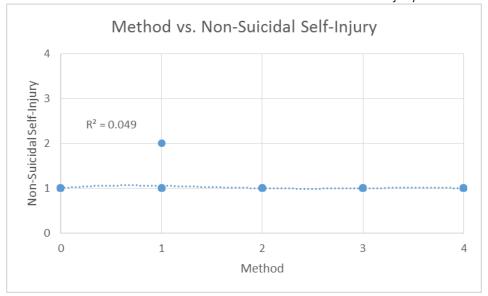
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.30 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.31: Seriousness of Active Suicidal Ideation and Non-Suicidal Self-Injury



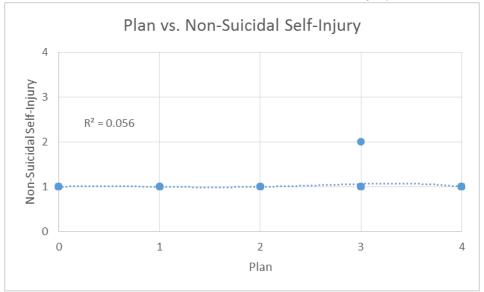
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.31 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.32: Seriousness of Suicide Method in Mind and Non-Suicidal Self-Injury



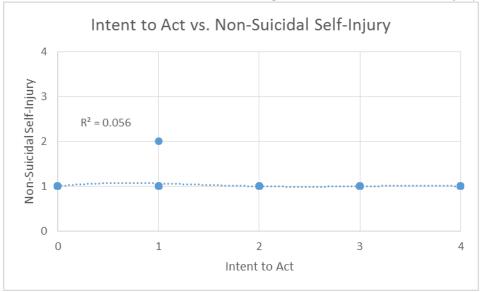
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.32 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.33: Seriousness of Suicide Plan in Mind and Non-Suicidal Self-Injury



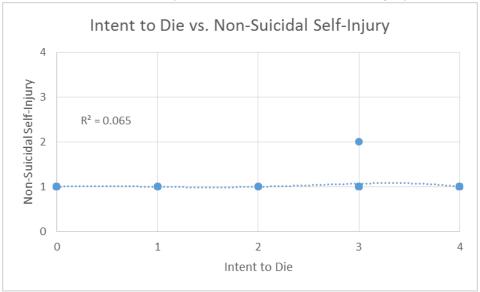
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.33 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.34: Seriousness of Intent to Act on Suicidal Thoughts and Non-Suicidal Self-Injury



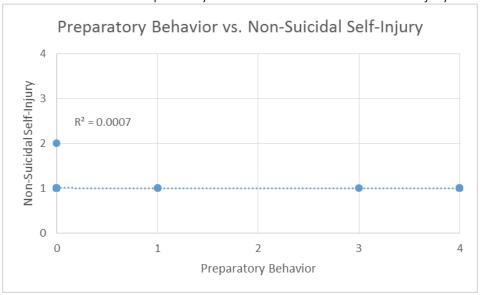
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.34 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.35: Seriousness of Intent to Die by Suicide and Non-Suicidal Self-Injury



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.35 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.36: Seriousness of Suicidal Preparatory Behavior and Non-Suicidal Self-Injury



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.36 shows an order 2 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.37: Seriousness of Intent to Die from Suicidal Accident and Suicide Attempt

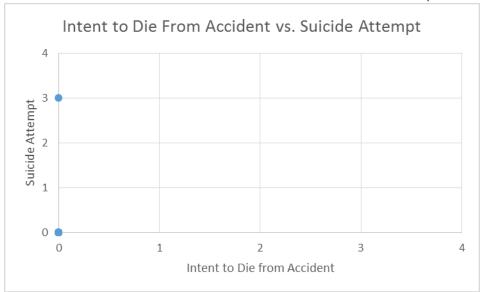
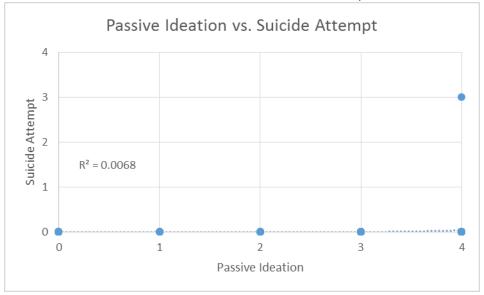


Figure 12.5.37 does not show a trendline or  $R^2$  value because the seriousness of the intent to die from a suicidal accident was a value of "0" across all timeframes of data collection.

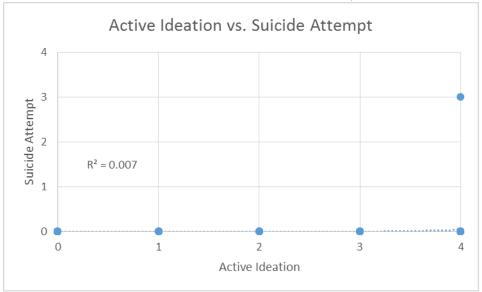
Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.38: Seriousness of Passive Suicidal Ideation and Suicide Attempt



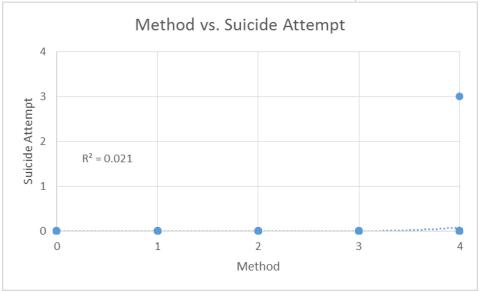
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.38 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.39: Seriousness of Active Suicidal Ideation and Suicide Attempt



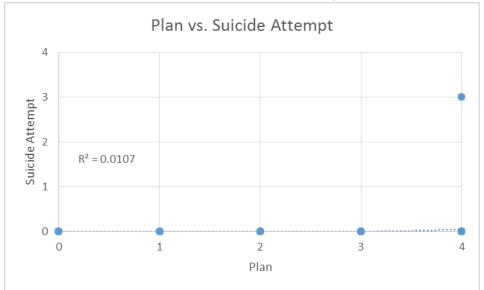
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.39 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.40: Seriousness of Suicide Method in Mind and Suicide Attempt



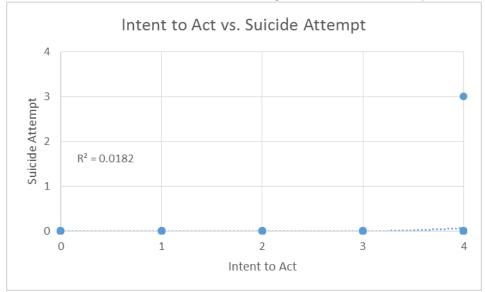
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.40 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.41: Seriousness of Suicide Plan in Mind and Suicide Attempt



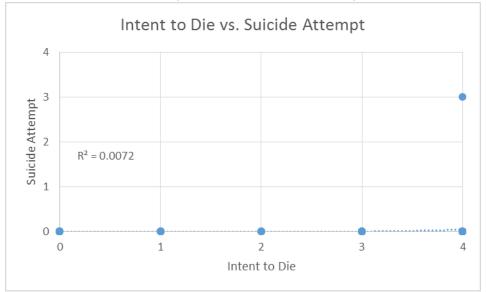
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.41 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.42: Seriousness of Intent to Act on Suicidal Thoughts and Suicide Attempt



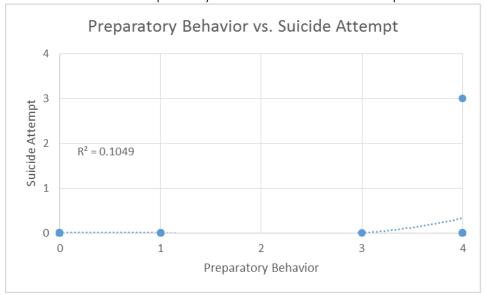
A polynomial regression trendline is the best fit to the dataset: Figure 12.5.42 shows an order 4 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.43: Seriousness of Intent to Die by Suicide and Suicide Attempt



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.43 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

Figure 12.5.44: Seriousness of Suicidal Preparatory Behavior and Suicide Attempt



A polynomial regression trendline is the best fit to the dataset: Figure 12.5.44 shows an order 3 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

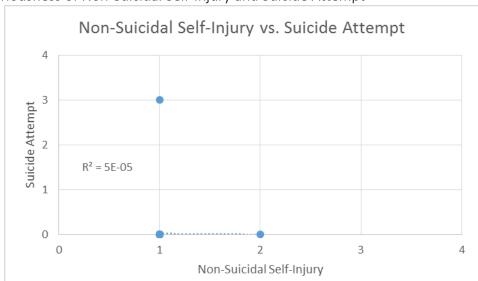


Figure 12.5.45: Seriousness of Non-Suicidal Self-Injury and Suicide Attempt

A polynomial regression trendline is the best fit to the dataset: Figure 12.5.45 shows an order 2 trendline. Sheehan DV, Giddens JM, Copyright 2015. All rights reserved.

#### Discussion

Figures 12.5.1, 12.5.2, 12.5.4, 12.5.7, 12.5.11, 12.5.16, 12.5.22, 12.5.29, and 12.5.37 do not contain a trendline because the value for the seriousness of the intent to die in a suicidal accident was "0" across all timeframes of data collection. For *all* other figures, the best fit for the trendline was a polynomial regression trendline. Most of these were an order 4 polynomial trendline.

"A polynomial trendline is a curved line that is used when data fluctuates. It is useful, for example, for analyzing gains and losses over a large data set. The order of the polynomial can be determined by the number of fluctuations in the data or by how many bends (hills and valleys) appear in the curve. An Order 2 polynomial trendline generally has only one hill or valley. Order 3 generally has one or two hills or valleys. Order 4 generally has up to three." 14

The data show that the relationship between any one suicidal phenomenon and any other suicidal phenomenon is not linear, but most of the time is polynomial. This non-linearity of relationships is consistent with the model presented in chapter2 suggesting that suicidality and the inter-relationships between suicidal phenomena are non-linear, dynamic, and complex. Using linear models to conceptualize suicidality whether in clinical settings or in research settings does not appear to be an accurate model reflecting the relationships between these phenomena in nature. Henceforth, clinicians and researchers should adopt a non-linear, dynamic model to better understand these relationships and their progression within an individual over time. Such a non-linear, dynamic model is more consistent with non-linear dynamics theory / non-linear systems theory / turbulent theory / chaos (theory) <sup>15</sup> <sup>16</sup> <sup>17</sup> <sup>18</sup> <sup>19</sup>.

<sup>&</sup>lt;sup>14</sup> Choosing the best trendline for your data. Microsoft Office. Retrieved September 25, 2015, from https://support.office.com/en-in/article/Choosing-the-best-trendline-for-your-data-1bb3c9e7-0280-45b5-9ab0-d0c93161daa8

<sup>&</sup>lt;sup>15</sup> Gleick, J. (1997). *Chaos: Making a new science*. Random House.

<sup>&</sup>lt;sup>16</sup> Stewart, I. (1997). Does God play dice?: The new mathematics of chaos. Penguin UK.

<sup>&</sup>lt;sup>17</sup> Cohen, J., & Stewart, I. (2000). The collapse of chaos: Discovering simplicity in a complex world. Penguin UK.

<sup>&</sup>lt;sup>18</sup> Stewart, I. (2011). *The mathematics of life*. Basic Books.

<sup>&</sup>lt;sup>19</sup> Lorenz, E. N. (1995). *The essence of chaos*. University of Washington Press.

#### Limitations

The limitations of this study are that it is a case report on only one subject. The results may not be generalizable to other cases of suicidality. Similarly, this subject meets criteria for only one of the of the suicidality disorders, Impulse Attack Suicidality Disorder (IASD), and these results may not be generalizable to other suicidality disorders.

## **Implications**

It will come as no surprise to experienced clinicians who deal with chronically suicidal patients that the progression of suicidality is non-linear, turbulent, dynamic, and complex and is not linear as the prevailing model would suggest. It is time to abandon and move beyond the prevailing linear "staircase" model of suicidality and to begin studying suicidality along the lines suggested by non-linear dynamic theory and reflected in the writings of many eminent mathematicians and physicists who have applied these principles to a broad range of sciences, including more recently the biological sciences and neuroscience. This may permit more accurate predictive modeling in the future, as such models have provided for meteorology and applied physics. It may also open up a broad range of applications for both the understanding of and more precise description and prediction of suicidal phenomena.

#### Conclusion

Suicidality is non-linear, dynamic, turbulent, and complex.

# 12.6

## What is a Patient Rated Scale Really?

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

A revised version of this case study was published in:

Giddens JM, Sheehan DV. How the Timing of a Patient's Self-ratings of Suicidality and the Relationship to the Recipient Affect Patient Responses: A Case Study. Innov Clin Neurosci. 2014;11(9–10):191–193. Available at <a href="http://innovationscns.epubxp.com/i/425963/190">http://innovationscns.epubxp.com/i/425963/190</a>

<sup>&</sup>lt;sup>1</sup> Tampa Center for Research on Suicidality, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

#### Abstract

## Objective

This paper investigates the stability of patient rated suicidality scores at several intervals and for different viewers. It investigates how the patient reports the data based on who they expect will view the data and their relationship with the viewer.

#### Method

Three scales (the *Sheehan-Suicidality Tracking Scale*, the *Suicidality Modifiers Scale*, and the *Dichotomous Impulsivity and Hopelessness Two Questions*) were answered in 3 ways for each of 24 timeframes. The first way the scales were answered was for the patient alone and was not to be shared with anyone, the second way was for the patient to share only with her therapist and was conducted immediately after the first, and the third way was completed a few days after the initial interview and was for the patient alone. The 3 ways the scales were answered were compared to find the deviations.

#### Results

There were clinically relevant deviations between these 3 ways the scales were answered. The patient offered insight into these deviations.

## Conclusion

Data collected using a self-rated symptom scale can vary significantly depending on the context, the timing, and the relationship between the patient and the scale reviewer.

## Introduction

Clinicians think of data collected using a self-rated symptom scale as if it was one data collection event that reliably captured unchanging data reflecting the patient's perception about their symptoms during a specific timeframe. In clinical research, data is typically collected at a visit to capture the symptoms over a fixed timeframe or since the last visit. Such data is assumed to most accurately reflect the symptoms experienced during this timeframe since it is in close proximity to the timeframe under examination.

In some sensitive areas like sex and suicide, clinicians understand that patients vary in their willingness to share this information accurately.

This paper investigates the stability of patient-rated suicidality scores at several intervals and for different viewers. It investigates how the patient reports the data based on who they expect will view the data and their relationship with the viewer (even when, several days later, the original rater rerates their symptoms by looking back on the original timeframe).

#### Methods

A 29-year-old female who experienced suicidality almost daily for more than twenty years collected data on her suicidality over the course of 3 months. The data collected included the computerized¹ 11/11/11 versions of the *Sheehan-Suicidality Tracking Scale* (*S-STS*)², the *Suicidality Modifiers Scale* (*SM*) scale (used in University of Alabama Birmingham *S-STS* Validation Study)³, and the *Dichotomous Impulsivity and Hopelessness Two Questions* (*IH Questions*) (used in the University of Alabama Birmingham *ISST-Plus* Validation Study)⁴ and any additional notes the patient felt relevant to document. This version of the *S-STS* is a 2-page scale with 11 questions about suicidal phenomena and 1 question on non-suicidal self-injury. Due to the fact that deviation occurred in the seriousness and count of non-suicidal self-injury, the answers for this question were used to calculate the total score for the *S-STS*. (This differs from the scoring instructions for the 1/4/14 version of the *S-STS*, but is consistent with the scoring instructions for the 11/11/11 version.) The 11/11/11 version of the *SM* is a 1 page scale with 5 questions about suicidal impulsivity and 5 questions about hopelessness. (The newest version contains 6 questions for each of 4 domains: suicidal impulsivity, hopelessness, loss of

<sup>&</sup>lt;sup>1</sup> Dolphin Electronic Data Capture (eMINI Professional Version 2.1.1 / R131112.1 Database Version 2.26) [Software]. (1994 - 2012). Retrieved from http://medical-outcomes.com/

<sup>&</sup>lt;sup>2</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from: http://innovationscns.epubxp.com/i/425963/32

<sup>&</sup>lt;sup>3</sup> Suicidality Modifiers developed by DV Sheehan, L Alphs, JM Giddens for the study reported in "Comparative Validation of the ISST-Plus, the S-STS and the C-SSRS for assessing suicidal thinking and behavior". Poster presented at the 14th International Congress on Schizophrenia Research (ICOSR), April 21-25, 2013, Orlando, Florida, USA. (L Alphs, personal communication).

<sup>&</sup>lt;sup>4</sup> Alphs L. Two dichotomized spectrum test questions (one assessing a impulsivity – caution dichotomous spectrum, the second using a hopefulness – hopelessness dichotomous spectrum) developed by L Alphs for the study reported in "Comparative Validation of the ISST-Plus, the S-STS and the C-SSRS for assessing suicidal thinking and behavior". Poster presented at the 14th International Congress on Schizophrenia Research (ICOSR), April 21-25, 2013, Orlando, Florida, USA. (L Alphs, personal communication)

enjoyment, and overwhelmed feeling.) Both the *S-STS* and the *SM* use a 0 - 4 (5 point) Likert scale with descriptive anchors (not at all / a little / moderately / very / extremely). Each question on the two *IH Questions* contained a range of 7 possible answers. The descriptive anchors on *IH Question 1* "usual impulsivity / caution" were "extremely cautious, very cautious, moderately cautious, in the middle, moderately impulsive, very impulsive, and extremely impulsive". The descriptive anchors on *IH Question 2* "usual hopefulness / hopelessness" were "extremely hopeful, very hopeful, moderately hopeful, in the middle, moderately hopeless, very hopeless, and extremely hopeless". For data analysis, the values for the *IH Questions* were converted to 1 - 7 point scores, respectively. The notes documented specific symptoms of the patient's suicidality, medication she took during the timeframe, and events she thought had an impact upon her suicidality (e.g. frustration from attempting to contact a health care provider about an increase in her symptoms and feeling as though her concerns were not respected). The notes, made at each assessment point by the subject, were reviewed for deviations between the 3 types of interviews (see below). The notes that deviated were aggregated under category headings, for ease of analysis. During the time of data collection the patient was under the care of both a psychiatrist and a therapist.

The patient scored all three scales (S-STS, SM, and IH Questions) in 3 ways for each of 24 timeframes (resulting in a total of 72 self-ratings [in this paper referred to as "interviews"]). The first interview dataset was for the patient alone (self-version [immediate]) and was not to be shared with anyone. The second interview, conducted immediately after the first (self-version [for therapist]) and was to be seen only by the patient and the therapist. The third interview was 1 to 5 days after the first two interviews and was not shared with the therapist (self-version [days later]). The timeframes ranged from 3 to 5 days with a mean timeframe of 3.96 days and a median timeframe of 4 days.

The data was compared in 3 ways. The self-version (immediate) was compared to the responses in the self-version (for therapist). The self-version (immediate) was compared to the responses in the self-version (days later). The self-version (days later) was compared to the responses in the self-version (for therapist). All of these 3 comparisons were reviewed based upon the individual question score, the total scores for each scale and overall interview, and the notes.

## Results

Table 12.6.1 illustrates the way this paper reports the relationship of the variables to each other. The result number listed in the table indicates which section of the paper discusses each of these relationships.

Table 12.6.1. Data Relationship Table

	Question			Scale / Interview			Notes		
	Self-version	Self-version	Self-version	Self-version	Self-version	Self-version	Self-version	Self-version	Self-version
	(Immediate)	(for Therapist)	(Days Later)	(Immediate)	(for Therapist)	(Days Later)	(Immediate)	(for Therapist)	(Days Later)
Self-version (Immediate)									
Self-version (for Therapist)	Result 1			Result 2			Result 3		
Self-version (Days Later)	Result 4	Result 7		Result 5	Result 8		Result 6	Result 9	

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

Self-version (Immediate) vs. Self-version (for Therapist)

#### Result 1

Table 12.6.2 shows the deviations in individual question scores for all of the scales between the self-version (immediate) and the self-version (for therapist). This includes the number of interviews when there was a deviation in the response to this question, the aggregate points of deviation in the responses to this question across all 24 interviews, the mean deviation (of count or score) when deviation occurred, and the mean deviation (of count or score) across all 24 interviews.

For example, the *count* of active suicidal ideation events deviated in 18 of the 24 interviews, deviated by a count of 1600 across all 24 interviews, deviated by a mean count of 88.9 during the 18 interviews when deviation occurred, and deviated by a mean count of 66.7 across all 24 interviews. In the column 2, a count may have been off by 3 points, but this counted as one deviation, not three. In column 3, a count may have been off by 3 points and this counted as 3 points of deviation.

For example, the *severity score* of the active suicidal ideation item deviated in 12 of the 24 interviews, deviated by a score of 12 across all 24 interviews, deviated by a mean score of 1 during the 12 interviews when deviation occurred, and deviated by a mean score of 0.5 across all 24 interviews. As with the calculation of counts, in column 2, a score may have been off by 3 points, but this counted as one deviation, not three. In column 3, a score may have been off by 3 points and this counted as 3 points of deviation.

Table 12.6.2. Individual Question Scores: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (for Therapist)

	The number of interviews	Aggregate points of	Mean deviation	Mean deviation
	when there was a deviation in the response	deviation in the responses to this guestion across all	(of count or score) when deviation occurred	(of count or score) across all 24 interviews
	to this question	24 interviews	(column 3 / column 2)	(column 3 / 24)
S-STS				
Severity Scores				
Intend Harm to Self Resulting from Accident	0	0	0	0
Passive Suicidal Ideation	9	9	1	0.4
Active Suicidal Ideation	12	12	1	0.5
Suicide Method in Mind	18	21	1.2	0.9
Suicide Plan in Mind	18	23	1.3	1
Intend to Act on Suicidal Thoughts	18	22	1.2	0.9
Intend to Die as Result of Suicidal Action	20	25	1.3	1.04
Make Preparations for Suicide	6	10	1.7	0.4
Self Injury without Intending to Die as Result	0	0	0	0.4
Attempt Suicide	0	0	0	0
Specific Preparation for Suicide	6	25	4.2	1.04
No / Yes	U	25	7.2	1.04
Did Accident Occur	0	0	0	0
Intend to Kill Self from Accident	0	0	0	0
Event Counts	v		· ·	Ū
Count of Passive Suicidal Ideation Events	17	1070	62.9	44.6
Count of Active Suicidal Ideation Events	18	1600	88.9	66.7
Count of Self Injury Events	12	270	22.5	11.3
Count of Suicide Attempts	0	0	0	0
Count of Specific Preparations Listed	5	7	1.4	0.3
Date Deviation	J	,	1.7	0.5
Date of Preparation for Suicide	6	8	1.3	0.3
Date of Treparation for Saidae	v	Ü	1.5	0.5
SM				
Strength of Suicidal Impulse	3	3	1	0.1
Difficulty Suppressing Suicidal Impulse	2	2	1	0.1
Lost Desire to Suppress Suicidal Impulse	14	17	1.2	0.7
Memories Influencing Desire to Suppress Suicidal Impulse	10	11	1.1	0.5
External Events Influencing Desire to Suppress Suicidal Impulse	11	12	1.1	0.5
Level of Hopelessness	17	19	1.1	0.8
Difficulty Being Hopeful	17	19	1.1	0.8
Lost Desire to be Hopeful	22	26	1.2	1.1
Memories Influencing Desire to be Hopeful	15	16	1.1	0.7
External Events Influencing Desire to be Hopeful	19	21	1.1	0.9
IH Questions				
Level of Usual Impulsivity / Caution	0	0	0	0
Level of Usual Hopefullness / Hopelessness	7	7	1	0.3
zever or obtain rioperalmess / Hoperessitess	,	,	1	0.5
Totals:	302	3255	201.8	135.6

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 1

The primary areas the patient minimized to the therapist in the *S-STS* were in the counts of suicidal ideation, severity and type of suicidal planning, and details of suicidal preparatory behaviors. During 6 interviews the patient failed to admit to the therapist that preparatory behaviors occurred even though some of these timeframes contained multiple preparatory behaviors.

The primary areas the patient minimized to the therapist in the *SM* were in the hopelessness questions, which occurred in 22 of the 24 interviews, and in the desire to resist impulsivity.

The primary area the patient minimized to the therapist in the *IH Questions* were in the level of usual hopefulness / hopelessness and occurred during 7 interviews.

The count of questions where answers for the therapist deviated from the patient's answers for themself was 302 deviations on 744 questions across all 24 interviews or 41% of all scale questions.

#### Result 2

Table 12.6.3 shows the deviations in scale totals for each of the scales and in the overall interview between the self-version (immediate) and the self-version (for therapist). This includes the number of interviews when there was a deviation in the each scale total or the overall interview, the aggregate points of deviation on each scale total or overall interview across all 24 interviews, the mean deviation (of score) when deviation occurred, and the mean deviation (of score) across all 24 interviews. The "overall interview" is the complete interview consisting of all 3 scales (*S-STS*, *SM*, and *IH Questions*).

For example, the total *severity score* for the *SM* deviated in 22 of the 24 interviews, deviated by a score of 144 across all 24 interviews, deviated by a mean score of 6.5 during the 22 interviews when deviation occurred, and deviated by a mean score of 6 across all 24 interviews.

For example, the *severity scores* in the overall interview deviated in 23 of the 24 interviews, deviated by a score of 273 across all 24 interviews, deviated by a mean score of 11.9 during the 23 interviews when deviation occurred, and deviated by a mean score of 11.4 across all 24 interviews.

Table 12.6.3. Total Scores for Each Scale and for Overall Interview: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (for Therapist)

	Self-version (Immed	liate) vs Self-version	(for Therapist)	
	The number of interviews when there was a deviation on this total score or overall interview	Aggregate points of deviationon this total score or overall interview across all 24 interviews	Mean deviation (of score) when deviation occurred (column 3 / column 2)	Mean deviation (of score) across all 24 interviews (column 3 / 24)
S-STS Total	21	122	5.8	5.1
SM Total	22	144	6.5	6
IH Questions Total	7	7	1	0.3
Overall Interview	23	273	11.9	11.4
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 2

The scale totals deviated between the version for self-version (immediate) and the self-version (for therapist) in almost all scale totals on both the *S-STS* and the *SM*. Considering that the *S-STS* is a 12 question scale with a possible total of 48 points (assuming the patient is still alive and did not engage in multiple preparatory behaviors and / or multiple suicide attempts), the mean deviation on the *S-STS* of 5 points is 10% of highest possible score. Similarly on the *SM* the mean deviation across all 24 interviews of 6 points, with a scale that only has a total of 40 points, results in a mean deviation that is 15% of the highest possible score.

The overall interview between the self-version (immediate) and the self-version (for therapist) did not deviate at all on only one interview (4%). The timeframe when this completely truthful interview occurred had the second lowest *S-STS* total score and the lowest *SM* and *IH Questions* total scores documented throughout all of data collection. The mean deviation across all 24 interviews on the

overall interview was 11 points, out of a total of 102 possible points, resulting in a mean deviation that is nearly 11% of the highest total possible points for the overall interview.

#### Result 3

Table 12.6.4 shows the deviations in note topics between the self-version (immediate) and the self-version (for therapist). This includes the number of interviews when there was a deviation in the note topic, the aggregate points of deviation in the note topics across all 24 interviews, the mean deviation (of count) when deviation occurred, and the mean deviation (of count) across all 24 interviews.

For example, the *count* of notes relating to the current severity of suicidality symptoms deviated in 5 of the 24 interviews, deviated by a count of 6 across all 24 interviews, deviated by a mean count of 1.2 during the 5 interviews when deviation occurred, and deviated by a mean count of 0.3 across all 24 interviews.

Table 12.6.4. Notes: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (for Therapist)

nstj				
Self-version	(Immediate) vs Self	-version (for Thera	oist)	
	The number of interviews when there was a deviation on this note topic	Aggregate points of deviation on this note topic across all 24 interviews	Mean deviation (of count) when deviation occurred (column 3 / column 2)	Mean deviation (of count) across all 24 interviews (column 3 / 24)
Notes Relating to Therapist	3	3	1	0.1
Example:				
"Emailed [therapist] an update Saturday night and [therapy] work Sunday morning, but [therapist] has yet to respond which is frustrating."				
Notes Relating to Planning An Attempt	10	11	1.1	0.5
Examples:				
"Began finalizing plans to die Friday morning."				
"Continued thoughts about the 13th. New thoughts about the 20th or the end of next month."				
"Still considering the end of July, but with less intent than in previous time frames."				
Notes Relating to Current Severity of Suicidality Symptoms	5	6	1.2	0.3
Examples:	3	U	1.2	0.5
"Experiencing high level of active ideation while completing interview."				
"Questioning how much longer until an attempt is made."				
"Frequently questioning the point in continuing to fight to live when life has very little quality."				
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 3

The information left out of the notes *for* the therapist is in notes *relating to* the therapist, to planning an attempt, and to the current severity of suicidality symptoms. Overall, the amount of deviation on note topics was minimal compared to the answers on the scales. However, some of the details in the note topics that were excluded from the version for the therapist contained critically important information for the therapist to know. The specific dates the patient was thinking about or planning to kill herself and the knowledge that the patient was completing plans to kill herself and were not relayed to the therapist. This prevented the therapist from having the complete picture of the patient's suicidality.

One of the notes in the table states "frequently questioning the point in continuing to fight to live when life has very little quality." This note conveys a high level of hopelessness and was additional important information for the therapist to know in order to help keep the patient safe.

#### Patient Commentary on Results 1 - 3

Although some deviation is to be expected, the extent of deviation between the self-version (immediate) and the self-version (for therapist) exceeded the authors' expectations and even the patient's expectations. When presented with the data in Tables 12.6.2 - 12.6.4 the patient became upset and stated "How can I expect my therapist to help me if I can't be honest with [them]?" Subsequently the patient admitted purposely minimizing some details of her symptoms when completing the version for therapist because, "other than hospitalization, which wasn't necessary at the time, there was nothing [the therapist] could do to help me so why worry [the therapist] with the details?" She went on to explain "I was thinking it would be better for [the therapist] to really not know how suicidal I was, in the event I did kill myself. This way [the therapist] would be more legally protected, since I specifically lied about my suicidality, and more emotionally protected, since [the therapist] wouldn't second guess any clinical judgment [the therapist] otherwise would have made about my treatment." When asked if those were the only reasons she minimized her answers, the patient admitted that some of the minimization was done in order to have "more freedom and the opportunity to make a suicide attempt." The patient added that she "exaggerated some of the answers, particularly the count of [non-suicidal] self-injury, so that [the therapist] would think I was coping better than I really was." The patient has a lengthy history of using non-suicidal self-injury as a coping mechanism. She added, "I thought I had a good relationship with [the therapist]. I can only imagine how much more I would have lied if [the completed interviews were] being viewed by someone I had a poor relationship with."

Self-version (Immediate) vs. Self-version (Days Later)

#### Result 4

Table 12.6.5 is similar to Table 12.6.2 except it shows the data for the self-version (immediate) compared to the self-version (days later).

Table 12.6.5. Individual Question Scores: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (Days Later)

	The number of interviews	Aggregate points of	Mean deviation	Mean deviation
	when there was a deviation in the response	deviation in the responses to this question across all	(of count or score) when deviation occurred	(of count or score) across all 24 interviews
	to this question	24 interviews	(column 3 / column 2)	(column 3 / 24)
S-STS				
Severity Scores				
Intend Harm to Self Resulting from Accident	0	0	0	0
Passive Suicidal Ideation	0	0	0	0
Active Suicidal Ideation	0	0	0	0
Suicide Method in Mind	2	2	1	0.1
Suicide Plan in Mind	0	0	0	0
Intend to Act on Suicidal Thoughts	3	3	1	0.1
Intend to Die as Result of Suicidal Action	4	4	1	0.2
Make Preparations for Suicide	1	3	3	0.1
Self Injury without Intending to Die as Result	1	1	1	0.04
Attempt Suicide	0	0	0	0.04
Specific Preparation for Suicide	0	0	0	0
No / Yes	U	U	U	- U
Did Accident Occur	1	1	1	0.04
Intend to Kill Self from Accident	0	0	0	0
Event Counts	U	0	U	U
Count of Passive Suicidal Ideation Events	1	1	1	0.04
Count of Active Suicidal Ideation Events	3	320	106.7	13.3
Count of Active Suicidal Ideation Events  Count of Self Injury Events	0	0	0	0
Count of Suicide Attempts	0	0	0	0
Count of Specific Preparations Listed	0	0	0	0
·	U	U	U	U
Date Deviation	0	0	0	0
Date of Preparation for Suicide	U	U	U	U
SM				
Strength of Suicidal Impulse	1	1	1	0.04
Difficulty Suppressing Suicidal Impulse	3	3	1	0.1
Lost Desire to Suppress Suicidal Impulse	0	0	0	0
Memories Influencing Desire to Suppress Suicidal Impulse	0	0	0	0
External Events Influencing Desire to Suppress Suicidal Impulse	0	0	0	0
Level of Hopelessness	3	3	1	0.1
Difficulty Being Hopeful	7	7	1	0.3
Lost Desire to be Hopeful	2	2	1	0.1
Memories Influencing Desire to be Hopeful	2	2	1	0.1
External Events Influencing Desire to be Hopeful	1	1	1	0.04
IH Questions				
Level of Usual Impulsivity / Caution	0	0	0	0
Level of Usual Hopefullness / Hopelessness	0	0	0	0
Level of Osual Hoperulliless / Hoperessiless	U .	U	U	U
Totals:	35	354	122.7	14.8

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 4

The primary areas the patient minimized to herself in the *S-STS* were in the counts of active suicidal ideation and severity of the intent to act and intent to die. The counts of active suicidal ideation deviated by 320 events during 3 interviews, which resulted in a mean deviation of nearly 107 events during these 3 interviews. The mean deviation when deviation occurred in the count of active ideation events was higher here (107 events) than it was when comparing the self-version (immediate) to the self-version (for therapist) (89 events). Overall on the *S-STS*, other than the seriousness of preparatory behaviors and the active ideation event counts, all of the answers to the questions deviated a mean of only 1 point when deviation occurred on those questions.

The primary areas the patient minimized to herself in the *SM* were in the difficulty in suppressing the suicidal impulse, the level of hopelessness, and the difficulty of being hopeful. Every time there was deviation on a *SM* question, the mean deviation was only 1 point of seriousness.

There was no deviation at all on the IH Questions.

The count of questions where answers for the self-version (immediate) deviated from the patient's answers for self-version (days later) was 35 deviations on 744 questions across all 24 interviews or 5% of all scale questions.

#### Result 5

Table 12.6.6 is similar to Table 12.6.3 except it shows the data for the self-version (immediate) compared to the self-version (days later).

Table 12.6.6. Total Scores for Each Scale and for Overall Interview: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (Days Later)

	Self-version (Imme	diate) vs Self-versior	(Days Later)	
	The number of interviews when there was a deviation on this total score or overall interview	Aggregate points of deviationon this total score or overall interview across all 24 interviews	Mean deviation (of score) when deviation occurred (column 3 / column 2)	Mean deviation (of score) across all 24 interviews (column 3 / 24)
S-STS Total	7	14	2	0.6
SM Total	7	19	2.7	0.8
IH Questions Total	0	0	0	0
Overall Interview	10	33	3.3	1.4
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 5

The scale totals deviated between the self-version (immediate) and the self-version (days later) in only 7 interviews on both the S-STS and the SM. In the S-STS and the SM this deviation resulted in a mean deviation across all 24 interviews of less than 1 point of seriousness each. There was no deviation on the IH Questions.

The overall interview deviated in 10 out of 24 interviews or 42% between the self-version (immediate) and the self-version (days later). The mean deviation in these 10 interviews was slightly more than 3 points of seriousness. However, the mean deviation across all interviews was only slightly more than 1 point of seriousness. Compared to the data in Result 2 (self-version [immediate] compared to self-version [for therapist]), this is a reduction in the mean deviation across all 24 interviews of nearly 88% or 10 points of seriousness.

#### Result 6

Table 12.6.7 is similar to Table 12.6.4 except it shows the data for the self-version (immediate) compared to the self-version (days later).

Table 12.6.7. Notes: Tracking the Self-version (Immediate) Compared to Tracking the Self-version (Days Later)

Self-version	(Immediate) vs Sel	f-version (Days Lat	er)	
	The number of interviews when there was a deviation on this note topic	Aggregate points of deviation on this note topic across all 24 interviews	Mean deviation (of count) when deviation occurred (column 3 / column 2)	Mean deviation (of count) across all 24 interviews (column 3 / 24)
Notes Relating to Current Severity of Suicidality Symptoms	4	5	1.3	0.2
Examples:				
"On verge of meltdown while completing interview."				
"Experiencing an intent to act while completing interview."				
"Less intense ideation during most of the timeframe."				
Notes Relating to Current Physical Symptoms	1	1	1	0.04
Example:				
"Consistent headaches Wednesday through present."				
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 6

The information left out of the notes for self-version (immediate) focused mainly on the current severity of suicidality symptoms and the current physical symptoms. It is not surprising that the patient's immediate notes deviated from the notes days later as the immediate notes may have been collected too close in time proximity to the patients current symptoms for the patient to easily admit to them, to cope with them, and to appropriately document them.

#### Patient Commentary on Results 4 - 6

When presented with the data in Tables 12.6.5 - 12.6.7 the patient was surprised with the results because she expected there to be more deviation. She believed she minimized some of her symptoms to herself at the time she was experiencing them because this "helps me cope with my current situation. If I acknowledge how bad my suicidal symptoms really are, I tend to feel overwhelmed and this leaves me less able to cope with the symptoms. It also results in a higher likelihood that I will need hospitalization when symptoms are more severe. So, it is surprising that I was able to be this honest with myself at a time that I was struggling to keep myself safe."

In reference to Table 12.6.5, the patient pointed out that it isn't necessarily helpful for a clinician to ask about the count of suicidal ideation events "because I lied to myself [in] 3 different [interviews] that resulted in minimizing 320 times when I thought about killing myself". She went on to state, "If I can't be honest with myself about how often I'm thinking about killing myself, how can I possibly be honest with anyone else? [...] Asking about the time I spend thinking about killing myself might be easier for me to acknowledge than the number of events. [...] There were three interviews where I minimized the active ideation event count. These minimizations were due to a higher event count in the 24 hours prior to data collection. These 3 particular interviews minimized the event count by about 100 events, but these 100 events [in aggregate] only lasted about an hour. It would have been easier for me to acknowledge one hour of suicidality than to admit to 100 events of active ideation. I could have had one event that lasted 1 hour, so an hour [in aggregate] is easier to admit than 100 events. [Conversely], it would be easier to admit to one event [lasting 20 hours] than to admit to 20 hours of suicidality in one event." We conclude from this that patients are likely to choose their way of reporting events based upon what will use the lowest numeric value.

In reference to Table 12.6.7, the patient questioned if the note that reads "less intense ideation throughout most of the timeframe" was not added during the immediate interview because she had tentatively selected a date to kill herself and was attempting to ignore that her symptoms were improving in order to "convince myself to finally give up and make an attempt. I felt exhausted from fighting so hard to keep myself alive and I just wanted everything to be over."

Self-version (Days Later) vs. Self-version (for Therapist)

#### Result 7

Table 12.6.8 is similar to Table 12.6.2 and Table 12.6.5 except it shows the data for the self-version (days later) compared to the self-version (for therapist).

Table 12.6.8. Individual Question Scores: Tracking the Self-version (Days Later) Compared to Tracking the Self-version (for Therapist)

Self-versi	on (Days Later) vs Sel	f-version (for Therapi	st)	
	The number of interviews when there was a deviation in the response to this question	Aggregate points of deviation in the responses to this question across all 24 interviews	Mean deviation (of count or score) when deviation occurred (column 3 / column 2)	Mean deviation (of count or score) across all 24 interviews (column 3 / 24)
	to this question	24 litterviews	(column 3 / column 2)	(colulliii 3 / 24)
S-STS				
Severity Scores				
Intend Harm to Self Resulting from Accident	0	0	0	0
Passive Suicidal Ideation	9	9	1	0.4
Active Suicidal Ideation	12	12	1	0.5
Suicide Method in Mind	20	23	1.2	1
Suicide Plan in Mind	18	23	1.3	1
Intend to Act on Suicidal Thoughts	21	25	1.2	1.04
Intend to Die as Result of Suicidal Action	24	29	1.2	1.2
Make Preparations for Suicide	7	13	1.9	0.5
Self Injury without Intending to Die as Result	1	1	1	0.04
Attempt Suicide	0	0	0	0
Specific Preparation for Suicide	6	25	4.2	1.04
No / Yes		-		
Did Accident Occur	1	1	1	0.04
Intend to Kill Self from Accident	0	0	0	0
Event Counts	•	-	-	•
Count of Passive Suicidal Ideation Events	18	1071	59.5	44.6
Count of Active Suicidal Ideation Events	21	1920	91.4	80
Count of Self Injury Events	12	270	22.5	11.3
Count of Suicide Attempts	0	0	0	0
Count of Specific Preparations Listed	5	7	1.4	0.3
Date Deviation				
Date of Preparation for Suicide	6	8	1.3	0.3
4,000		-		
SM				
Strength of Suicidal Impulse	4	4	1	0.2
Difficulty Suppressing Suicidal Impulse	5	5	1	0.2
Lost Desire to Suppress Suicidal Impulse	14	17	1.2	0.7
Memories Influencing Desire to Suppress Suicidal Impulse	10	11	1.1	0.5
External Events Influencing Desire to Suppress Suicidal Impulse	11	12	1.1	0.5
Level of Hopelessness	20	22	1.1	0.9
Difficulty Being Hopeful	24	26	1.1	1.1
Lost Desire to be Hopeful	24	28	1.2	1.2
Memories Influencing Desire to be Hopeful	17	18	1.1	0.8
External Events Influencing Desire to be Hopeful	20	22	1.1	0.9
IH Questions				
Level of Usual Impulsivity / Caution	0	0	0	0
Level of Usual Hopefullness / Hopelessness	7	7	1	0.3
Totals:	337	3609	202.9	150.4
Note: All values rounded.				
		2044 2045 All		

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 7

The primary areas the deviations occurred in the *S-STS* were in the counts of suicidal ideation, the count of non-suicidal self-injury, the severity and type of suicidal planning, and the seriousness of preparatory behaviors. The minimizations in intent to die and in the seriousness of specific preparatory behaviors are troubling. They suggest the patient was coping better than she really was and this lack of information being shared with the therapist gives the therapist a higher false sense of patient safety.

The primary areas the patient minimized to the therapist in the *SM* were in all of the hopelessness questions, which occurred during all 24 interviews.

The primary area the patient minimized to the therapist in the *IH Questions* were in the level of usual hopefulness / hopelessness and occurred during 7 interviews.

The count of questions where answers for the self-version (days later) deviated from the self-version (for therapist) was 337 deviations on 744 questions across all 24 interviews or 45% of all scale questions.

#### Result 8

Table 12.6.9 is similar to Table 12.6.3 and Table 12.6.6 except it shows the data for the self-version (days later) compared to the self-version (for therapist).

Table 12.6.9. Total Scores for Each Scale and for Overall Interview: Tracking the Self-version (Days Later) Compared to Tracking the Self-version (for Therapist)

	Self-version (Days L	ater) vs Self-version	(for Therapist)	
	The number of interviews when there was a deviation on this total score or overall interview	Aggregate points of deviationon this total score or overall interview across all 24 interviews	Mean deviation (of score) when deviation occurred (column 3 / column 2)	Mean deviation (of score) across all 24 interviews (column 3 / 24)
S-STS Total	22	136	6.2	5.7
SM Total	22	163	7.4	6.8
IH Questions Total	7	7	1	0.3
Overall Interview	23	306	13.3	12.8
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 8

The scale totals deviated between the self-version (days later) and the self-version (for therapist) in almost all scale totals on both the *S-STS* and the *SM*. Considering that the *S-STS* is a 12 question scale with a possible total of 48 points (assuming the patient is still alive and the patient did not engage in multiple preparatory behaviors and / or multiple suicide attempts), the mean deviation on the *S-STS* of nearly 6 points is nearly 12% of highest possible score. Similarly on the *SM* the mean deviation across all interviews of nearly 7 points, with a scale that only has a total of 40 points, results in a mean deviation that is 17% of the highest possible score.

The overall interview between the self-version (days later) and the self-version (for therapist) did not deviate at all on only one interview (4%). The timeframe when this completely truthful interview

occurred had the second lowest *S-STS* total score and the lowest *SM* and *IH Questions* total scores documented throughout all of data collection. The mean deviation across all interviews on the interview totals was nearly 13 points, out of a total of 102 possible points, resulting in a mean deviation that is nearly 13% of the highest total possible points for the overall interview.

#### Result 9

Table 12.6.10 is similar to Table 12.6.4 and Table 12.6.7 except it shows the data for the self-version (days later) compared to the self-version (for therapist).

Table 12.6.10. Notes: Tracking the Self-version (Days Later) Compared to Tracking the Self-version (for Therapist)

Self-version	Days Later) vs Self-	version (for Therap	oist)	
	The number of interviews when there was a deviation on this note topic	Aggregate points of deviation on this note topic across all 24 interviews	Mean deviation (of count) when deviation occurred (column 3 / column 2)	Mean deviation (of count) across all 24 interviews (column 3 / 24)
			_	
Notes Relating to Therapist	3	3	1	0.1
Example:				
"Purposely delayed any appointments with [therapist] until able to focus on something other than suicidality."				
Notes Relating to Planning An Attempt	10	11	1.1	0.5
Examples:				
"Frequently considering the 13th of July as a date."				
"Still considering the end of July, but with less intent than in				
previous time frames."				
Notes Relating to Current Severity of Suicidality Symptoms	8	11	1.4	0.5
Examples:				
"Intent to act has lessened."				
"Experiencing complete lack of desire to continue living while completing interview."				
"Experiencing passive and active ideation while completing interview."				
Notes Relating to Current Physical Symptoms	1	1	1	0.04
Example:				
"Consistent headaches Wednesday through present."				
Note: All values rounded.				

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 9

The information that deviated between the notes for self-version (days later) and the self-version (for therapist) is in notes *relating to* the therapist, to planning an attempt, to the current severity of suicidality symptoms, and to current physical symptoms. The amount of deviation on note topics was minimal compared to the answers on the scales. However, some of the details in the note topics that deviated were important notes. These notes contained or left out information for the therapist to know in order to help keep this patient safe.

#### Patient Commentary on Results 7 - 9

When presented with the data in Tables 12.6.8 - 12.6.10 the patient was not surprised by these results after seeing the prior results. The patient said, "it makes sense that the deviations would be higher since there is distance between the symptoms I had during and immediately surrounding the interview for the therapist. The distance in time allows me to better acknowledge those symptoms." The patient went on to say, "I don't think I would have expected so many deviations to happen here if I had

not already seen the prior tables. The reality of this is difficult for me emotionally. I really thought I had a good relationship with [the therapist] at the time I did these interviews. At the same time I also saw a psychiatrist and could not have been anywhere near as honest with [the psychiatrist] as I was with [the therapist] out of fear [the psychiatrist] would really overreact and I would end up in the hospital every few weeks."

Highest Deviation in the Same Timeframe

#### Result 10

Table 12.6.11 shows the highest aggregate points of deviation on the total scale scores for the three interviews. It also shows the percentage of those aggregate points of deviation divided by the highest possible scale scores. (Forty-eight points was used as the highest possible scale score for the *S-STS* because this is the highest possible scale score if the patient is still alive and does not engage in multiple preparatory behaviors and / or multiple attempts.)

Table 12.6.11. Highest Deviations for Each Scale

riighest Deviations for Lacif Sca				
Hig	ghest Deviation			
	Highest aggregate points of deviation on total score within the same timeframe	on total score v	within the s al possible s	nts of deviation ame timeframe cale points ale points <sup>1</sup> ) * 100
S-STS				
	42	,	27.40/	
Self-version (Immediate) vs Self-version (for Therapist)	13	,	27.1%	
Self-version (Immediate) vs Self-version (Days Later)	3		6.3%	
Self-version (Days Later) vs Self-version (for Therapist)	13		27.1%	
SM				
Self-version (Immediate) vs Self-version (for Therapist)	16		40%	
Self-version (Immediate) vs Self-version (Days Later)	5		12.5%	
Self-version (Days Later) vs Self-version (for Therapist)	16		40%	
·				
IH Questions				
Self-version (Immediate) vs Self-version (for Therapist)	1		7.1%	
Self-version (Immediate) vs Self-version (Days Later)	0		0	
Self-version (Days Later) vs Self-version (for Therapist)	1		7.1%	
Nata All select recorded	Tatal Bassible Code Bai	C CTC 40	C14 40	#1 Quarties a
Note: All values rounded.	Total Possible Scale Poi	nts: S-STS = 48	SM = 40	IH Questions = 1

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 10

The highest aggregate points of deviation between the 2 exclusively self-versions (immediate and days later) on the one side and the self-version (for therapist) on the other side have the same values here (27%). This is because the timeframes with the highest deviations between these versions were the times the patient was able to be completely honest with herself (but not necessarily with the therapist) about the symptoms of her suicidality. When comparing the self-version (immediate) to the self-version (days later), the highest aggregate points of deviation and the percentage of those aggregate points of deviation ranged from 0 to 13% for the 3 scales. When comparing the 2 exclusively self-versions (immediate and days later) on one side versus the self-version (for therapist) on the other there was a deviation of 27% and 40% of total possible scale points on the *S-STS* and *SM*, respectively. This appears to be clinically relevant. These findings are consistent with the findings and commentary related to Results 2, 5, and 8.

#### Result 11

Table 12.6.12 shows the highest aggregate points of deviation on the overall interview for the three interviews. It also shows the percentage of those aggregate points of deviation divided by the highest possible scale points.

Table 12.6.12. Highest Deviations By Overall Interview

	<b>Highest Deviation</b>	
	Highest aggregate points of deviation on overall interview within the same timeframe	% of highest aggregate points of deviation on overall interview within the same timeframe out of total possible scale points (column 2 / total possible interview points <sup>1</sup> ) * 100
Self-version (Immediate) vs Self-version (for Therapist)	27	26.5%
Self-version (Immediate) vs Self-version (Days Later)	6	5.9%
Self-version (Days Later) vs Self-version (for Therapist)	27	26.5%
Note: All values rounded.		<sup>1</sup> Total Possible Interview Points = 102

Sheehan DV, Giddens JM, Copyright 2014 - 2015. All rights reserved.

#### Commentary on Result 11

The highest aggregate points of deviation between the 2 exclusively self-versions (immediate and days later) on the one side and the self-version (for therapist) on the other side have the same values here (27%). This is because the timeframes with the highest deviations between these versions were the times the patient was able to be completely honest with herself (but not necessarily with the therapist) about the symptoms of her suicidality. These findings are consistent with the findings and commentary related to Results 2, 5, 8, and 10.

#### Discussion

When the patient was presented with the data reported in this paper she made several cogent observations that merit consideration.

She noted that it would be difficult for any type of psychotherapy developed specifically for suicidality to be fully effective if a patient with suicidality cannot be completely honest with their therapist (or even with themself) about the nature and extent of their suicidality. However, this need to withhold information for a variety of reasons about suicidality seems to be inherent in the nature of communications between people about this topic at this point in our culture.

The patient suspected that when she completed the interviews in the middle of a flare up in her symptoms of suicidality, the deviation in answers was greater than when the interviews were done with some distance from the flare up in symptoms. There were times the patient minimized active ideation to the therapist, but exaggerated passive ideation to make up for the minimization.

There are countless types of patient ratings, all dependent upon the viewer of the scale and the relationship the patient has with that viewer.

While referring to the therapist and the psychiatrist the patient was seeing at the time of data collection, the patient stated:

I went to these people for help, but I couldn't be honest with them. I see this problem as 4-fold. The first part is my responsibility since I am not completely honest with them because I'm afraid to trust them. The second part of it is their responsibility since they make it difficult for me to share details of my suicidality by either overreacting or by clearly showing how uncomfortable they are with the subject. The third part relates to my prior experiences with other health care providers who have overreacted, refused to listen to me, or labeled me as 'borderline' so they could justify ignoring my suicidality all together or considering me unreliable. The final part is the responsibility of lawmakers who, in hopes of keeping people from attempting suicide, have created laws requiring clinicians to put us in the hospital just because they are concerned we will make a suicide attempt. Similar legislation allows judges to keep us in hospitals for extended periods if they think we are likely to make a suicide attempt. Even short-term hospitalizations can disrupt my life to the point that I end up more suicidal. This is partially due to the social stigma associated with consistent suicidality. All of these parts of the issue collide every time a clinician asks me about my suicidality and I have to weigh all of this in my mind before even attempting to answer them.

The potential value of using multiple self-ratings in assessing suicidality along the lines outlined above needs further investigation. For example, a patient purchased a gun, which he intended to use to make a suicide attempt last month. The following week he completed a self-rated suicidality assessment at his psychiatrist's office and failed to acknowledge the purchase of the gun. It is possible that at a later time in the future he may be more willing to provide information and details relating to this gun purchase. However, if the clinician always assumes the patient is being honest with them during the initial interview about the timeframe under scrutiny, the clinician will never ask the patient again about the timeframe in which he purchased the gun. Clinicians should consider regularly asking patients if there is any information about their suicidality that they now feel comfortable discussing that they did not share in the past. Such a statement conveys to patients that the clinician understands that they feel a need to temporarily withhold some information. If this question is regularly asked, patients also learn that the clinician remains open to and accepts their need to discuss these things when they are ready.

The patient's notes also reflect her recurrent wish that a clinician would ask "what do you (the patient) need from me (the clinician)?" instead of assuming that they know what the patient needs at any point in time.

#### Limitations

The limitations of this study are that it is a case report on one subject. The subject may be outlier and the findings may not be generalizable to other cases of suicidality. After data collection the patient stated "it's possible some of the answers are skewed because I knew [the authors] would review the data at some point in the future." The patient continued by stating "that the answers might have been different if I knew I would never look at the data and / or if I knew no one else would ever look at the data, including [the authors] and myself. I feel that I could be completely honest about my symptoms if no one would ever see the results. Just knowing that I might look at the results at some point in the future may have had an impact upon my honesty." This issue may have influenced both the version

for the patient alone (self-version [immediate]) and the self-version collected days later. However great the deviations reported above appear to be they might have been even greater if the patient had kept a database of the 100% honest phenomena reports that no one else, including herself, would ever see in the future.

#### Conclusion

In the final analysis data collected using a self-rated symptom suicidality scale about is not one data collection event that reliably captures unchanging data reflecting the patient's perception about their symptoms during a specific timeframe. It can vary significantly depending on the context, the timing, and the relationship between the patient and the scale reviewer. The same issues might also relate to clinician-rated suicidality scales.

## 13

# One Hypothesis to Guide the Development of Specific Anti-Suicidality Medications

#### Introduction

Magnesium is a chemical element. It is the 4<sup>th</sup> most common element on planet Earth, the 4<sup>th</sup> most abundant metal ion in cells (per mole) and the 11<sup>th</sup> most abundant element in the human body. It belongs to the Group 2 alkaline earth metals of the periodic table. It has a similar electron configuration and crystal structure to the other five elements in this group, including calcium and sodium. It plays a central role in cellular and enzymatic function. Enzymes that use nucleotides to synthesize DNA and RNA are magnesium2+dependent. It has a stabilizing effect on excitatory neuronal action. It stabilizes cell membranes. It is a common ingredient in laxatives. It was reported in 1618 to help rashes and scratches.

Although the site of action of the high magnesium / low calcium intake regimen described in Chapters 9.1 and 12.3 in not known, we hypothesize that its action relevant to the treatment of suicidality is at the NMDA receptor, and specifically in stabilizing the firing of voltage sensitive trans-membrane segment 4 of voltage-gated NMDA receptors.

#### What are NMDA Receptors?

The NMDA receptor is an ionotropic glutamate receptor around a calcium channel. It is important in the control of synaptic plasticity, synaptic integration and gene expression.

Figure 13.0.1: The NMDA Receptor Complex in the Resting State

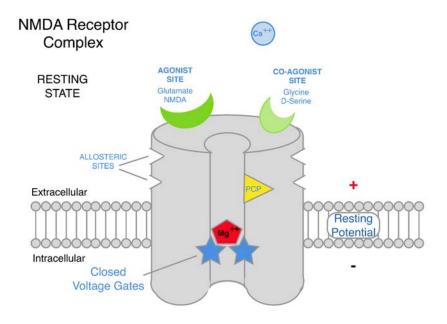
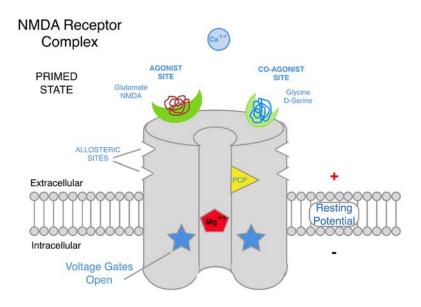


Figure 13.0.2: The NMDA Receptor Complex in the Primed State



Sheehan DV, Sheehan MF, Copyright 2015. All rights reserved.

NMDA Receptor Complex AGONIST **CO-AGONIST DEPOLARIZED** SITE STATE Glutamate **NMDA** Glycine D-Serine ALLOSTERIC SITES Extracellular Resting Potential Intracellular **Voltage Gates** Open

Figure 13.0.3: The NMDA Receptor Complex in the Depolarized State

Extracellular Mg2+ blocks these ion channels at rest. Priming of these receptors results in the opening of the "gates" in the calcium ion channel. This priming is voltage-dependent and ligand-gated. The receptor's ligand gating is co-activated at 2 agonist sites (one called an agonist and the other the co-agonist site), one by glutamate or NMDA and the other by glycine or D-serine. The transit of a negative charge along the extracellular space immediately outside the voltage gated channel results in the displacement of the Mg2+, pulling it out of the channel, and opening up the channel for the influx of Ca2+. In addition, the inflow of Ca2+ and Na+ ions into the cell, and K+ out of the cell is voltage-gated.

Voltage sensitive calcium channels (VSCCs) are not structured as depicted in cartoon illustrations showing a pipe running through a membrane (as in Figures 13.0.1 - 13.0.3 above). They are long "slinky-like" structures, made up of amino acids, with unusual shapes, which change their configuration and opening frequency in response to a stimulus. The main channel pore, known as the alpha1 unit, is structured from 4 subunits. Figures 13.0.4 and 13.0.5 below depict a horizontal cross section of the main channel pore made up of these 4 subunits. Figure 13.0.6 below depicts one of these 4 subunits. Each subunit is believed to have 6 trans-membrane segments (labeled 1 through 6 in the graphics).

Figure 13.0.4: A Horizontal Cross Section of the 4 Subunits of the alpha1 unit of the NMDA Receptor Complex in the Resting State

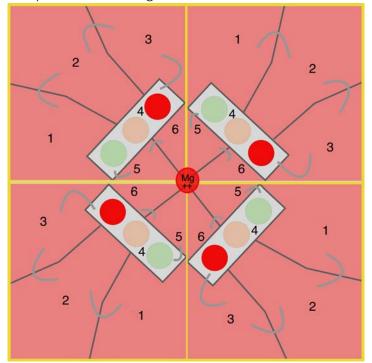
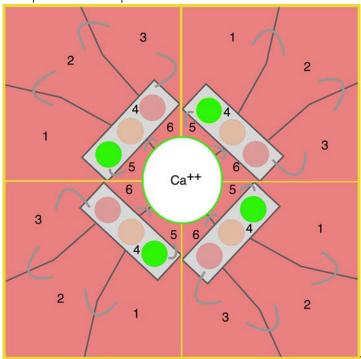


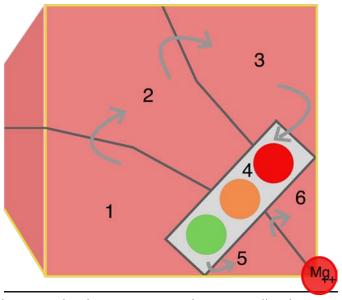
Figure 13.0.5: A Horizontal Cross Section of the 4 Subunits of the alpha1 unit of the NMDA Receptor Complex in the Depolarized State



Sheehan DV, Sheehan MF, Copyright 2015. All rights reserved.

Figure 13.0.6: A Horizontal Cross Section of one of the 4 Subunits of the alpha1 unit of the NMDA Receptor Complex in the Resting State

One of 4 Subunits of Alpha1 unit of the NMDA Receptor



The role of trans-membrane segment 4 is to act like a voltmeter and to detect the change in ion charge across the cell membrane. Depolarization of the neuron activates voltage-sensitive trans-membrane segment 4. This segment then communicates this information to the rest of the protein. In response the protein changes its shape in a way that allows the channel to open. These actions trigger the displacement of Mg2+ from within the ion channel. Alterations in the firing rate of segment 4 can lead to an increase in the frequency of the opening of the ion channel.

Both the ligand and voltage gates are closed at rest. There is no action at the agonist or co-agonist sites in the resting state. During the resting phase Mg2+ blocks the ion channel. Three things are necessary before the NMDA receptor complex ion channel opens. Glutamate must occupy its NMDA binding site, glycine must occupy its NMDA binding site and depolarization must occur. First the ligand-gates are activated by the two co-ligands glutamate and glycine (both are amino acids and co-transmitters). But the Mg2+ remains in place, and the channel does not open until the trans-membrane action potential changes and the neuron is depolarized, and in turn the voltage-dependent trans-membrane segment 4 is activated. The ligand and the voltage gates now open up. This leads to displacement of the Mg2+ from within the ion channel. When the ligand and voltage gates are opened up, Ca2+ and Na+ flow into the cell and K+ flows out. In turn this is excitatory or activating to the cell's specific function. Between trans-

membrane segments 5 and 6 is an extracellular amino acid loop. This loop acts as an "ionic filter" which regulates the influx of calcium into the cell.<sup>1</sup>

#### The Turbulent Calcium Channel in the NMDA Receptor (TCCN) Hypothesis of Suicidality

We hypothesize that in some suicidality disorders, and especially in Impulse Attack Suicidality Disorder, that this voltmeter trans-membrane segment 4, is over firing in a fibrillation like fashion or like the hyper-peristalsis in an irritable bowel syndrome.

Trans-membrane segment 4 we hypothesize acts like a pacemaker in the heart to signal the frequency or rate of gate opening and gate closing of the alpha1 subunit. This is not unlike the AV node in the heart firing and signaling the muscle in a heart chamber to contract or to signaling for the peristalsis action in the gastro-intestinal tract. Segment 4 is like the trigger for an oscillator. The ion channel in the healthy state oscillates in a predictable way in response to this firing. However if the trigger over-fires, the oscillation rate will increase. The greater the over-firing, the more turbulent the oscillations become, the greater the turbulence within the channel, until finally the turbulence becomes "chaotic", like water in a river with ever rapid currents flowing in a chaotic, turbulent manner, in response to a sudden flood. It is also like atrial fibrillation in response to rapid firing of cardiac stimuli, and finally appearing "chaotically" out of control. The resulting "chaotic" flows now resemble complicated aperiodic motion<sup>2</sup>, the non-linear dynamics in non-linear systems theory, or the effects seen in "chaos" science or non-linear turbulence theory<sup>3</sup>. This apparent non-linear chaos within the ion channel has its own order, but it is a non-linear order and can be best understood in the context of non-linear dynamics<sup>4 5 6</sup>. It is also consistent with the non-linear dynamics seen in the natural history and symptom progression of the suicidality as they progressed over time and reflected in the case of Impulse Attack Suicidality Disorder (IASD) described in chapters 6.2 and 12.3 and its devolution to equilibrium in the response to treatment with high magnesium and low calcium in the case described in chapters 9.11 and 12.3.

The physiology of the firing action of transmembrane segment 4 merits more investigation. Ligand gating receives more attention in psychopharmacology than voltage gating, because it is easier to understand pharmacologically, and it appears to provide more opportunities for pharmacological manipulation.

<sup>&</sup>lt;sup>1</sup> The authors wish to acknowledge the indebtedness to Stahl's Essential Psychopharmacology, 4<sup>th</sup> Edition, Cambridge University Press, Cambridge, United Kingdom, 2013 for this understanding of voltage sensitive Calcium Channels.

<sup>&</sup>lt;sup>2</sup> Edward N Lorenz. The Essence of Chaos. University of Washington Press. Seattle 1993.

<sup>&</sup>lt;sup>3</sup> James Gleik. Chaos: Making a New Science. Penguin Books. New York, New York. 2008.

<sup>&</sup>lt;sup>4</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> Edward N Lorenz. The Essence of Chaos. University of Washington Press. Seattle 1993.

<sup>&</sup>lt;sup>6</sup> Stewart I. Does God Play Dice?: The New Mathematics of Chaos. 2<sup>nd</sup> Edition. 1997. Blackwell Publishing. Malden, Massachusetts, USA.

There are feedback loops in voltage gated ion channels. Disruptions can occur in these feedback loops. It is possible that Mg2+, which is known to be a signaling molecule, has an important in these feedback loops and a role in modulating and restoring to equilibrium of the above-hypothesized dysregulation of electrical firing action of transmembrane segment 4. It is possible that single nucleotide polymorphisms in genes that code for magnesium transport proteins could contribute to the failure of such proteins to function properly in transporting magnesium across cell membranes. This could lead to magnesium being less available to modulate this electrical firing action and to irregularities in the electrical firing that regulates voltage gated calcium ion channels.

#### Restoring Equilibrium from Non-Linear Chaos

We posit that the effect of the high magnesium / low calcium dietary intake regimen is to restore the equilibrium seen in the healthy state. The over firing of trans-membrane segment 4 could result from a structural defect in the configuration of the amino acids in the NMDA receptor complex, requiring segment 4 to over fire against resistance in the channel structure. It could also be due to a defect in the structure or physiology of transmembrane segment 4 itself, leading to over firing, like a sick sinus syndrome in cardiology. Any of these could result from a single nucleotide polymorphism in one of the genes associated with suicidality. This pattern is consistent with the non-linear, chronic, persistent and impulsively chaotic nature of Impulse Attack Suicidality Disorder (IASD) and its failure to return to equilibrium on its own. Yet in response to high magnesium / low calcium, healthy equilibrium is restored and maintained for as long as this regimen is maintained (See the case study on Magnesium treatment in Chapter 12.3). We posit that the final common pathway for anti-suicidality drug development is to reset the oscillator / trigger by getting it to stop firing in an arrhythmic fashion, to lessen the channel turbulence and to get the oscillator to go back to its correct firing rhythm.

#### How is Ketamine Believed to Work?

Ketamine binds to the PCP site within the NMDA receptor calcium ion channel where phencyclidine binds. This action blocks the excitatory action of glutamate. Ketamine overrides the usual response of the NMDA receptor to fully open its channel in response to depolarization and in turn impedes ion flow through the ion channel<sup>7</sup>.

This effect of ketamine is magnesium sensitive, and apparently magnesium dependent. Ketamine may be better able than other NMDA receptor antagonists to impede ion flow

<sup>&</sup>lt;sup>7</sup> Gideons ES, Kavalali ET, Monteggia LM: Mechanisms underlying differential effectiveness of memantine and ketamine in rapid antidepressant responses. Proc Natl Acad Sci USA 2014; 111:8649–8654.

or perhaps to bind to the binding site within the channel or to resist the receptor's own physiologic magnesium dependent voltage-gating<sup>8</sup> <sup>9</sup>.

Ketamine appears to have magnesium like effects on suicidality, but acts very rapidly within an hour and achieves good anti-suicidality and antidepressant effects that last for 3 - 4 days, before returning to baseline by day 7. Hence the recommended 3 times weekly (Monday - Wednesday - Friday) of ketamine treatments over the first 4 weeks to maintain the anti-suicidality benefit during the initial danger period, during which time other longer acting treatments may have an opportunity to take over the anti-suicidal treatment benefit. There are concerns about the use of ketamine long term, because of its abuse liability and abuse potential, but unknown long-term toxicity. It may be possible to use ketamine acutely in conjunction with other safer anti-suicidality treatments long term. In the meantime, we think there should be more focus on the value and short-term use and development of ketamine for the acute treatment of suicidality, and as a proof of concept medication, than for its use in the long-term treatment of treatment resistant mood disorders. We also think this anti-suicidality indication is a more economically viable indication in the near term. (See Newport DJ et al.<sup>10</sup>).

#### Conclusion

We hope that the above <u>Turbulent Calcium Channel of the NMDA receptor (TCCN)</u> hypothesis outlined above, will have some heuristic value in encouraging others to search for and to develop other anti-suicidality medications like the high magnesium / low calcium regimen presented in Chapters 9.1 and 12.3, even if these medications, like magnesium do not have apparent direct or immediate antidepressant effects. Magnesium coupled with low calcium may have value in some cases of mood disorders, especially in treatment resistant mood disorders by augmenting existing standard treatments, since some of these treatments may need higher magnesium to achieve better efficacy. Magnesium may play a role in the binding of some antidepressants or mood stabilizers, as it does for some antibiotics. It may be important for gene expression.

These findings may also have implications for the modulation of CNS and other conditions that involve dysregulation in the firing of oscillators in voltage gated calcium ion channels (e.g. cardiac arrhythmias, Panic Disorder, Tic Disorders, some epileptic conditions, irritable bowel syndrome).

<sup>&</sup>lt;sup>8</sup> Mealing GAR, Lanthorn TH, Murray CL, et al: Differences in degree of trapping of low-affinity uncompetitive N-methyl-D-aspartic acid receptor antagonists with similar kinetics of block. J Pharmacol Exp Ther 1999; 288:204–210.

<sup>&</sup>lt;sup>9</sup> Mathews DC, Henter ID, Zarate CA Jr: Targeting the glutamatergic system to treat major depressive disorder: rationale and progress to date. Drugs 2012; 72:1313–1333.

<sup>&</sup>lt;sup>10</sup> Newport DJ et al. Ketamine and other NMDA Antagonists: Early Clinical Trials and Possible Mechanisms in Depression. Am J Psychiatry 2015; 172:950-966;doi:10.1176/appi.ajp.2015.15040465.

Non-linear dynamics and non-linear mathematics contributed to improvements in the accuracy and safety of cardiac pacemakers. The TCCN hypothesis may have similar utility in developing neuro-modulation treatments (TMS, ECT, deep brain stimulation, and VNS) through the application of non-linear dynamics theoretical concepts and non-linear differential equations to neuroscience.

# 14

# Appendices of Scales and Related Documents

14.1	S-STS (Sheehan - Suicidality Tracking Scale)
14.2	S-STS CMCM (Sheehan - Suicidality Tracking Scale Clinically Meaningful Change Measure version)
14.3	Pediatric S-STS (Pediatric Sheehan - Suicidality Tracking Scale)
14.4	S-STS Related Documents
14.5	S-STS Validation and Reliability
14.6	SPTS (Suicide Plan Tracking Scale)
14.7	SPTS Related Documents
14.8	SMS (Suicidality Modifiers Scale)
14.9	SIAS (Suicidal Impulse Attack Scale)
14.10	Visit Face Sheet

14.11 MINI 7.0.1 for Suicidality Disorders Studies (Mini International Neuropsychiatric

14.12 MINI 7.0.1 for Psychotic and Suicidality Disorders Studies

Interview)

# 14.1

Sheehan - Suicidality Tracking Scale (S-STS)

Adapted from: Sheehan DV, Giddens JM, Sheehan IS. Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Innov Clin Neurosci. 2014;11(9–10):93–140. <a href="http://innovationscns.epubxp.com/i/425963/92">http://innovationscns.epubxp.com/i/425963/92</a>

#### Introduction

A suicidality scale should assess the full range of suicidality phenomena. It should be capable for use as both a safety and an efficacy outcome measure in research and in clinical settings. In the context of efforts to find and develop anti-suicidality medications, it is important that such a scale be very sensitive in detecting anti-suicidality effects in modest sample sizes.

The Sheehan - Suicidality Tracking Scale (S-STS) was developed to provide a balance of being comprehensive, brief and efficient, yet sensitive to change in assessing suicidality.

The primary goals in the design of the S-STS were for it to be:

- short and inexpensive
- simple, clear and easy to administer or self-rate
- highly sensitive i.e. able to detect a high proportion of patients who are suicidal
- specific i.e. able to screen out those who are not suicidal
- sensitive to change in suicidality
- compatible with FDA categories for prospective assessment of suicidal ideation and behavior
- useful in clinical as well as research settings
- useful in detecting an efficacy signal for anti-suicidality medications (although the S-STS Clinically Meaningful Change Measure [CMCM] version is more ideal for this purpose)
- capable of use in pediatric settings (although the 3 linguistically validated pediatric versions of the S-STS are more ideal for this purpose)
- capable of use in geriatric settings

Because of the risks associated with suicidality and in the interest of safety, the expectations and hurdles for such a suicidality scale are higher than for other scales in psychiatry. To meet these expectations and in response to much valuable feedback, the S-STS has evolved over time. This chapter provides a 2014 version of the standard S-STS (in contrast to the S-STS CMCM and the 3 pediatric versions of the S-STS).

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS)

INSTRUCTIONS: PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY, TIME SPENT AND TIME FRAME IN YOUR RESPONSES.
THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT, EXPERIENCE OR BEHAVIOR "DID NOT OCCUR AT ALL".
THROUGHOUT THE SCALE THE WORD INTEND OR INTENT MEANS ANY INTENTION GREATER THAN ZERO. SCORE THE MOST SERIOUS EPISODE THAT OCCURRED.

In th	ne past (timeframe):					
1.	did you have any accident? (this includes taking too much of your medication accidentally) IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:		NO $\square$	Y	ES 🗌	
1a.	how seriously did you plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?  IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), SKIP TO QUESTION 2.  IF THE SCORE IS 1 OR HIGHER, GO TO QUESTION 1b:	Not at all	A little	Moderately 2	Very 3	Extremely 4
1b.	did you intend to die as a result of any accident?		νο □	Υ	ES 🗆	
In th	the past (timeframe), how seriously did you: think (even momentarily) that you would be better off dead, need to be dead or wish you were dead? How many times?	Not at all	A little	Moderately 2	Very 3	Extremely 4
3.	think (even momentarily) about harming or hurting or injuring yourself – with at least some intent or awareness that you might die as a result – or think about suicide (killing yourself)?  How many times?	0	1	2	3	4
4.	have a voice or voices telling you to kill yourself or have dreams with any suicidal content?  mark either or both:  a voice or voices  a dream	0	1	2	3	4
5.	have any suicide method in mind (i.e. how)? #	0	1	2	3	4
6.	have any suicide means in mind (i.e. with what)? #	0	1	2	3	4
7.	have any place in mind to attempt suicide (i.e. where)? * #	0	1	2	3	4
8.	have any date / timeframe in mind to attempt suicide (i.e. when)?*#	0	1	2	3	4
9.	intend to act on thoughts of killing yourself?  mark either or both: did you intend to act:   at the time   at some time in the future	0	1	2	3	4
10.	intend to die as a result of a suicidal act?  mark either or both: did you intend to die:   at the time   at some time in the future	0	1	2	3	4
11.	feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  mark either or both: was this:	0	1	2	3	4
12.	take active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)?	0	1	2	3	4
13.	injure yourself on purpose without intending to kill yourself? How many times?	0	1	2	3	4
14.	attempt suicide (try to kill yourself)?	0	1	2	3	4

"A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him- or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.

A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1,2</sup>). \* Note: Items 7 & 8 on S-STS ("a plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). Both events can occur separately over the same timeframe. # Note: clinician should ask for details.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - EVENTS REPORT

#### 15. IF ANSWER 14 IS POSITIVE ASK:

In the past (timeframe), how many times did you attempt suicide?								
When?	How?	How serious was each attempt?						
dd/MMM/yyyy		Not at all	A little	Moderately	Very	Extremely	Level	
1.		0	1	2	3	4		
2.		0	1	2	3	4		
3.		0	1	2	3	4		
4.		0	1	2	3	4		
5. Add rows as neede		0	1	2	3	4		
Level 1: You started the suicide attempt, but then you decided to stop and did not finish the attempt.  Level 2: You started the suicide attempt, but then you were interrupted and did not finish the attempt.  Level 3: You went through the suicide attempt completely as you meant to.  16. IF ANSWER 12 IS POSITIVE ASK:  In the past (timeframe), how many times did you take active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)? (Include only the times when you stopped short of making an actual suicide attempt.)								
When?	How?	How ser	ious was	each prepa	ration?			
dd/MMM/yyyy  1.		Not at all	A little	Moderately 2	Very	Extremely 4	Level	
2.		0	1	2	3	4		
3.		0	1	2	3	4		
4.		0	1	2	3	4		
5. Add rows as neede		0	1	2	3	4		
Level 1: You took active steps to prepare to kill yourself, but you did not start the suicide attempt.  Level 2: You were about to try to kill yourself, but then you stopped yourself just before harming yourself.  Level 3: You were about to try to kill yourself, but then someone or something stopped you just before harming yourself.  TIME SPENT PER DAY WITH ANY SUICIDAL IMPULSES, THOUGHTS OR ACTIONS OVER THE PAST (TIMEFRAME):  Usual time spent per day: hours minutes.  Least amount of time spent per day: hours minutes.  Most amount of time spent per day: hours minutes.								

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - CLINICIAN USE ONLY

Complete this section *if the patient does not return for the scheduled follow up visit* and is not available to permit completion of pages 1 and 2.

FOR CLINICIAN USE C	ONLY			NO	YES	
17. Missed appointment - reason: subject died from a completed suicide?						
18. Missed appointme	ent - reason: subject died, but r	not enough information to code as a suicide	e?	0	0	
19. Missed appointme	ent - reason: subject died from	cause(s) other than suicide?		0	0	
20. Missed appointme	ent - reason: subject alive, but r	not available because of a suicide attempt?	,	0	4	
21. Missed appointme	ent - reason: subject alive, but r	not available for known reasons other than	suicide?	0	0	
22. Missed appointme	ent - reason: subject alive, but r	not available, for uncertain reasons, or "los	t to follow up"?	0	0	
Total Scale Score		a + 2 through 11 + [the highest of ighest of 14 or any row of 15] + 17 + 20	TOTAL			
☐ I have reviewed	the answers on Pages 1 and 2	with the patient.				
Clinician Signatu	ure	dd/MMM/yyyy				
□ I have reviewed	I the answers on Pages 1 and 2	with my doctor or clinician.				
Patient Signatur	re	dd/MMM/yyyy				

#### References

- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

The author is grateful to JM Giddens for very valuable advice in the development of the S-STS and of the S-STS CMCM versions.

#### Conclusion

The S-STS allows clinicians to assess and monitor suicidality in clinical, research, and other settings. The above 2014 version of the S-STS and the related documents in the following chapters provide clinicians, researchers, and those charged with the responsibility to assess and monitor suicidality, answers to frequently asked questions on the current version of the scale. The following chapters also contain the S-STS CMCM version, the 3 pediatric versions of the S-STS, and information on the validity and reliability of the S-STS.

## 14.2

Sheehan - Suicidality Tracking Scale
Clinically Meaningful Change Measure Version (S-STS CMCM)

Adapted from: Sheehan DV, Giddens JM, Sheehan IS. Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Innov Clin Neurosci. 2014;11(9–10):93–140. http://innovationscns.epubxp.com/i/425963/92

#### Introduction

The Clinically Meaningful Change Measure (CMCM) version of the S-STS is a much more expanded version of the standard S-STS. It was developed to specifically test the anti-suicidality effects of medications. The S-STS CMCM was designed to address an expectation of European regulators that any drug given regulatory approval for an anti-suicidality indication should demonstrate a clinically meaningful change. This clinically meaningful change effect should be in addition to showing statistically significant superiority over a placebo on a suicidality scale, given the risks and gravity related to suicidality. The effects of an anti-suicidality medication should be impressive enough so that it is able to alter the clinician's judgment of risk and decisions about the acute clinical management or disposition of the case. The S-STS CMCM is designed to meet

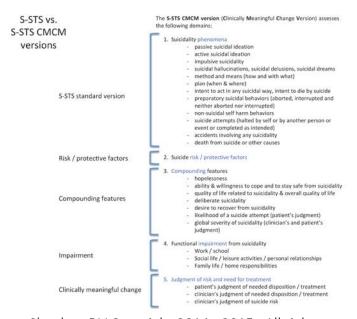
that need. The S-STS CMCM shows the additional domains that should be altered by an anti-suicidality treatment and how these domains are measured, anchored, and analyzed (as seen in the chapter on S-STS scoring instructions), in a way that any clinician can judge the extent of an anti-suicidality medication's clinically meaningful effect.

The S-STS CMCM version can be helpful in more thoroughly assessing and treating suicidal patients. It affords the clinician a bigger picture view of the patient's suicidality and opens doors in exploring and identifying areas of therapeutic importance for individual patients.

#### Organizational Structure of S-STS CMCM

The CMCM version of the S-STS is organized into 5 conceptual sections (see figures 14.2.1 and 14.2.2 below). Section one covers the suicidality phenomena. This section is identical to the standard S-STS. The second section provides an opportunity to rate a series of risk or protective factors that might be important aggravating or relieving factors in the subject's suicidality. The third section is a series of 11-point (0–10) discretized visual analog (DISCAN) scales on which a patient can rate various compounding features (e.g. their ability and willingness to cope with their suicidality, their ability and willingness to "stay safe," the extent to which their suicidality is deliberate, the extent to which it is impulsive, and the extent to which it has impacted the quality of the patient's life). The fourth section measures the extent to which the suicidality has impaired the patient's work, social, or family life. The fifth section of the S-STS CMCM rates the judgment of risk and level of treatment needed.

Figure 14.2.1: Organizational Structure of S-STS CMCM vs. S-STS Standard Version



Sheehan DV Copyright 2014 - 2015. All rights reserved.

Figure 14.2.2: S-STS CMCM Clusters Contributing to Judgment of Risk and Treatment Needed

# Risk / protective factors Suicidality phenomena Judgment of suicide risk

#### Judging risk and treatment needed in clinical practice

Sheehan DV Copyright 2014 - 2015. All rights reserved.

#### Operational Use S-STS CMCM

In practice the easiest way to use it is as follows: pages 1 and 2 can be patient-rated or clinician-rated; pages 4 through 10 are patient-rated; and the clinician reviews pages 1 through 10, asks any additional probe questions the clinician deems necessary to complete the assessment, and then completes pages 12 and 13. The scale can be used in other patient-rated / clinician-rated formats, but the above appears to be the most efficient for most settings. The lower portion of page 13 (questions 17 through 22) is completed by the clinician only if the patient misses a follow up appointment, and is not available to complete the scale.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS CMCM Version)

**INSTRUCTIONS**: PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY, TIME SPENT AND TIME FRAME IN YOUR RESPONSES. THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT, EXPERIENCE OR BEHAVIOR "DID NOT OCCUR AT ALL". THROUGHOUT THE SCALE THE WORD **INTEND OR INTENT** MEANS ANY INTENTION GREATER THAN ZERO. SCORE THE MOST SERIOUS EPISODE THAT OCCURRED.

In th	ne past (timeframe):					
1.	did you have any accident? (this includes taking too much of your medication accidentally) IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:		NO $\square$	Y	ES 🗌	
1a.	how seriously did you plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?  IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), SKIP TO QUESTION 2.  IF THE SCORE IS 1 OR HIGHER, GO TO QUESTION 1b:	Not at all	A little	Moderately 2	Very 3	Extremely 4
1b.	did you intend to die as a result of any accident?		NO $\square$	Υ	ES 🗆	
In th	the past (timeframe), how seriously did you: think (even momentarily) that you would be better off dead, need to be dead or wish you were dead? How many times?	Not at all	A little	Moderately 2	Very 3	Extremely 4
3.	think (even momentarily) about harming or hurting or injuring yourself – with at least some intent or awareness that you might die as a result – or think about suicide (killing yourself)?  How many times?	0	1	2	3	4
4.	have a voice or voices telling you to kill yourself or have dreams with any suicidal content?  mark either or both:  a voice or voices  a dream	0	1	2	3	4
5.	have any suicide method in mind (i.e. how)? #	0	1	2	3	4
6.	have any suicide means in mind (i.e. with what)? #	0	1	2	3	4
7.	have any place in mind to attempt suicide (i.e. where)? * #	0	1	2	3	4
8.	have any date / timeframe in mind to attempt suicide (i.e. when)?*#	0	1	2	3	4
9.	intend to act on thoughts of killing yourself?  mark either or both: did you intend to act:   at the time   at some time in the future	0	1	2	3	4
10.	intend to die as a result of a suicidal act?  mark either or both: did you intend to die:  at the time at some time in the future	0	1	2	3	4
11.	feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  mark either or both: was this:	0	1	2	3	4
12.	take active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)?	0	1	2	3	4
13.	injure yourself on purpose without intending to kill yourself?  How many times?	0	1	2	3	4
14.	attempt suicide (try to kill yourself)?	0	1	2	3	4

"A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him- or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.

A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1.2</sup>). \* Note: Items 7 & 8 on S-STS ("plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). Both events can occur separately over the same timeframe. # Note: clinician should ask for details.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS CMCM Version) - EVENTS REPORT

#### 15. IF ANSWER 14 IS POSITIVE ASK:

In the past (timeframe), how many times did you attempt suicide?								
When?	How?	How serious was each attempt?						
dd/MMM/yyyy		Not at all	A little	Moderately	Very	Ex <u>treme</u> ly	Level	
1.		0	1	2	3	4		
2.		0	1	2	3	4		
3.		0	1	2	3	4		
4.		0	1	2	3	4		
5. Add rows as need		0	1	2	3	4		
Levels of Attempt (halted by self, by another person or event, or not at all)  Level 1: You started the suicide attempt, but then you decided to stop and did not finish the attempt.  Level 2: You started the suicide attempt, but then you were interrupted and did not finish the attempt.  Level 3: You went through the suicide attempt completely as you meant to.  16. IF ANSWER 12 IS POSITIVE ASK:  In the past (timeframe), how many times did you take active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)? (Include only the times when you stopped short of making an actual suicide attempt.)								
When?	How?	How ser	ous was	each prepa	ration?			
dd/MMM/yyyy		Not at all	A little	Moderately 2	Very 3	Extremely 4	Level	
2.		0	1	2	3	4		
3.		0	1	2	3	4		
4.		0	1	2	3	4		
5. Add rows as need	ded.	0	1	2	3	4		
Level 1: You took active steps to prepare to kill yourself, but you did not start the suicide attempt.  Level 2: You were about to try to kill yourself, but then you stopped yourself just before harming yourself.  Level 3: You were about to try to kill yourself, but then someone or something stopped you just before harming yourself.  TIME SPENT PER DAY WITH ANY SUICIDAL IMPULSES, THOUGHTS OR ACTIONS OVER THE PAST (TIMEFRAME):  Usual time spent per day: hours minutes.  Least amount of time spent per day: hours minutes.								
Most amount of time spent per day: hours minutes.								

## **PATIENT RATED PAGES**

# **Clinically Meaningful Change Measures for Suicide Outcomes Assessment**

(S-STS CMCM VERSION, PATIENT RATED DOMAINS ARE ON PAGES 4 THROUGH 10)

## **Current Factors to Consider in Making the Clinically Meaningful Change Assessment**

Some consider the factors below as risk factors for suicidality. However they are all not necessarily so and sometimes they can be protective factors. The impact of each factor can change over time within an individual.

The factors are intended to serve as useful prompts during the evaluation and in tracking both initial and newly emerging factors during follow up. If any of the factors disturb you, please discuss it with your clinician.

Indicate the impact of the factors below on your suicidality over the past (timeframe).

	Factor	Does Not Apply	Lessens Suicidality A lot	Lessens Suicidality Moderately	Lessens Suicidality A little	No impact on Suicidality	Increases Suicidality A little	Increases Suicidality Moderately	Increases Suicidality A lot
	Suicidality		71.00	oue.uce.y	71	ou.o.uu,	71	oue.uce.y	71.00
1	Any suicidal impulses, ideation and behavior from pages 1 & 2 of the S-STS CMCM	0	0						0
2	Amount of time spent daily with suicidal ideation and behaviors								
3	Feeling a need to make an attempt sooner rather than later								
4	Hearing voices telling or commanding you to kill yourself or someone else								
5	Overwhelmed feeling								
6	Exhaustion from struggling against suicide								
7	Hopeless feeling or nothing to live for								
8	Easy access to guns or means for suicide								
9	Seriousness of past suicide attempt(s)								
10	Religious or spiritual reasons that influence your decision to kill yourself Family / Social								
11	Recent loss or death of a loved one								
12	Recent anniversary of the death of a loved one								
13	Recent conflict or break up with family, spouse, partner or close friends		0	0	0	0	0	0	
14	Lonely or socially isolated or homeless								
15	Lack of close family or social support								
16	Withdrawal from family, work or social responsibilities								
17	Bisexual, homosexual or transgender or uncertain sexual or gender orientation with resulting unsupportive family or support system			_					П
18	First or second degree relative with a history of suicidal impulses, ideation or behavior (including attempts or completed suicide)								0

	Factor	Does Not Apply	Lessens Suicidality A lot	Lessens Suicidality Moderately	Lessens Suicidality A little	No impact on Suicidality	Increases Suicidality A little	Increases Suicidality Moderately	Increases Suicidality A lot
	Personal History			,		•		•	
19	Had a recent major life change or loss (e.g. loss of job, school failure, financial loss, gambling loss, mounting financial debt)								
20	Recent trouble with the law or serious legal problems or recent incarceration								
21	Recent deep sense of shame or loss of reputation								
22	Survivor of sexual abuse, sexual violence or rape								
23	Survivor of violence, torture bullying or emotional abuse Witnessed or caused serious								
24	violence or death to another person								
25	Recent military service or service in a war zone or a war survivor								
26	History of or current aggressive or violent behavior or high irritability								
27	Spending time on suicide or death related internet sites								
28	History of impulsive suicidality								
29 30	History of risk taking Male over 55								
	Health								
31 32	Depression or bipolar disorder Panic attacks or high anxiety or								
33	agitation Schizophrenia or schizoaffective								
33	disorder								
34	Alcohol abuse								
35	Substance (drug) abuse								
36	Posttraumatic Stress Disorder								
37	Recent sleep disturbance								
38	Have an "incurable disease" or severe chronic or terminal illness								
39	In severe physical pain (acute or chronic or fluctuating)								
40	Recent unplanned pregnancy or sexually transmitted disease						0		0
41	Recent infection, inflammatory states (allergies or asthma) or an autoimmune disease flare up (e.g. Crohn's Disease, Lupus or	_					_		
	Multiple Sclerosis)								
42	Head injury								
43	Unable to get needed psychiatric treatment or medication								
44	Switched from a medication or a formulation or a dose that was effective or you were not taking your medication as directed								
45	Recently started on a psychiatric or an antiepileptic medication								
46	Other:								
47	Other:								

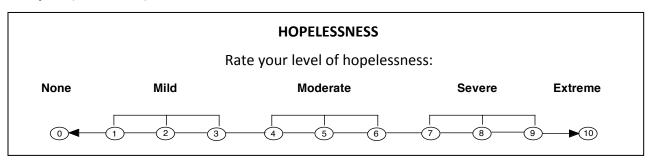
Add and score additional "other" factors as necessary.

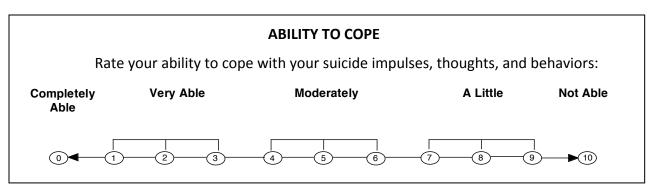
# **SHEEHAN - SUICIDALITY TRACKING SCALE (CMCM Version)**

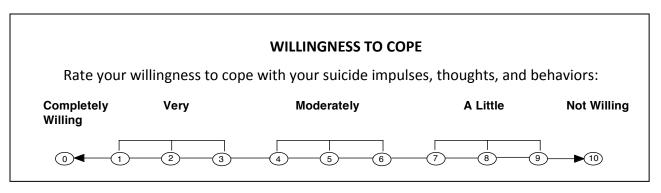
#### CLINICALLY MEANINGFUL CHANGE MEASURES (PATIENT RATED)

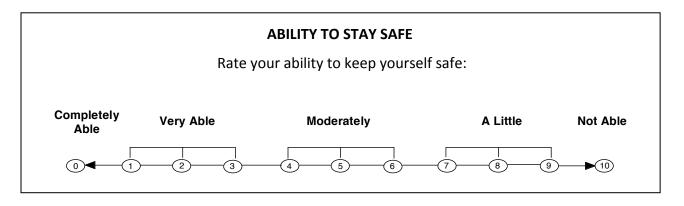
(Please mark ONE circle for each category.)

## In the past (timeframe):

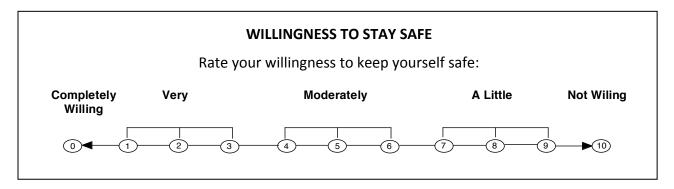


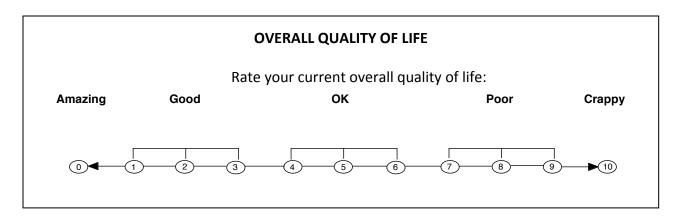


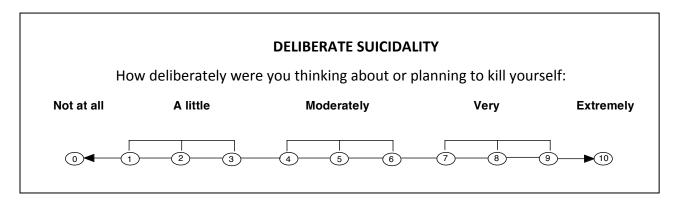


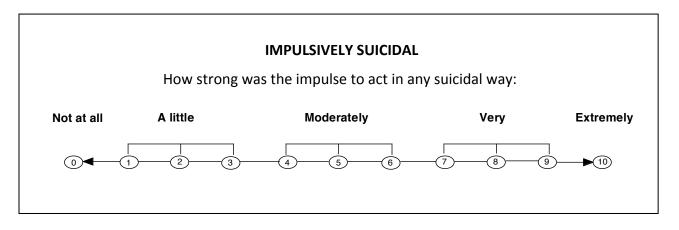


# In the past (timeframe):







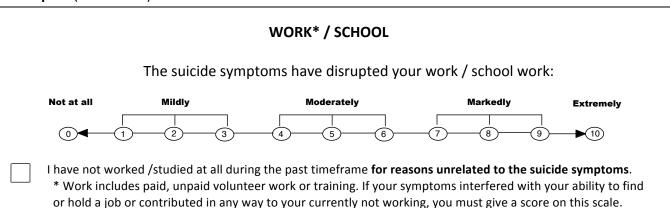


## SHEEHAN - SUICIDALITY TRACKING SCALE (CMCM Version)

#### LIFE IMPAIRMENT FROM SUICIDALITY (PATIENT RATED)

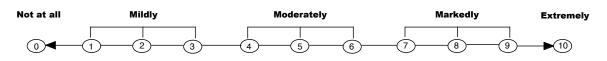
Please mark ONE circle for each category.

## In the past (timeframe):



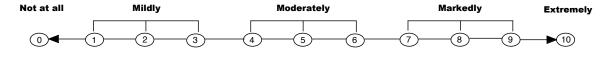
#### **SOCIAL LIFE**

The suicide symptoms have disrupted your social life / personal relationships / leisure activities:



## **FAMILY LIFE / HOME RESPONSIBILITIES**

The suicide symptoms have disrupted your family life / home responsibilities:



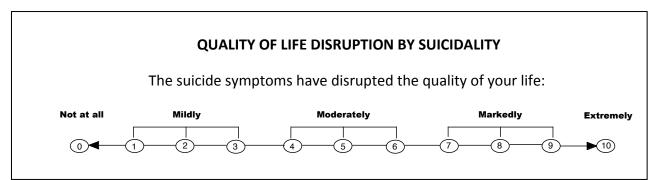
#### DAYS LOST

How many days in the last (timeframe) did you miss from work or school or were unable to carry out your normal responsibilities because of your suicide thoughts, impulses, and behaviors? \_\_\_\_\_

#### DAYS UNDERPRODUCTIVE

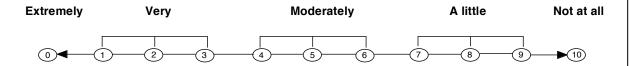
How many days in the last (timeframe) were you less productive while at work or at school or during your daily responsibilities because of your suicide thoughts, impulses, and behaviors? \_\_\_\_\_

## In the past (timeframe):



#### **DESIRE TO RECOVER FROM SUICIDALITY**

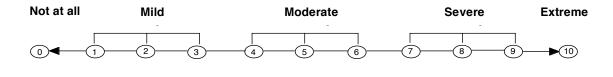
Rate your desire to recover from your suicide impulses, thoughts and behaviors:



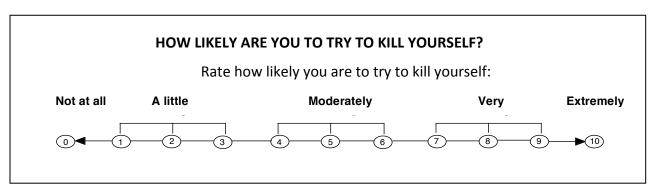
If you can't imagine the possibility of recovery, choose "10"

## GLOBAL SEVERITY OF SUICIDAL IMPULSES, THOUGHTS, AND BEHAVIORS

Rate the overall severity of all your suicide impulses, thoughts, and behaviors:



## Over the next (timeframe):



Patient Rated: Circle the score that best describes your current treatment needs:

# At this time:

Score	Treatment level you think you currently need for suicidal impulses, thoughts or behaviors
10	I need to be in the hospital for more than 24 hours, with someone watching or protecting me at all times and
	I need or I request physical or medication restraints to protect me from trying to kill myself.
	(24/7 inpatient with constant one-on-one observation, possible need or request for physical or chemical
	restraints)
9	I need to be in the hospital for more than 24 hours, with someone watching or protecting me at all times.
	(24/7 inpatient one-on-one)
8	I need to be in the hospital for more than 24 hours, with someone watching or checking on me every 15
	minutes.
	(24/7 inpatient on suicide precautions (e.g. 15 minute checks))
7	I need to be in the hospital for more than 24 hours.
	(24/7 inpatient)
6	I need to be in the hospital for more than 24 hours and be allowed to leave the ward or to go on visits outside
	the hospital from time to time.
	(24/7 inpatient with privileges to leave ward on visits outside hospital)
5	I need to stay up to 24 hours in the Emergency Room and then talk to the doctor again to decide if it is safe to
	discharge me home <u>or</u> if I need to be admitted to the hospital ward <u>or</u> if I need to attend therapy for several
	hours multiple times a week.
	(Stay up to 24 hours in Emergency Room then re-evaluate whether to admit or discharge <u>or</u> partial
	hospitalization <u>or</u> intensive outpatient program)
4	I only need outpatient weekly visits with daily calls to tell my doctor or therapist if I am OK (what are called
	daily check-ins).
3	I only need outpatient weekly visits.
2	I only need outpatient visits at least monthly.
1	I only need outpatient visits as needed and I would like to be monitored in case my suicidal thoughts or
	behaviors get worse.
0	I need no treatment at all.

# **CLINICIAN RATED PAGES**

# **Clinically Meaningful Change Measures for Suicide Outcomes Assessment**

(S-STS CMCM VERSION, CLINICIAN RATED DOMAINS ARE ON PAGES 13 AND 14)

## **Clinically Meaningful Change Measures for Suicide Outcomes Assessment**

(CLINICIAN RATED)

This Sheehan - Suicidality Tracking Scale, Clinically Meaningful Change Measures version (S-STS, CMCM version) is for use in evaluating whether a treatment for suicidality has a clinically meaningful impact beyond the suicidal phenomena alone.

Suicide risk cannot be accurately predicted at an individual level. However, based on all the information available on pages 1 and 2, pages 3 through 10 in the S-STS, CMCM version, and using your clinical experience, provide on the horizontal analog scale below and using the anchors in the table below, your best judgment of this patient's current level of clinically meaningful suicide risk and need for treatment of suicidality. This clinician "judgment of suicide risk" may drive your "judgment of level of management needed". Ask any additional probe questions or for any clarifications as needed.

In making this judgment, factor in and make balanced trade-offs between the following elements in each case:

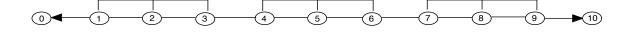
- Suicidal ideation (including suicidal impulses, and dreams, hallucinations and delusions involving suicide)
- · Suicidal planning
- Suicidal intent and patient's perception of how likely they are to attempt suicide again in the future
- Suicidal behaviors (including impulsive suicidality)
- Suicide risk / protective factors
- Ability and willingness to cope with and to stay safe from suicidality
- · Desire to recover from suicidality
- History of suicidality
- Quality of life
- % of suicidal ideation that is willful or deliberate
- Time spent in suicidality
- Global severity of suicidal impulses, ideation and behaviors
- Type of suicide disorder

These factors and trade-offs vary from one case to the next and over time in the same case.

#### At this time:

# **Clinically Meaningful Change Measure for Suicide Outcomes Assessment**

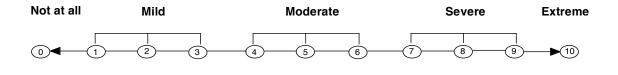
Anchor your judgment of the suicide risk and level of clinically meaningful management needed, with a single score, based on the table below:



Score	Judgment of Suicide Risk	Judgment on Level of Management Needed for Suicidality
10		24/7 in this to the second of t
10	Imminent	24/7 inpatient with constant one-on-one observation and with possible need or patient request for physical or chemical restraints
9	Severe	24/7 inpatient one-on one hospitalization with constant one-on-one observation
8	High	24/7 inpatient hospitalization with suicide precautions (e.g. 15 minute observation checks)
7	Major	24/7 inpatient hospitalization
6	Elevated	24/7 inpatient hospitalization with privileges to leave ward on visits outside hospital
5	Moderate	Up to 24 hours in ER, then re-evaluate whether to admit or discharge or partial hospitalization
		<u>or</u> intensive outpatient program
4	Modest	Outpatient weekly visits with daily check-ins
3	Mild	Outpatient weekly visits
2	Slight	Outpatient visits at least monthly
1	Remote	Outpatient visits as needed and if in treatment monitor for treatment emergent suicidality
0	No apparent risk	None

## GLOBAL SEVERITY OF SUICIDAL IMPULSES, THOUGHTS, AND BEHAVIORS

Rate the overall severity of the patient's suicide impulses, thoughts, and behaviors:



# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - CLINICIAN USE ONLY

Complete this section *if the patient does not return for the scheduled follow up visit* and is not available to permit completion of pages 1 and 2.

ı	F	n	R	CI	IN	ICI	ΔΙ	N	U	SE	O	N	I١	1

17. Missed	appointment - reaso	n: subject died from a	completed suicide?		0	100
18. Missed	appointment - reaso	n: subject died, but no	t enough information to code	as a suicide?	0	0
19. Missed	appointment - reaso	n: subject died from ca	ause(s) other than suicide?		0	0
20. Missed	appointment - reaso	n: subject alive, but no	ot available because of a suicio	de attempt?	0	4
21. Missed	appointment - reaso	n: subject alive, but no	ot available for known reasons	other than suicide?	0	0
22. Missed	appointment - reaso	n: subject alive, but no	ot available, for uncertain reas	ons, or "lost to follow up"?	0	0
Total Scal	12 or an of 15] +	res from Questions 1a yrow of 16] + [the hig 17 + 20 [on page 13].  ers above with the pat		of <b>TOTAL</b>		
Clinici	an Signature		dd/MMM/yyyy			
□ I have	discussed the answ	ers above with my doc	tor or clinician.			
Patier	t Signature		dd/MMM/yyyy			

- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

The author is grateful to JM Giddens for very valuable advice in the development of the S-STS and of the S-STS CMCM versions.

#### Conclusion

The S-STS CMCM was developed to specifically test the anti-suicidality effects of medications. It shows the additional domains that should assessed before and during treatment and how these domains are measured in a way that any clinician can judge the extent of an anti-suicidality medication's clinically meaningful effect. This scale provides a roadmap to "open doors" to a thorough "big picture" exploration and tracking of key features of suicidality for individual patients.

# 14.3

Pediatric Versions of the Sheehan - Suicidality Tracking Scale (S-STS)

Adapted from: Amado DM, Beamon DA, Sheehan DV. The linguistic validation of the Pediatric versions of the Sheehan-Suicidality Tracking Scale (S-STS). Innov Clin Neurosci 2014;11(9–10):141–163.

http://innovationscns.epubxp.com/i/425963/140

#### Introduction

A pediatric suicidality scale should assess the full range of suicidality phenomena in children and adolescents. It should be cognitively appropriate and linguistically understood by children and adolescents across the spectrum of the ages from childhood into adulthood. Such a scale should be able to prospectively follow suicidality from the earliest ages into adulthood in cohorts of children using the same instrument in its staged linguistic validation forms across the spectrum of ages. Any pediatric suicidality scale should allow children and adolescents a way to communicate suicidality to clinicians in an age appropriate fashion.

The scale should be capable for use as both a safety and an efficacy outcome measure in research and in clinical settings. In the context of efforts to find and develop anti-suicidality

medications, it is important that such a scale be very sensitive in detecting anti-suicidality effects in modest sample sizes of children and adolescents.

Allowing individual clinicians the discretion in how to appropriately phrase the adult questions or target symptoms into each child's age appropriate language is to allow an unacceptable level of inter-rater unreliability and increases the likelihood of both type I and type II errors. Developing age and cognitive appropriate versions of a scale for children and adolescents should not be left entirely up to the subject judgments of individual "experts" in choosing the most appropriate choice of language, but should be based on empirical studies in language development over the spectrum of age groups.

The Pediatric versions of the Sheehan-Suicidality Tracking Scale (S-STS) were developed to provide a balance of being comprehensive, brief, efficient, and linguistically and cognitively age appropriate, yet sensitive to change in assessing suicidality in children and adolescents.

#### Development of the Pediatric Versions of the S-STS

To achieve this aim Darlene Amado suggested using the empirically based system already in place and widely adopted by school systems throughout the United States, Canada, and the United Kingdom for linguistic validation of educational texts. This resulted in working with a group of reading specialists whose recommendation was to make three versions: one for 6- to 8-year-olds, a second for 9- to 12-year-olds, and a third for 13- to 17-year-olds. The sight word lists of Dolch and Fry and the grade level vocabulary lists of Beck, Farr and Strickland et al to adapt the adult version to each age group. See Amado et al 2014 for more detailed information about this linguistic validation process<sup>1</sup>.

#### Operational Use Pediatric Versions of the S-STS

An Education Advisory Committee; comprised of faculty in academic departments of education who specialized in elementary and high school education, child and adult psychiatrists, and elementary school teachers in both the public and private sector; made a number of recommendations about the implementation of the pediatric scales:

1. The 6- to 8-year-olds version should be clinician-rated, by reading the scale orally to the child. A parent or guardian should ideally be present during the interview, though this may not be appropriate in some situations, and should be asked at the start of the interview to avoid answering for the child unless the child provides information that appears to the parent to be erroneous. If there is discrepant information, the clinician should try to resolve the discrepancy in the interest of making an accurate assessment.

<sup>&</sup>lt;sup>1</sup> Amado DM, Beamon DA, Sheehan DV. The linguistic validation of the Pediatric versions of the Sheehan-Suicidality Tracking Scale (S-STS). Innov Clin Neurosci 2014;11(9–10):141–163. Available from: <a href="http://innovationscns.epubxp.com/i/425963/140">http://innovationscns.epubxp.com/i/425963/140</a>

- 2. The 9- to 12-year-olds version should be either clinician-rated or self-rated. Usually this is best done with the parent and clinician present, rather having the child self-rate alone. Some children may need less or more independence while self-rating the scale.
- 3. The 13- to 17-year-olds version should be self-rated. Adolescents tend to be less likely to involve parents and others in their inner lives or in interviews.
- 4. The 6- to 8-year-olds and some of the 9- to 12-year-olds may have difficulty properly understanding the spectrum of graded response options to the questions. Comprehension of the graded response options can be tested at the beginning of the interview. If needed, clinicians can use a variety of adjunctive aids to visually illustrate the escalating and graded nature of the response options. An increasing number of physical objects, like blocks or other manipulables can be used for this purpose.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) – Child Version (6-8 years)

**INSTRUCTIONS:** PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY AND TIME FRAME IN YOUR RESPONSES. THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT OR BEHAVIOR "DID NOT OCCUR AT ALL".

1.	In the past (timeframe), did you have an accident? (this includes taking too much of your medication by accident). IF NO, GO TO QUESTION 2. IF YES, GO TO QUESTION 1a:	NO $\square$		YES 🗆		
1a	. How much did you try to <b>get hurt</b> in an accident, or how much did you try to <b>hurt yourself</b> in an accident?	Not at all	A little	In the middle	A Lot	Really a Lot
	IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), GO TO QUESTION 2. IF IT IS SCORED 1 OR HIGHER, GO TO QUESTION 1b:					
1b	. Did you try to die or make yourself dead because of an accident?	NO $\square$		YES 🗆		
In 1	the past (timeframe), how much did you:	Not at all	Λ little	In the middle	A Lot	Really a Lot
2.	wish you were dead? How many times?	0	1	2	3	4
3.	think about hurting yourself, <b>knowing</b> you could die, or how much did you think about making yourself dead **? How many times?	0	1	2	3	4
4.	hear a voice telling you to make yourself dead or have a dream or a nightmare about making yourself dead **?	0	1	2	3	4
5.	think about <b>how</b> to make yourself dead **?	0	1	2	3	4
6.	think about what you would use to make yourself dead **?	0	1	2	3	4
7.	think about where you would go to make yourself dead **?	0	1	2	3	4
8.	think about when you would make yourself dead **?	0	1	2	3	4
9.	mean to <b>go ahead and</b> make yourself dead **?	0	1	2	3	4
10	mean to make yourself dead from hurting yourself?	0	1	2	3	4
11	mean to do things suddenly to make yourself dead **?	0	1	2	3	4
12	do things to <b>get ready</b> to make yourself dead **?	0	1	2	3	4
13	hurt yourself <b>without</b> trying to make yourself dead **?  How many times?	0	1	2	3	4
14	try to make yourself dead * (**)?	0	1	2	3	4

<sup>\* &</sup>quot;A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance." A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1,2</sup>). \* Note: Items 7 & 8 on S-STS ("plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). However, both events can occur separately over the same timeframe. \*\* Some children may relate better to the wording "to kill yourself" rather than "to make yourself dead".

# 15. IF THE ANSWER TO QUESTION 14 IS 1 OR HIGHER ASK:

In the past (timefran	ne), how many times did you	try to make yourself dead	d?	_			
When?	How?	How har	d did y	ou try each ti	me?		
dd/MMM/yyyy		Not at all	A little	In the middle	A lot	Really a lot	Level
2.		0	1	2	3	4	
3.		0	1	2	3	4	
4.		0	1	2	3	4	
5. Add rows as need	lad	0	1	2	3	4	
but then someone o Level 3: You did ever  16. IF THE ANSWER  In the past (timefran	to try to make yourself dead, r something stopped you. Thing you could to try to material to try to material to the try to material try to the try to make yourself dead, respectively.	ake yourself completely d  GHER ASK:  do things to get ready to	ead. make y	ourself dead			
(CLINICIAN: Include o	only the times when the child	stopped before starting t	to kill th	nemselves). *	*		
When?	How?	How har	d did y	ou try each ti			
dd/MMM/yyyy			-		me?	Really a lot	Level
dd/MMM/yyyy		Not at all	A little	ou try each ti In the middle	me?		Level
dd/MMM/yyyy  1.		Not at all	A little	ou try each ti In the middle	me?	4	Level
dd/MMM/yyyy  1.		Not at all 0	A little  1	ou try each ti In the middle 2	me?  A lot  3	4	Level
dd/MMM/yyyy  1.  2.  3.	How?	Not at all 0 0	A little  1  1	ou try each ti In the middle 2 2 2	A lot 3	4	Level
dd/MMM/yyyy  1.  2.  3.  4.  5.  Add rows as need  Levels of Getting Re  Level 1: You ONLY di  Level 2: You ONLY di  Level 3: You ONLY di	How?	Not at all 0 0 0 0 0 0 vyourself dead, but you de yourself dead, but then	A little  1  1  1  1  id not s  you sto	ou try each ti In the middle 2 2 2 2 2 attart to make pped yourse	A lot 3 3 3 yourse	4 4 4 4 If dead.	yourself.
dd/MMM/yyyy  1.  2.  3.  4.  5.  Add rows as need  Levels of Getting Receivel 1: You ONLY di Level 2: You ONLY di Level 3: You ONLY di yourself.	How?  Hed.  Hed.  Ady to Make Yourself Dead of things to get ready to make distribution of the things to get ready to make distributions.	Not at all 0 0 0 0 0 0 ve yourself dead, but you de yourself dead, but then se yourself dead, but the yourself dead, but th	A little  1  1  1  1  id not s you sto	ou try each ti  In the middle  2  2  2  2  tart to make pped yourselne or someth	A lot 3 3 3 yourse	4 4 4 4 If dead.	yourself.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - CLINICIAN USE ONLY

Complete this section *if the patient does not return for the scheduled follow up visit* and is not available to permit completion of pages 1 and 2.

FOR CLINICIAN USE C	ONLY				
17. Missed appointme	ent - reason: subject died from	n a completed suicide?		<b>NO</b>	<b>YES</b> 100
18. Missed appointme	ent - reason: subject died, but	not enough information to code as a suicide	<u> </u>	0	0
19. Missed appointme	ent - reason: subject died from	n cause(s) other than suicide?		0	0
20. Missed appointme	ent - reason: subject alive, but	not available because of a suicide attempt?		0	4
21. Missed appointme	ent - reason: subject alive, but	not available for known reasons other than	suicide?	0	0
22. Missed appointme	ent - reason: subject alive, but	not available, for uncertain reasons, or "los	t to follow up"?	0	0
Total Scale Score		1a + 2 through 11 + [the highest of highest of 14 or any row of 15] + 17	TOTAL		
☐ I have reviewed	the answers on Pages 1 and 2	2 with the patient.			
Clinician Signatu	ure	dd/MMM/yyyy			
☐ I have reviewed	the answers on Pages 1 and 2	2 with my doctor or clinician.			
 Patient Signatur		dd/MMM/yyyy			

#### References

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1.
   U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceS/Drugs/GuidanceS/Drugs/Guidances/UCM225130.pdf</a>
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

The author is grateful to for very valuable advice in the development of the pediatric versions of the S-STS to Darlene Amado and Darlene Beamon and to JM Giddens in developing the adult S-STS and adult S-STS CMCM versions.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) – Child Version (9-12 years)

**INSTRUCTIONS:** PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY AND TIME FRAME IN YOUR RESPONSES. THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT OR BEHAVIOR "DID NOT OCCUR AT ALL".

1.	In the past (timeframe), did you have an accident? (this includes taking too much of your medication by accident). IF NO, GO TO QUESTION 2. IF YES, GO TO QUESTION 1a:	NO $\square$		YES		
1a	. How seriously did you plan or expect to hurt yourself on purpose in an accident?	Not at all	A little	Somewhat 2	Very 3	Extremely 4
	IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), GO TO QUESTION 2. IF IT IS SCORED 1 OR HIGHER, GO TO QUESTION 1b:					
1b	. Did you try to die as a result of an accident?	NO $\square$		YES $\square$		
In t	the past (timeframe), how much did you:	Not at all	A 1:441 a	Comowhat	Vomi	Futuamalu
2.	think that you would be better off dead or wish you were dead?  How many times?	Not at all	A little	Somewhat 2	Very 3	Extremely 4
3.	think about hurting yourself, with the possibility that you might die? Or <b>how much</b> did you think about killing yourself **? How many times?	0	1	2	3	4
4.	hear a voice telling you to kill yourself, or have a dream or a nightmare about killing yourself **?	0	1	2	3	4
5.	think about <b>how</b> to kill yourself **?	0	1	2	3	4
6.	think about what you would use to kill yourself **?	0	1	2	3	4
7.	think about where you would go to kill yourself **?	0	1	2	3	4
8.	think about <b>when</b> to kill yourself **?	0	1	2	3	4
9.	want to <b>go through with a plan to</b> kill yourself **?	0	1	2	3	4
10	want to die from hurting yourself?	0	1	2	3	4
11	think about killing yourself ** sooner rather than later?	0	1	2	3	4
12	do things to <b>prepare</b> to kill yourself **?	0	1	2	3	4
13	hurt yourself on purpose <b>without</b> trying to kill yourself **?  How many times?	0	1	2	3	4
14	try to kill yourself * (**)?	0	1	2	3	4

<sup>\* &</sup>quot;A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.". A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1,2</sup>). \* Note: Items 7 & 8 on S-STS ("plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). However, both events can occur separately over the same timeframe. \*\* Some children may relate better to the wording "to make yourself dead" rather than "to kill yourself".

15. IF THE ANSWER TO QUESTION 14 IS 1 OR HIGHER A	SK:
---	-----

When?	How?		ŀ	low har	d did yo	u try each t	ime?		
dd/MMM/yyyy			N	lot at all	A little	Somewhat 2	Very 3	Extremely 4	Level
				0	1	2	3	4	
				0	1	2	3	4	
				0	1	2	3	4	
Add rows as nee	ded			0	1	2	3	4	
IF THE ANCIA/FR									
	TO QUESTION 1								
the past (timefra	me), how many ti	mes did you d	o things to <b>prep</b> a				**		
<b>the past</b> (timefra	me), how many ti	mes did you d	o things to <b>prep</b> atopped before s	tarting t	o kill the			ne?	
the past (timefrai INICIAN: Include	me), how many ti only the times wh	mes did you d	o things to <b>prep</b> atopped before s	tarting t	o kill the	emselves.) *		ne?  Extremely  4	Level
the past (timefrai INICIAN: Include When?	me), how many ti only the times wh	mes did you d	o things to <b>prep</b> atopped before s	tarting t low mu	ch did y	emselves.) * ou prepare   Somewhat	each tin	Extremely	Level
the past (timefrai INICIAN: Include When?	me), how many ti only the times wh	mes did you d	o things to <b>prep</b> atopped before s	tarting t low mu	ch did y	emselves.) * ou prepare   Somewhat 2	very 3	Extremely 4	Level
the past (timefrai INICIAN: Include When?	me), how many ti only the times wh	mes did you d	o things to <b>prep</b> atopped before s	tarting to the following the f	ch did y	somewhat 2	very 3	Extremely 4	Level
the past (timefrai LINICIAN: Include When?	me), how many ti only the times wh How?	mes did you d	o things to <b>prep</b> atopped before s	tarting the downward of the do	o kill the	somewhat 2 2	Very 3 3	Extremely 4 4	Level
the past (timefrant LINICIAN: Include When?  dd/MMM/yyyy  Add rows as nee wels of Preparing vel 1: You did thin vel 2: You did thin	me), how many tion only the times when the How?  How?  ded.  to Kill Yourself gs to get ready to gs to get g	mes did you donen the child s	things to prepared topped before some some some some some some some som	How much lot at all 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	A little  1  1  1  kill yourself j	self. ust before y	very 3 3 3 3 vou hurt	Extremely 4 4 4 4 4 4 4 yourself.	
the past (timefrai	me), how many tionly the times where the How?  How?  ded.  to Kill Yourself gs to get ready to gs to get gs to get get gs to get get gs to	o kill yourself, bo kill yours	but you did not stout then <b>you sto</b>	tarting the downward of the do	A little  1  1  1  which did your sourself is mething.	self. ust before y	very 3 3 3 3 vou hurt	Extremely 4 4 4 4 4 4 4 yourself.	

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - CLINICIAN USE ONLY

Complete this section *if the patient does not return for the scheduled follow up visit* and is not available to permit completion of pages 1 and 2.

17. Missed appointme	ent - reason: subject died from	a completed suicide?	NO         YES           0         100
18. Missed appointme	ent - reason: subject died, but r	not enough information to code as a suicide?	0 0
19. Missed appointme	ent - reason: subject died from	cause(s) other than suicide?	0 0
20. Missed appointme	ent - reason: subject alive, but ı	not available because of a suicide attempt?	0 4
21. Missed appointme	ent - reason: subject alive, but ı	not available for known reasons other than suicide?	0 0
22. Missed appointme	ent - reason: subject alive, but ı	not available, for uncertain reasons, or "lost to follow up"?	0 0
Total Scale Score		a + 2 through 11 + [the highest of nighest of 14 or any row of 15] + 17	
☐ I have reviewed	I the answers on Pages 1 and 2	with the patient.	
Clinician Signatu	ure	dd/MMM/yyyy	
☐ I have reviewed	I the answers on Pages 1 and 2	with my doctor or clinician.	
Patient Signatur	re	dd/MMM/yyyy	

#### References

FOR CLINICIAN USE ONLY

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1.
   U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceS/Drugs/GuidanceS/Drugs/GuidanceS/UCM225130.pdf</a>
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

The author is grateful to for very valuable advice in the development of the pediatric versions of the S-STS to Darlene Amado and Darlene Beamon and to JM Giddens in developing the adult S-STS and adult S-STS CMCM versions.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - Child Version (13-17 years)

**INSTRUCTIONS**: PLEASE USE DATA FROM ALL SOURCES AND CONSIDER SEVERITY, FREQUENCY AND TIME FRAME IN YOUR RESPONSES. THE RESPONSE "NOT AT ALL" TO ANY QUESTION MEANS "NONE" AND MEANS THAT THE THOUGHT OR BEHAVIOR "DID NOT OCCUR AT ALL".

1.	In the past (timeframe), did you have any accident? (this includes taking too much of your medication by accident). IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:	NO			YES		
1a	How seriously did you plan or expect to hurt yourself on purpose in any accident or put yourself in a position where you could be hurt? IF THE ANSWER TO QUESTION 1a IS 0 (= Not at all), SKIP TO QUESTION 2. IF IT IS SCORED 1 OR HIGHER, GO TO QUESTION 1b:	Not at 0	all	A little	A fair a	Very 3	Extremely 4
1b	. Did you want to die as a result of any accident?	NO			YES		
	think that you would be better off dead or wish you were dead or	Not at	all	A little	A fair a	 Very 3	Extremely 4
2	need to be dead? How many times? think about hurting yourself, with the possibility that you might						
э.	die? Or how seriously did you think about killing yourself? How many times?	0		1	2	3	4
4.	hear a voice or voices telling you to kill yourself or have a dream or a nightmare about killing yourself?	0		1	2	3	4
5.	have a way or a method (how) in mind to kill yourself?	0		1	2	3	4
6.	think about what you would use to kill yourself?	0		1	2	3	4
7.	think about where you would go to kill yourself?	0		1	2	3	4
8.	think about <b>when</b> you could kill yourself?	0		1	2	3	4
9.	expect to <b>go through with a plan to</b> kill yourself?	0		1	2	3	4
10	did you intend to act: at the time \( \sime \) at some time in the future \( \sime \) <b>expect</b> to die from hurting yourself?  did you intend to die: at the time \( \sime \) at some time in the future \( \sime \)	0		1	2	3	4
11	feel the need to kill yourself sooner rather than later?  was this: for no good reason  for some good reason	0		1	2	3	4
12	do things to <b>prepare</b> to kill yourself?	0		1	2	3	4
13	hurt yourself on purpose <b>without</b> trying to kill yourself? How many times?	0		1	2	3	4
14	try to kill yourself *?	0		1	2	3	4

<sup>\* &</sup>quot;A suicide attempt is a potentially self-injurious behavior, associated with at least some intent (> 0) to die as a result of the act. Evidence that the individual intended to kill him or herself, at least to some degree, can be explicit or inferred from the behavior or circumstance." A suicide attempt may or may not result in actual injury." (FDA 2012 definition<sup>1,2</sup>). \* Note: Items 7 & 8 on S-STS ("plan for suicide") means not going beyond ideas or talking about a plan for suicide. If actual behaviors occurred, the event should not be coded on item 7 or 8, but as "preparatory behavior" (item 12). However, both events can occur separately over the same timeframe.

15. IF THE ANSWER TO QUESTION 14 IS 1 OR HIGHER ASK:							
In the past (timeframe), how many times did you try to kill yourself? **							
When?	How?	How seriously did you try each time?					
dd/MMM/yyyy  1.		Not at all A little A fair amount Very Extremely Level  0 1 2 3 4					
2.		0 1 2 3 4					
3.		0 1 2 3 4					
4.		0 1 2 3 4					
5. Add rows as neede	ed.	0 1 2 3 4					
Level 1: You started to kill yourself, but then you decided to stop and did not finish trying.  Level 2: You started to kill yourself, but then someone or something stopped you.  Level 3: You did everything you wanted to do in trying to kill yourself.  16. IF THE ANSWER TO QUESTION 12 IS 1 OR HIGHER ASK:  In the past (timeframe), how many times did you do things to prepare to kill yourself? **  (Include only the times when you stopped before starting to kill yourself.) **							
When?	How?	How seriously did you prepare each time?					
dd/MMM/yyyy  1.		Not at all A little A fair amount Very Extremely Level  0 1 2 3 4					
2.		0 1 2 3 4					
3.		0 1 2 3 4					
4.		0 1 2 3 4					
5. Add rows as neede	ed.	0 1 2 3 4					
Levels of Preparing to Kill Yourself Level 1: You did things to get ready to kill yourself, but you did not start to kill yourself.							

Level 2: You did things to get ready to kill yourself, but then you stopped yourself just before you hurt yourself.

Level 3: You did things to get ready to kill yourself, but then someone or something stopped you just before you hurt yourself.

	_
HOW MUCH TIME DO YOU SPEND EVERY DAY THINKI	NG AROUT MAKING VOURSELE DEAD?

Not at all.	A little.	In the Middle.	A lot.	Really	y A lot.

# SHEEHAN-SUICIDALITY TRACKING SCALE (S-STS) - CLINICIAN USE ONLY

Complete this section *if the patient does not return for the scheduled follow up visit* and is not available to permit completion of pages 1 and 2.

FOR CLINICIAN USE C	DNLY				
17. Missed appointme	ent - reason: subject died from	a completed suicide?		<b>NO</b>	<b>YES</b> 100
18. Missed appointme	ent - reason: subject died, but	not enough information to code as a suici	de?	0	0
19. Missed appointme	ent - reason: subject died from	cause(s) other than suicide?		0	0
20. Missed appointme	ent - reason: subject alive, but	not available because of a suicide attemp	t?	0	4
21. Missed appointme	ent - reason: subject alive, but	not available for known reasons other tha	an suicide?	0	0
22. Missed appointme	ent - reason: subject alive, but	not available, for uncertain reasons, or "le	ost to follow up"?	0	0
Total Scale Score		a + 2 through 11 + [the highest of nighest of 14 or any row of 15] + 17	TOTAL		
☐ I have reviewed	I the answers on Pages 1 and 2	with the patient.			
Clinician Signatu	ure	dd/MMM/yyyy			
☐ I have reviewed	I the answers on Pages 1 and 2	with my doctor or clinician.			
Patient Signatur		dd/MMM/yyyy			

#### References

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1.
   U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/</a> Direct download from <a href="https://www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf">www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf</a>
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

The author is grateful to for very valuable advice in the development of the pediatric versions of the S-STS to Darlene Amado and Darlene Beamon and to JM Giddens in developing the adult S-STS and adult S-STS CMCM versions.

#### **Next Steps**

We need further reliability and cognitive debriefing studies in diverse demographic, ethnic and cultural groups to make the current versions more reliable, generalizable and useful. It will then be necessary to conduct inter-rater, intra-rater, and test-retest reliability on these versions, before conducting a psychometric validation against another acceptable, linguistically validated, standardized pediatric suicidality scale.

#### Conclusion

The Pediatric versions of the S-STS are empirically based, age-appropriate, and linguistically validated. Their use enables clinicians to better understand child and adolescent suicidality. They allow clinicians to assess and monitor suicidality in clinical, research, and other settings. The above 2014 versions of the Pediatric S-STS provide clinicians, researchers, and those charged with the responsibility to assess and monitor suicidality in children and adolescents using an empirically based, age-appropriate, and linguistically validated approach. They also allow children and adolescents a structured format to openly communicate about their suicidality. We hope this will start a process that may protect children and adolescents and reduce the tragic loss of life internationally from this silent and often preventable epidemic.

14.4

S-STS Related Documents

#### Introduction

This chapter contains the directions and scoring and tracking log instructions, the tracking logs, recommendations for the use in rapid onset of action studies, study stopping rules, mapping tables and their scoring forms, and the training slides created for the Sheehan - Suicidality Tracking Scale (S-STS).

The S-STS scoring instructions assist clinicians in understanding how to use the scale, what scores can be calculated from the answers to the scale, and the related tracking logs. The directions give an overview of how to use the scale and specific issues to focus on when administering the scale. The scoring instructions explain 12+ scores recommended for use and give instructions on how to calculate them. This includes the rationale behind the choice of timeframes for different clinical and research settings and agendas. For example, this document explains the rationale for choosing a 13-month timeframe rather than a 1-year timeframe.

# **Sheehan-Suicidality Tracking Scale (S-STS)**

General Directions & Scoring Instructions for the standard and CMCM versions

- Use data from all sources.
- The S-STS can be a) patient rated and/or b) clinician administered and then c) any differences reconciled (reconciliation version), if they are blindly done to each other (patient rating first).
- Consider severity, frequency and time frame in your responses.
- Different timeframes may be used with this scale (e.g. "in the past week", "in the past month", "since the last visit", or "ever"). See the discussion of timeframes on page 4 below.

All clinicians using this scale in clinical trials should receive instruction using approved training materials for S-STS. This is to ensure consistency in the understanding and application of definitions for each scale item and each C-CASA item coded.

# At Screening (for past 13 month timeframe), exclude anyone with a score of:

(A 13 month timeframe used to capture anniversary reactions.)

- 3 or 4 on Question 2 or 13.
- 2 or higher on any Question 1a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 14.

## During the study call the medical monitor:

- if the score is 3 or 4 on Question 2 or 13.
- if the score is 2 or higher on any Question 1a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 20 or if suicide results in death (question 17 is Yes).
- on items of concern in your clinical judgment, clarify and ask for examples from patient.

# During any study exclude anyone:

- if the score is 3 or 4 on Question 2, 3, 4, 5, 6, 7, 8 or 13.
- if the score is 2 or higher on any Question 1a, 9, 10, 11, 12, (on the highest score of 14 or 15), 20 or if suicide results in death (Question 17 is Yes).
- more conservative thresholds should be set by the study sponsor or the FDA if they
  judge this necessary in the interest of safety. The above levels are set at a high

threshold and reflect a significant level of concern about the wisdom of continuing such a subject in a research study.

## **Suicidality studies:**

In studies designed for the study of suicide, the above recommendations need to be altered to meet the needs of the protocol under investigation.

### **Tracking Log:**

In tracking suicidality over time, use the 2 "Tracking Logs". The first log tracks item scores and the 2nd log tracks total and factor scores. This permits quick comparisons and visual tracking over time.

## **Scoring S-STS**

12 scores are derived from the S-STS in addition to individual item scores:

## 1) Total S-STS Score

Sum the scores (0-4) for each of the following:

Questions 1a, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, (highest of 12 or any row of 16), (highest of 14 or any row of 15), 17 and 20.

# 2) Suicidal Ideation/Intent Factor Score

Sum the scores (0-4) for each of the following:

Questions 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11.

# 3) Suicidal Planning Factor Score

Sum the scores (0-4) for each of the following:

Questions 5, 6, 7, 8 and 11.

# 4) Suicidal Behavior Factor Score

Sum the scores (0-4) for each of the following:

Questions 1a, (highest of 12 or any row of 16), (highest of 14 or any row of 15),

17 and 20. Note question 13 is not a suicidal behavior.

# 5) Non Suicidal Self Injury Score

From Question 13.

# 6) Total Number of Suicidal Ideation Events

From Questions 2 plus 3.

# 7) Total Number of Events of Preparatory Acts Toward Suicidal Behaviors (the preparatory acts not immediately connected with a suicide attempt)

From Question 16.

# 8) Total Number of Suicide Attempt Events

From Question 15.

## 9) Total Number of Non Suicidal Self Injury Events

From Question 13.

# 10) Usual Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors

From bottom of page 2.

# 11) Least Amount of Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors

From bottom of page 2.

# 12) Most Amount of Time Spent Per Day with Suicidal Impulses, Ideations, or Behaviors

From bottom of page 2.

Additional Scores from the S-STS Clinically Meaningful Change Measure (CMCM) version

# Total Risk / Protective Factor Score =

Add up all the scores on pages 4 and 5 by applying the following scoring system:

Does Not Apply = 0

Lessens Suicidality A lot = -3

Lessens Suicidality Moderately = -2

Lessens Suicidality A little = -1

No Impact on Suicidality = 0

Increases Suicidality A little = +1

Increases Suicidality Moderately = +2

Increases Suicidality A lot = +3

This score may be a plus or a minus score. However the clinician should not rely exclusively on the numeric value of the total score in assessing this total score without assessing the relative importance of the trade offs in each individual.

**Total Risk Factor Score** = Add up all the plus scores

# **Total Protective Factor Score** = Add up all the minus scores

## **Total Clinically Meaningful Impairment Score (CMCM version only)**

Add up all the 15 individual domain score on pages 6 through 9 (do not include in the calculation the days lost or days underproductive on page 8). The maximum score here is 150.

# **Functional Impairment from Suicidality Scores** (from page 8)

Work impairment
Social Life / Leisure Activities Impairment
Family Life / Home responsibilities Impairment
Total Functional impairment = Total of the above 3 scores

Patient Rated Management Needed Score (from page 10)

Clinician Rated Clinically Meaningful Change Measure (CMCM) Score (from page 12)

Patient Rated Clinically Meaningful Change Measure (CMCM) Score (from page 10)

**Global Severity of Suicidal Impulses, Thoughts and Behavior Score** (from page 13)

There are no numeric scores assigned for responses to questions 1 or 1b in the calculation of the Total Score, the Suicidal Ideation score or the Suicidal Behavior score.

If information from the S-STS needs to be coded as an adverse event in a research study, classify the adverse event by the C-CASA or FDA-CASA 2012 category number and C-CASA or FDA-CASA 2012 category name when naming the adverse event (see S-STS to C-CASA and FDA-CASA 2012 mapping Tables). *Mapping tables* are available for the S-STS to both the 2010 (C-CASA and 2012 FDA-CASA Draft Guidance Documents.

Interrupted attempts and aborted attempts are <u>NOT</u> classified as suicide attempts, but should be scored under suicide preparatory behaviors (Question 12) and classified accordingly in the "Level" column of Question 16.

S-STS accommodates the same *definitions* for suicide assessment as outlined in:

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1. U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM225130.pdf">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM225130.pdf</a>
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043.

In *research studies,* I recommend using all 3 pages of S-STS to be in compliance with FDA expectations outlined in the following 3 documents:

- The FDA Guidance Document on Suicidality Assessment. (Guidance for Industry. Suicidality: Prospective Assessment of Occurrence in Clinical Trials. Draft Guidance. September 2010. U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research [CDER]).
- The FDA Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials Draft Guidance August 2012 Revision 1 [10302 dft.doc 08/06/12].
- The definitions for the 5 levels of suicidal behavior adopted by the Centers for Disease Control and Prevention [Crosby, Ortega, et al 2011].

In *treatment outcome studies* where the S-STS CMCM version is used as an efficacy measure, the items on page 4 through 10 of S-STS CMCM should also be included.

In *clinical settings* not involved in research, where the goal is to assess and monitor suicidality in a simple, thorough, yet efficient manner, use Page 1 in addition to asking about time spent (bottom of page 2) at the very least.

Print Page 1 of the S-STS and pages 1, 4 and 5 of the S-STS CMCM version in color.

#### **Timeframe Choices** for S-STS and for the S-STS CMCM versions

The following look-back timeframes may be used with the S-STS depending on the clinical or research needs or questions of interest:

- 1. Over the past (timeframe)
  - In your lifetime ("Ever")
  - In the past year
  - In the past 13 months (to accommodate anniversary reactions)
  - In the past 3 months (12 weeks)
  - In the past month
  - In the past week or In the past 7 days
  - Since your last visit
- 2. During the most recent suicidal event (for use during or immediately after a crisis or in an emergency room)
  - "Concerning your most recent attempt or suicidal event:"
- 3. Look-forward timeframe assessments (e.g. 1- 3 months) may be valuable in future planning. These highlight the suicidal phenomena or risk / protective factors the patient expects to experience. Clinicians can then formulate a plan with the patient to cope with these expected issues. For example, the timeframe question prefacing questions on page 1 could read: "Over the next (timeframe), how serious do you expect the following to be:". Anyone wishing this forward-looking version of the S-STS or the S-STS CMCM should contact the author for these versions.

Because of problems of recall, the optimal time frames to balance reliability and clinical value in making clinical decisions for suicidal impulses, ideation, preparatory behaviors and attempts are as follows:

- Each study should adopt a consistent timeframe throughout the study if the scale is to be used as an outcome measure. The next 3 bullet points below may serve as a guide to the user in choosing the appropriate time frame to use based on the focus and needs of each study or each clinical setting.
- Ideation, impulses, command hallucinations or dreams "in the past month" or "in the past week" or "during your most recent or current suicidal event",
- Preparatory behaviors "In the past 13 months" to accommodate anniversary reactions
- Attempts "In your lifetime".
- For Screening Visit assessments in research studies a variant of the S-STS using all 3 of the above as indicated within the same S-STS may provide the most accurate data.
- The "In the past 7 days" timeframe yields the most reliable and accurate data.

- Be careful using the "Since your last visit" version in research studies if the interval between all the visits is not constant. If the S-STS is used as a safety data capture system only, then "since the last visit" is the most appropriate
- On the "Likelihood of a suicide attempt" domain in the S-STS CMCM version, use the same timeframe in looking forward as used in the look-back for the other domain assessments. This will vary by study or by clinical setting, based on the goals. There may be circumstances when these 2 timeframes may need to be different.

## **Optimal Timeframe choices in treatment outcome studies**

The optimal choices for timeframes in treatment outcome studies are the following:

At screening visit: a lifetime look-back – "Over the course of your lifetime:".

At **baseline** visit: a look-back timeframe that equals the full length of the acute phase of the clinical study (e.g. 8, 10 or 12 weeks) AND in addition a look-back timeframe of to correspond to the interval between visits and suicidality assessments during the clinical study (e.g. 1 week). A treatment emergent suicidal phenomenon will be defined as "treatment emergent" during the study only if it exceeds the seriousness score for that item at the baseline assessment timeframe that is equivalent to the duration of the acute phase of the study. In some studies (e.g. on Seasonal Affective Disorder) variants on this recommendation may be appropriate.

# The **S-STS CMCM version** (Clinically Meaningful Change Version) assesses the following domains:

# 1. Suicidality phenomena

- passive suicidal ideation (5)
- active suicidal ideation
- impulsive suicidality
- suicidal hallucinations
- suicidal delusions
- suicidal dreams
- suicide plan method (how)
- suicide plan means (with what)
- suicide plan date (when)
- suicide plan place (where)
- suicide plan thinking about any task you want to complete before killing yourself

- intent to act in any suicidal way,
- intent to die by suicide
- preparatory suicidal behaviors (aborted = halted by self)
- preparatory suicidal behaviors (interrupted = halted by another person or event)
- preparatory suicidal behaviors (neither aborted nor interrupted)
- suicide attempts (halted by self)
- suicide attempts (halted by another person or event)
- suicide attempts (completed as intended)
- accidents involving any suicidal accident
- death from suicide

Other phenomena needing assessment to enhance accuracy of suicidality data collection

- non-suicidal self harm behaviors
- death from other causes

# 2. Suicide risk / protective factors

# 3. **Compounding** features

- hopelessness
- ability & willingness to cope and to stay safe from suicidality
- quality of life related to suicidality & overall quality of life
- deliberate suicidality
- desire to recover from suicidality
- likelihood of a suicide attempt (patient's judgment)
- global severity of suicidality (clinician's and patient's judgment)

# 4. Functional impairment from suicidality

- Work / school
- Social life / leisure activities / personal relationships
- Family life / home responsibilities

# 5. Judgment of risk and need for treatment

- patient's judgment of needed disposition / treatment
- clinician's judgment of needed disposition / treatment
- clinician's judgment of suicide risk

At the end of the assessment, it is useful to ask the patient if there is **anything else** they didn't share about their suicidality, that they are now willing to share.

The S-STS (in contrast to the S-STS CMCM version) assesses all the suicidal phenomena in item 1 above only.

**Judging Clinically Meaningful Change** Using the S-STS CMCM as a Treatment Outcome Measure in Research Studies

On the "Clinically Meaningful Change Anchors for Suicide Outcomes Assessment" on Page 12 of the CMCM version, a clinically meaningful change for a sample is deemed to be all of the following:

- a score of 3.0 or less in >33% of patients and
- a mean reduction for the entire sample by >2.0 points and
- a statistically significant difference between the drug and the placebo at endpoint.

For an individual patient a clinically meaningful change for a sample is deemed to be:

- a score of 3 or less and
- a mean reduction by >2 points

#### Additional Scores to extract from the S-STS CMCM version

In addition to the scoring instructions listed above for the standard version of S-STS the following additional scores may be extracted from the S-STS CMCM version:

- 1. Clinician's judgment of suicide risk (score from page 12 same score as 2 below)
- 2. Clinician's judgment of management needed disposition / treatment (score from page 12)
- 3. Patient's judgment of needed disposition / treatment (score from page 10)
- 4. Risk/protective factors for suicide score (score from pages 4 + 5). Add all the scores from pages 4 & 5 as follows: does not apply = 0; lessens a lot = -3; lessens moderately = -2; lessens a little = -1; no impact = 0; increases a little = +1; increases moderately = +2; increases a lot = +3. These scores can change from visit to visit even on the factor item. A risk factor at one point or for one patient may be a protective factor at another point or for another patient and vice versa. Some studies may wish to further subdivide and analyze these factors into their 4 subcategories + a total risk / protective factor score (suicidality phenomena factors; family / social factors; personal history factors; health factors).
- 5. Functional impairment and quality of life impairment from suicidality a. Work impairment (score from page 8)
  - b. Social life & personal relationships & leisure activities impairment (score from page 8)

- c. Family life & home responsibilities impairment (score from page 8)
- d. Total impairment (sum of scores of 5a + 5b + 5c above)
- e. Quality of life impairment related to suicidality (score from page 9)
- 6. Days lost from work / school due to suicidality (score from page 8)
- 7. Days underproductive at work / school due to suicidality (score from page 8)
- 8. Hopelessness (score from page 6)
- 9. Ability & willingness to cope and to stay safe (4 scores from pages 6 & 7)
- 10. Deliberate suicidality (from page 7)
- 11. Impulsive suicidality ("impulse to act in any suicidal way" from page 7)
- 12. Desire to recover from suicidality (page 9)
- 13. Overall quality of life (page 7) and quality of life disruption (scores from page 9)
- 14. Global severity of suicidal impulses, thoughts and behavior (score from page 9)
- 15. Likelihood of a suicide attempt (page 9).

If an anti-suicidal treatment impacts all or a meaningful number of the above domains to a meaningful degree (especially reflected on the "Clinician's judgment of suicide risk score" on page 12 and the "Patient's judgment of suicide risk score" of the S-STS CMCM version on page 10), then it may reasonably be assumed that it is having a clinically meaningful effect above and beyond a statistically significant effect on suicidality scale scores.

The *tracking logs* allow a clinician to track the details of a patient's suicidality over time. There are 2 tracking logs for the S-STS and 1 additional tracking log for the S-STS CMCM. Below are the 2015 S-STS tracking logs.

## S-STS Suicidality Item Tracking Log

Sponsor:	Subject:
Protocol Number:	Subject Number:

Date	Visit Number	Self Harm Accidents	Passive Ideas	Active Ideas	Command Hallucinations for Suicide or Suicide Dreams	Method	Means	Plan Date	Plan Location	Intent to Act	Intent to Die	Sense of Urgency	Preparatory Acts***	Suicide Attempt	Clinician Initials
12/12/12	1	Not explored	2	3**	1	2**	2**	2**	2**	3**	3**	2**	0	0	DS
In the rows belo	ow record the	highest score	at each visit										Use the highe	st score from	pages 1 or 2
													Ŭ		

<sup>\*\*</sup> These Scores Exceed Acceptable Thresholds. Refer to the S-STS to see the source and interpretation of these scores. Data on 12/12/12 is just an example.

<sup>\*\*\*</sup> Not connected directly to a suicide attempt.

## S-STS Suicidality Total and Factor Score Tracking Log

Sponsor:						_			Subject:					
Protocol Nu	mber:					-			Subject Nur	nber:				
Date	Visit Number	Total Score	Ideation / Intent Factor Score	Planning Factor Score	Behavior Factor Score	Number of Ideation Events	Number of Preparatory Behavior Events***	Non Suicidal Self Injury Score	Number of Non Suicidal Self Injury Events	Number of Suicide Attempts	Usual Time per day with SIB**	Least Time per day with SIB**	Most Time per day with SIB**	Clinician initials
12/12/12	1	22	18	4	4	22	2	0	0	0	2 hrs 5 mins	1 hr 3 mins	3hrs 10 mins	DS
In the rows be	low record the hi	ghest score at	t each visit											

<sup>\*\*</sup> SIB = Suicidal Ideation and Behavior. Refer to the S-STS Scoring Instructions as the source for these Total and Factor scores.

Data on 12/12/12 is just an example.

\*\*\* Not connected directly to a suicide attempt.

The use of S-STS in detecting rapid onset of action in studies gives an overview of how to use the S-STS CMCM version in rapid onset of action studies. Such studies might involve the use of intravenous, intranasal, intramuscular, or possibly oral medications capable of delivering a very rapid onset of action in controlling suicidality. Recent examples include the use of ketamine. Since the onset of action and the interval between assessments in such studies is usually, of necessity, very short there is not enough time to use the full version of any of the scales to assess suicidality during this time interval. The one exception to this is the use of the SIAS (discussed in chapter 14.9). Below is the current recommendation for the use of the S-STS in rapid onset of action studies.

## Using the S-STS CMCM to detect a rapid onset of anti-suicidality action

How to use the S-STS to detect and document a rapid onset of anti-suicidality action (e.g. in a ketamine infusion study)

Use "within the past week" as the look-back timeframe for the full CMCM version at the "Screening" assessment

Provide a copy of the response options for the patient to visualize while responding

How frequently to use each dataset of questions?

Within a single infusion / acute treatment visit, use the following recommendation:

3 baselines assessments (-60, -40, -20)

-60: Dataset 4

-40: Dataset 1

-20: Dataset 1, 2 & 3, then clinician rated pages 12 and 13 and patient rated page 10

0: Start treatment

+20: Dataset 1

+40: Dataset 1 & 2

+60: Dataset 1

+80: Dataset 1, 2 & 3

+100: Dataset 1

+120: Dataset 1 & 2

+140: Dataset 1

+160: Dataset 1, 2 & 3

+180: Dataset 1

+200: Dataset 1, 2, 3 & 4, then the clinician rated pages 12 and 13 and the patient rated page 10

If the visit duration is shorter than 200 minutes, use the +200 minute recommendation at the earlier endpoint.

For follow up visits not involving an infusion or another repeat acute treatment, use the following recommendation:

If seen more frequently than weekly thereafter: Dataset 1, 2 & 3 at each visit.

If seen at *weekly or longer* intervals thereafter use the full S-STS CMCM, including clinician rated pages 12 and 13 and patient rated page 10 at each visit

**Dataset 1**: every 20 minutes – Question on "Likelihood to try to kill yourself" on page 10 and CMCM on page 11.

**Dataset 2**: every 40 minutes – Questions 2 through 12 on page 1. Encourage patient to answer these questions quickly and instinctively without obsessing too much.

**Dataset 3**: every 80 minutes - pages 6, 7, and 9 without question on "Likelihood to try to kill yourself".

**Dataset 4**: -60 baseline and endpoint - Clinician rated Factors (pages 4 and 5 only). Patient is given a paper copy of the Factors response options only (without all the Factors questions) to consult throughout this Factors assessment by the clinician.

### Look-back Timeframes:

Dataset 1 look-back timeframe is 20 minutes

Dataset 2 look-back timeframe is 40 minutes

Dataset 3 look-back timeframe is 80 minutes

Dataset 4 look-back timeframe is 3 hours

The *study stopping rules* give recommendations on rules to use in making decisions about taking individuals out of clinical trials or of temporarily or permanently stopping the entire trial. This document is focused on the use of the S-STS in most medication trials with CNS medications or with medications where there is some concern about treatment emergent suicidality. Below are the study stopping rule recommendations. The recommendations need to be altered for the study of suicide or a treatment for suicide. In such studies patients with suicidality are the focus of the study and need to be retained, rather than excluded.

## **Study Stopping Rules**

## Using the S-STS for Suicide Assessment in Clinical Research

# Proposal to stop a study or a drug development program because of <u>completed</u> suicides

If 4 or more completed suicides are judged to be related to the study drug by a Data Safety Monitoring Board (DSMB) in the drug development program, with an imbalance of 2 or more cases versus placebo, the DSMB will consider study (per indication) or program discontinuation.

# Proposal to stop a study or a drug development program because of <u>suicidal</u> Ideation / behavior

**Level 1. Continue study** or drug development program, but offer to share the imbalance data with the FDA expeditiously and engage in dialogue with the Division, as needed if there is:

• A total score of 2 or higher on the aggregate of questions 2 - 12 & 14 on the S-STS, with an imbalance versus placebo (not active comparator, since the active comparator may have its own increased or decreased risk), such that the Odds Ratio relative to placebo is 1.5x that observed with antidepressants or antiepileptic medications. The published increased odds ratio for suicidal ideation and behavior for antidepressants and antiepileptics over placebo is approximately 2.0 in adults (Stone et al) — the odds ratio for fluoxetine was 0.71 and for escitalopram was 2.44 and 1.95 for Pregabalin and up to 4.97 (on venlafaxine) in children & adolescents (see the attached Table below). This is the basis for the calculation 2 X 1.5 = 3. This odds ratio of 3.0 is only slightly higher than the average seen in adult studies on antidepressants and antiepileptic medications and below the highest odds ratio seen in children and adolescents on antidepressants.

	Increased Risk
All	1.95
Venlafaxine XR	4.97*
Paroxetine	2.65*
Sertraline	1.48*
Citalopram	1.37*
Fluoxetine	1.52*

Not statistically significant (24 trials involving 4400 patients)

Source: FDA analysis of pediatric clinical trials. Wall Street Journal 9/17/2004.

**Level 2. Temporarily stop the study** or drug development program and engage in dialogue with the FDA expeditiously if there is:

• A total score of 2 or higher on the aggregate of questions 2 - 12 & 14 on the S-STS, with an imbalance versus placebo (not active comparator, since PGB has its own increased risk), such that the Odds Ratio is **3x** that observed with antidepressants or antiepileptic medications. The published increased odds ratio for suicidal ideation and behavior for antidepressants and antiepileptics over placebo is approximately 2.0 in adults (Stone et al) – the odds ratio for fluoxetine was 0.71 and for escitalopram was 2.44 and 1.95 for Pregabalin and up to 4.97 (on venlafaxine) in children & adolescents (see the attached Table above). This is the basis for the calculation 2 X 3 = 6. This odds ratio of 6.0 is only slightly higher than the average seen in adult studies on antidepressants and antiepileptic medications and below the highest odds ratio seen in children and adolescents on antidepressants.

## **Global Stopping Rules**

There are differences in suicide rates in many regions of the world. In spite of these regional differences the above stopping rule proposals are reasonable to apply to a global program since the imbalances versus placebo should remain the same because the placebo will account for and reflect the influence of background rates (i.e. serve as an internal control).

# How early in a study or drug development program should the rules be implemented?

The rule on completed suicides should kick in at any sample size level. However, for the 2 intermediate levels it seems reasonable that they should kick in when the sample size is 100 subjects per treatment arm for all the ongoing aggregate studies up to that point. This needs to be revisited at least every 100 additional subjects per treatment arm in the aggregate ongoing studies thereafter.

## **Individual Stopping Rules for Suicide in Clinical Research**

## At Screening (for past 13 month timeframe), exclude anyone with a score of: (A 13 month timeframe used to capture anniversary reactions.)

- 3 or 4 on Question 2 or 13.
- 2 or higher on any Question 1a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 or 14.

## During the study call the medical monitor:

- if the score is 3 or 4 on Question 2 or 13.
- if the score is 2 or higher on any Question 1a, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 20 or if suicide results in death (Question 17 is Yes).
- on items of concern in your clinical judgment, clarify and ask for examples from patient.

## **During any study exclude anyone:**

- if the score is 3 or 4 on Question 2, 3, 4, 5, 6, 7, 8 or 13.
- if the score is 2 or higher on any Question 1a, 9, 10, 11, 12, (on the highest score of 14 or 15), 20 or if suicide results in death (Question 17 is Yes).
- more conservative thresholds should be set by the study sponsor or the FDA if they judge this necessary in the interest of safety. The above levels are set at a

high threshold and reflect a significant level of concern about the wisdom of continuing such a subject in a research study.

## **Suicidality studies:**

In studies designed for the study of suicide or a treatment for suicide the above recommendations need to be altered to meet the needs of the protocol under investigation.

### References:

Stone M, Laughren T, Jones ML, Levenson M, Holland PC, Hughes A, Hammad TA, Temple R, Rochester G. Risk of suicidality in clinical trials of antidepressants in adults: analysis of proprietary data submitted to US Food and Drug Administration. BMJ. 2009 Aug 11;339:b2880.

FDA analysis of pediatric clinical trials. Wall Street Journal 9/17/2004

Mathews, AW, Windham C. (2004, August 25). FDA Finds Prozac Least Risky for Teens. *Wall Street Journal*. Retrieved from http://online.wsj.com/news/articles/SB109338561985000129

The *mapping tables* and the related *scoring forms* for these mapping tables are useful in converting the item scores on the S-STS or the S-STS CMCM to the FDA draft guidance categories (both 2010 and 2012). Currently, the ability of a suicidality scale to map to the FDA draft guidance categories or the C-CASA categories is a regulatory requirement for the use of any suicidality scale in a CNS medication registration study being submitted for regulatory approval. This requirement also extends to studies involving any medication that may cause treatment emergent suicidality. Below are the 2010 and 2012 mapping tables and related scoring forms.

## S-STS to C-CASA 2010 Mapping Table

C-CASA Code Number	C-CASA Category	Did event code occur during this coding interval?	# of times event occurred	How S-STS questions map to each C-CASA category
1	Completed suicide	Yes or No	If >0 to 17, 1. If 0 to 17, 0	A Yes response to 17
2	Suicide attempt (Potentially self-injurious behavior associated with some intent to die. Intent can be stated or inferred by rater.)	Yes or No	From 15 or 20	A positive response to 14 or 20 or A Yes response to 1b
3	Preparatory acts toward imminent suicide behavior (Person takes steps to injure self but is stopped by self or other. Intent to die is either stated or inferred.).	Yes or No	From 16	A positive response to 12
4	Suicidal ideation (Passive thoughts about wanting to be dead or active thoughts about killing oneself, not accompanied by preparatory behavior.)	Yes or No	Number of times from questions 2 plus 3.	A positive response to 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
5	Self-injurious behavior, intent unknown (Self- injurious behavior where associated intent to die is unknown and cannot be inferred.)	Yes or No		A positive response to 1a, with 1b and 9 and 10 and 12 and 14 and 15 and 16 and 17 and 20 unanswered
6	Not enough information (fatal)	Yes or No		A Yes response to 18
7	Self-injurious behavior, no suicide intent	Yes or No	Number of times in 13	A positive response to 13 or A positive response to 1a and a negative response to 1b
8	Other (accidental, psychiatric, medical), no deliberate self-harm	Yes or No		(A positive or blank response to 1 and a negative response to questions 1a, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 18, and 1b has a NO response or is skipped) or a positive response to 19
9	Not enough information (non fatal)	Yes or No		A Yes response to 21 or if there is missing or incomplete information on S-STS beyond the explicit S-STS rules above to allow mapping to codes 1-8 in C-CASA. Use information from all sources in coding

#### Note:

- 1. Items 7 & 8 on S-STS ("plan for suicide") is construed as not going beyond ideas or verbalizations of a plan for suicide. If actual preparatory behaviors occur (i.e., buying a gun or taking other steps see item 12 on S-STS), the event should be regarded as "preparatory behavior" and coded as C-CASA Code Number 3.
- 2. If information from the S-STS is coded as an adverse event in a research study, classify the adverse event by the C-CASA category number and category name when naming the adverse event.
- 3. A "negative response" means a score of zero on that question, while a "positive response" means a score of > 1 on that question.

## S-STS to C-CASA 2010 Mapping Table Scoring Form

C-CASA Code Number	C-CASA Category	Did event code occur during this coding interval?	# of times event occurred	How S-STS questions map to each C-CASA category
1	Completed suicide	Yes or No		A Yes response to 17
2	Suicide attempt (Potentially self-injurious behavior associated with some intent to die. Intent can be stated or inferred by rater.)	Yes or No		A positive response to 14 or 20 or A Yes response to 1b
3	Preparatory acts toward imminent suicide behavior (Person takes steps to injure self but is stopped by self or other. Intent to die is either stated or inferred.).	Yes or No		A positive response to 12
4	Suicidal ideation (Passive thoughts about wanting to be dead or active thoughts about killing oneself, not accompanied by preparatory behavior.)	Yes or No		A positive response to 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11
5	Self-injurious behavior, intent unknown (Self- injurious behavior where associated intent to die is unknown and cannot be inferred.)	Yes or No		A positive response to 1a with 1b and 9 and 10 and 12 and 14 and 15 and 16 and 17 and 20 unanswered
6	Not enough information (fatal)	Yes or No		A Yes response to 18
7	Self-injurious behavior, no suicide intent	Yes or No		A positive response to 13 or A positive response to 1a and a negative response to 1b
8	Other (accidental, psychiatric, medical), no deliberate self-harm	Yes or No		(A positive or blank response to 1 and a negative response to questions 1a 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 18, and 1b has a NO response or is skipped), or a positive response to 19
9	Not enough information (non fatal)	Yes or No		A Yes response to 21 or if there is missing or incomplete information on S-STS beyond the explicit S-STS rules above to allow mapping to codes 1-8 in C-CASA. Use information from all sources in coding

Note: Items 7 & 8 on S-STS ("plan for suicide") is construed as not going beyond ideas or verbalizations of a plan for suicide. If actual preparatory behaviors occur (i.e., buying a gun or taking other steps – see item 12 on S-STS), the event should be regarded as "preparatory behavior" and coded as C-CASA Code Number 3.

If information from the S-STS is coded as an adverse event in a research study, classify the adverse event by the C-CASA category number and category name when naming the adverse event. A "negative response" means a score of zero on that question, while a "positive response" means a score of  $\geq 1$  on that question.

## S-STS to FDA-CASA 2012 Guidance Document Mapping Table

	C-CSSRS / Expanded C-CASA Code Number	C-CSSRS (FDA 2012 Expanded C- CASA) Category	Did event code occur during this coding interval?	# of times event occurred	How S-STS questions map to each C-CSSRS / FDA 2012 Expanded C-CASA category
1	SI-1*	Passive Suicidal ideation	Yes or No	From 2	A positive response to 2 or to 4
2	SI-2	Active Suicidal Ideation: Non specific (no method, intent or plan)	Yes or No		A positive response to 3 and A negative response to 5 and 6 and 7 and 8 and 9 and 10 and 11
3	SI-3	Active Suicidal Ideation: method, but no intent or plan	Yes or No		A positive response to 3 and to (5 or 6) and A negative response to 7 and 8 and 9 and 10 and 11
4	SI-4	Active Suicidal Ideation: method and intent, but no plan	Yes or No		A positive response to 3 and (5 or 6) and (9 or 10) and A negative response to 7 and 8 and 11
5	SI-5	Active Suicidal Ideation: method, intent and plan	Yes or No		A positive response to 3 and (5 or 6) and (7 or 8 or 11) and (9 or 10)
		Active Suicidal Ideation	Yes or No	From 3	A positive response to 3
			Highest Active Suicidal Ideation Code (HASIC) from SI-2 through SI-5 above during this time period		Specify highest C-CASA code from (SI-2 through SI-5) achieved during this timeframe in column 2, and its name in column 3
	NPNASI-NOS	Not Passive and Not Active Suicidal Ideation: Not otherwise specified	Yes or No		SI-1, SI-2, SI-3, SI-4, SI-5, are all NO and 2 and 3 are both NO and any of (5 or 6 or 7 or 8 or 9 or 10) is YES
	ASI-NOS	Active Suicidal Ideation: Not otherwise specified	Yes or No		SI-2, SI-3, SI-4, SI-5, are all NO and 3 is YES and any of (5 or 6 or 7 or 8 or 9 or 10) is YES
6	SB-1*	Completed Suicide	Yes or No	If >0 to 17, 1. If 0 to 17, 0.	A Yes response to 17
7	SB-2	Suicide Attempt	Yes or No	From 15 or from 20	A positive response to 14 or 20 or A Yes response to 1b
8	SB-3	"Interrupted Suicide Attempt"	Yes or No	From 16	A positive response to 12 with at least one Level 3 on 16
9	SB-4	"Aborted Suicide Attempt"	Yes or No	From 16	A positive response to 12 with at least one Level 2 on 16
10	SB-5	Preparatory acts towards imminent suicidal behavior - not counting "Aborted or Interrupted Attempts".	Yes or No	From 16	A positive response to 12 with at least one Level 1 on 16

## S-STS to FDA-CASA 2012 Guidance Document Mapping Table

11	NSSIA-1* (Non suicidal self injury)	Self-Injurious Behavior (Act) Without Suicidal Intent	Yes or No	From 13	A positive response to 13 or A positive response to 1a and negative response to 1b	
12	NSSIA-2 (Non suicidal self injury)	Self-Injurious Behavior (Act), Intent unknown	Yes or No		A positive response to 1a with 1b and 9 and 10 and 12 and 14 and 15 and 17 and 20 are unanswered	
	Usual Time spent	Usual Time spent with Suicidal Ideation or behavior	Yes or No	From Bottom of Page 2	Not applicable	
	Least Time spent	Least Time spent with Suicidal Ideation or behavior	Yes or No	From Bottom of Page 2	Not applicable	
	Most Time spent	Most Time spent with Suicidal Ideation or behavior	Yes or No	From Bottom of Page 2	Not applicable	
13	13	Not enough information (fatal)	Yes or No		A Yes response to 18	
14	14	Not enough information (non fatal)	Yes or No		A Yes response to 21 or if there is missing or incomplete information on S-STS beyond the explicit S-STS rules above to allow mapping to codes 1 through 13 or 15. Use information from all sources in coding	
15	15	Other (accidental, psychiatric medical), no deliberate self-harm	Yes or No		(A positive or blank response to 1 and a negative response to questions 1a, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 18, and 1b has a NO response or is skipped), or a positive response to 19	

Note: Items 7 and 8 on S-STS ("plan for suicide") are construed as not going beyond ideas or verbalizations of a plan for suicide. If actual preparatory behaviors occur (i.e., buying a gun or taking other steps – see item 12 on S-STS), the event should be regarded as "preparatory behavior" and coded as Code Number 3.

If information from the S-STS is coded as an adverse event in a research study, classify the adverse event by the category number and category name when naming the adverse event. A "negative response" means a score of zero on that question, while a "positive response" means a score of > 1 on that question. All the above "Suicidal Ideation and

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1. U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/</a> Direct download from <a href="http://www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf">www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf</a>
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043

Behavior Category" definitions are based on and should fully reflect and follow the definitions outlined in

<sup>\*</sup> SI-1 through SI-5 refers to Suicidal Ideation categories 1 through 5 identified in the August 2012 FDA Guidance Document draft above.

<sup>\*</sup> SB-1 through SB-5 refers to Suicidal Behavior categories 1 through 5 identified in the August 2012 FDA Guidance Document draft above.

<sup>\*</sup> NSSIA-1 and NSSIA-2 refer to the Self Injurious Behavior category identified in the August 2012 FDA Guidance Document draft above.

## S-STS to FDA-CASA 2012 Guidance Document Mapping Table Scoring Form

	C-CSSRS / Expanded C-CASA Code Number	C-CSSRS (FDA 2012 Expanded C-CASA) Category	Did event code occur during this coding interval?	# of times event occurred	How S-STS questions map to each C-CSSRS / FDA 2012 Expanded C-CASA category
1	SI-1*	Passive Suicidal ideation	Yes or No		A positive response to 2 or to 4
2	SI-2	Active Suicidal Ideation: Non specific (no method, intent or plan)	Yes or No		A positive response to 3 and A negative response to 5 and 6 and 7 and 8 and 9 and 10 and 11
3	SI-3	Active Suicidal Ideation: method, but no intent or plan	Yes or No		A positive response to 3 and to (5 or 6) and A negative response to 7 and 8 and 9 and 10 and 11
4	SI-4	Active Suicidal Ideation: method and intent, but no plan	Yes or No		A positive response to 3 and (5 or 6) and (9 or 10) and A negative response to 7 and 8 and 11
5	SI-5	Active Suicidal Ideation: method, intent and plan	Yes or No		A positive response to 3 and (5 or 6) and (7 or 8 or 11) and (9 or 10)
		Active Suicidal Ideation	Yes or No		A positive response to 3
			Highest Active Suicidal Ideation Code (HASIC) from SI-2 through SI-5 during this time period		Specify highest C-CASA code from (SI-2 through SI-5) achieved during this timeframe in column 2, and its name in column 3
	NPNASI-NOS	Not Passive and Not Active Suicidal Ideation: Not otherwise specified	Yes or No		SI-1, SI-2, SI-3, SI-4, SI-5, are all NO and 2 and 3 are both NO and any of (5 or 6 or 7 or 8 or 9 or 10) is YES
	ASI-NOS	Active Suicidal Ideation: Not otherwise specified	Yes or No		SI-2, SI-3, SI-4, SI-5, are all NO and 3 is YES and any of (5 or 6 or 7 or 8 or 9 or 10) is YES
6	SB-1*	Completed Suicide	Yes or No		A Yes response to 17
7	SB-2	Suicide Attempt	Yes or No		A positive response to 14 or 20 or A Yes response to 1b
8	SB-3	Interrupted Suicide Attempt	Yes or No		A positive response to 12 with at least one Level 3 on 16
9	SB-4	Aborted Suicide Attempt	Yes or No		A positive response to 12 with at least one Level 2 on 16
10	SB-5	Preparatory acts towards imminent suicidal behavior - not counting Aborted or Interrupted Attempts	Yes or No		A positive response to 12 with at least one Level 1 on 16

## S-STS to FDA-CASA 2012 Guidance Document Mapping Table Scoring Form

11	NSSIA-1*	Self-Injurious Behavior (Act) Without Suicidal Intent	Yes or No		A positive response to 13 or
					A positive response to 1a and negative response to 1b
12	NSSIA-2*	Self-Injurious Behavior (Act), Intent unknown	Yes or No		A positive response to 1a with 1b and 9 and 10 and 12 and 14 and 15 and 17 and 20 are unanswered
	Usual Time spent	Usual Time Spent per day with Suicidal Ideation or behavior	Yes or No	hours minutes	Not applicable
	Least Time spent	Least Time Spent per day with Suicidal Ideation or behavior	Yes or No	hours minutes	Not applicable
	Most Time spent	Most Time Spent per day with Suicidal Ideation or behavior	Yes or No	hours minutes	Not applicable
13	13	Not enough information (fatal)	Yes or No		A Yes response to 18
14	14	Not enough information (non fatal)	Yes or No		A Yes response to 21 or if there is missing or incomplete information on S-STS beyond the explicit S-STS rules above to allow mapping to codes 1 through 13 or 15. Use information from all sources in coding
15	15	Other (accidental, psychiatric medical), no deliberate self-harm	Yes or No		(A positive or blank response to 1 and a negative response to questions 1a, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 18, and 1b has a NO response or is skipped), or a positive response to 19

Note: Items 7 and 8 on S-STS ("plan for suicide") are construed as not going beyond ideas or verbalizations of a plan for suicide. If actual preparatory behaviors occur (i.e., buying a gun or taking other steps – see item 12 on S-STS), the event should be regarded as "preparatory behavior" and coded as Code Number 3. If information from the S-STS is coded as an adverse event in a research study, classify the adverse event by the category number and category name when naming the adverse event. A "negative response" means a score of zero on that question, while a "positive response" means a score of > 1 on that question. All the above "Suicidal Ideation and

- Guidance for Industry Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. August 2012. Revision 1. U.S Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Silver Spring, MD 20992-0002. <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/</a> Direct download from www.fda.gov/downloads/Drugs/Guidances/UCM225130.pdf
- 2. Posner K, Oquendo MA et al. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. C-CASA Definitions in Table 2, page 1037. Am J Psychiatry 2007; 164:1035-1043
- \* SI-1 through SI-5 refers to Suicidal Ideation categories 1 through 5 identified in the August 2012 FDA Guidance Document draft above.

Behavior Category" definitions are based on and should fully reflect and follow the definitions outlined in

- \* SB-1 through SB-5 refers to Suicidal Behavior categories 1 through 5 identified in the August 2012 FDA Guidance Document draft above.
- \* NSSIA-1 and NSSIA-2 refer to the Self Injurious Behavior category identified in the August 2012 FDA Guidance Document draft above.

We developed a set of *training slides* to help train clinicians in the use of the S-STS. These slides summarize the use of the S-STS outside research settings. *Any clinician using the S-STS in a study or clinical trial must be trained by a rater-training agency or by a pharmaceutical company approved by the author of the S-STS.* The 2015 version of the S-STS training slides will soon be available on the Harm Research Press website (<a href="http://www.HarmResearch.org">http://www.HarmResearch.org</a>). Training videos are in development at the time of this writing.

### Conclusion

The scoring instructions, use of S-STS in detecting rapid onset of anti-suicidality action, study stopping rules, mapping tables to C-CASA and FDA draft guidance categories and the related scoring forms for these mapping tables, and training slides help clinicians understand how to use the S-STS in clinical, research, and other settings. The domains of suicidality can fluctuate or evolve over time. The scores and tracking logs enable clinicians to get both a more detailed understanding and a bigger picture of a patient's suicidality. This helps clinicians more completely assess and monitor suicidality.

## 14.5

## S-STS Validation and Reliability Studies

There are 3 validation studies on the S-STS or the S-STS CMCM.

The first of these studies validated the clinician-rated, patient-rated and reconciliation versions of the S-STS against the Columbia-Suicidality Severity Rating Scale (C-SSRS)<sup>1</sup> and the InterSePT Scale for Suicidal Thinking-Plus (ISST-Plus)<sup>2</sup>. The authors of all 3 scales trained all the raters in the study in the use of their respective scales. Using mapping to both the FDA 2010<sup>3</sup> and the FDA 2012<sup>4</sup> draft guidance categories as the standard, concordance of the ISST-Plus and S-STS to the C–SSRS was acceptable for categories 1, 5, 6, 10, and 11, but not for the active suicidal ideation categories 2, 3, 4, or for the aborted and interrupted suicide attempt categories 8 and 9<sup>5</sup>. Concordance between the S-STS and the ISST-Plus was 80% or higher for all the categories. This concordance was

<sup>&</sup>lt;sup>1</sup> Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., ... & Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American Journal of Psychiatry*.

<sup>&</sup>lt;sup>2</sup> Meltzer, H. Y., Alphs, L., Green, A. I., Altamura, A. C., Anand, R., Bertoldi, A., ... & Potkin, S. (2003). Clozapine treatment for suicidality in schizophrenia: international suicide prevention trial (InterSePT). *Archives of general psychiatry*, *60*(1), 82-91.

<sup>&</sup>lt;sup>3</sup> Food and Drug Administration, U.S. Department of Health and Human Services. *Suicidality: Prospective Assessment of Occurrence in Clinical Trials, Draft Guidance*, issued in September 2010.

<sup>&</sup>lt;sup>4</sup> US Food and Drug Administration. (2012). Guidance for industry: suicidal ideation and behavior: prospective assessment of occurrence in clinical trials. *Silver Springs, MD: US Food and Drug Administration Available at:* 

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm315156.htm. Accessed November 6, 2015.

<sup>&</sup>lt;sup>5</sup> Sheehan, D. V., Alphs, L. D., Mao, L., Li, Q., May, R. S., Bruer, E. H., ... & Williamson, D. J. (2014). Comparative validation of the S-STS, the ISST-Plus, and the C–SSRS for assessing the suicidal thinking and behavior FDA 2012 suicidality categories. *Innovations in clinical neuroscience*, *11*(9-10), 32. Available from: <a href="http://innovationscns.epubxp.com/i/425963/32">http://innovationscns.epubxp.com/i/425963/32</a>

unexpected because the two scales were developed independently, have different source origins, and at face inspection look different from each other in approach, lines of questioning, and in the format used to elicit information. In contrast these 2 scales while consistent with each other were discrepant from the C-SSRS as noted above on several items, notably on most of the suicidal ideation items. These findings and the related implications are discussed in detail in the scientific report on this validation study. Subjects were given the clinician-rated scales in random order assignment. All three scales demonstrated good to excellent intra- and inter-rater reliability for categorizing suicidality in this patient sample with a broad spectrum of suicidality<sup>6 7</sup>.

The second study validated the S-STS against the C-SSRS in a large inpatient and emergency room sample of patients with suicidal ideation and / or behaviors. The authors of all 3 scales trained all the raters in the study in the use of their respective scales. The study used both the FDA 2010 and the FDA 2012 draft guidance categories as the standard. The results (reported at International Society for CNS Clinical Trials and Methodology [ISCTM] 2013 and American Society of Clinical Psychopharmacology [ASCP] 2013) found good agreement between both scales using mapping to the 2010 C-CASA categories<sup>8</sup>. The results of the reliability of both scales mapped to the FDA 2012 categories are pending<sup>9</sup>.

The third study validates the Suicidal Ideation and Behavior Assessment Tool (SIBAT)<sup>10</sup> (an extension of the ISST-Plus) against the S-STS Clinically Meaningful Change Measure (CMCM) version and the C-SSRS. This study is currently ongoing and should be completed by July 2016 with the results to be reported in posters and presentations at scientific meetings and in scientific articles shortly thereafter.

<sup>&</sup>lt;sup>6</sup> Ibid.

<sup>&</sup>lt;sup>7</sup> Williamson DJ, Mao L, Sheehan DV, May RS, Bruer EH, McCullumsmith CB, Alphs L. Reliably Assessing Suicidal Ideation and Behavior: A Comparison of 3 Scales. Poster Presented at the International Society for CNS Clinical Trials and Methodology 11<sup>th</sup> Annual Scientific Meeting, February 17–19, 2015; Washington, DC, USA.

<sup>&</sup>lt;sup>8</sup> Youngstrom, E. A., Hameed, A., Mitchell, M., Van Meter, A., Freeman, A. J., Perez Algorta, G., ... & Meyer, R. E. (2014). Direct comparison of the psychometric properties of multiple interview and patient-rated assessments of suicidal ideation and behavior in an adult psychiatric inpatient sample. *Journal of Clinical Psychiatry*.

<sup>&</sup>lt;sup>9</sup> Youngstrom, E. A. and Hameed, A. and Mitchell, M. and Van Meter, A. and Freeman, A. J. and Perez Algorta, Guillermo and White, A. and Clayton, P. and Gelenberg, A. and Meyer, R. E. (2015) *Direct comparison of the psychometric properties of multiple interview and patient-rated asessments of suicidal ideation and behavior in an adult psychiatric inpatient sample.* Journal of Clinical Psychiatry. ISSN 0160-6689. (In Press).

<sup>&</sup>lt;sup>10</sup> Alphs, L., Canuso, C., & Williamson, D. (2015). P. 1. k. 032 The Suicide Ideation and Behavior Assessment Tool: development of a novel measure of suicidal ideation and behavior and perceived risk of suicide. *European Neuropsychopharmacology*, 25, S371

## 14.6

## Suicide Plan Tracking Scale (SPTS)

### Introduction

The Suicide Plan Tracking Scale (SPTS) is designed to capture many details of suicide planning and to allow clinicians to track suicide planning over time. It provides the patient a way to share the details of suicide plans with their clinician. It offers the clinician a format to better understand the extent of patient's suicide planning. The use of the SPTS can help the patient get appropriate, individualized care, which may help them be safe. The SPTS covers 7 domains of suicide planning: method, means, location, date / timeframe, intent, incomplete preparations, and people involved. We recommend the use of a systematic, structured approach to elicit information on suicide planning and to track these details over time. The SPTS can be used in both research and clinical settings. It can be rated in 3 ways: 1. patient-rated; 2. clinician-rated; or 3. patient-rated followed by a blind clinician-rating, followed by a reconciliation of these ratings in a joint interview. Below is the current 2014 version of the SPTS.

# Suicide Plan Tracking Scale (SPTS) Directions for patients

Talking about any thoughts or plans to kill yourself can be very difficult. Your clinician may ask
you to answer the following questions again at future appointments in order to understand if you
have made any further planning or if your thoughts have changed over time. There are a number
of questions that you will be asked to answer and, although it may be difficult, please do your
best to be honest. If you are really uncomfortable answering any of the questions, please leave
them blank instead of giving a dishonest answer. One of the answers to many of the questions
is "Not at all". Only use this answer if you had absolutely no thoughts about the topic of the
question during the timeframe. If you have any questions about the meaning of words, phrases,
and / or questions ask your clinician.

□ I have read and I understand th	ne above paragraph.		
Patient Signature:		Date:	
Unpublishe	ed work © 2011 - 2014 Jer	nnifer M Giddens. All Rights Reserved.	
□ Patient Rated □ Clinician Rated	Clinician Initials:		
Patient ID:	Date:	06/20/14	SPTS Page 1 of 7

## **Suicide Plan Tracking Scale (SPTS)**

Over the past (timeframe):

	Method	Not at all	A little	Partially	Mostly	Totally
1.	How seriously have you <u>thought about</u> any <u>methods</u> you might use to kill yourself?	0	1	2	3	4
	1.a. How many methods have you thought about using to kill yourself?					
2.	How completely have you <u>decided</u> on any methods you might use to kill yourself?	0	1	2	3	4
	Means					
3.	How seriously have you thought about any means you might use to kill yourself? Means are anything you would use in the process of killing yourself.	9 0	1	2	3	4
	3.a. How many means have you thought about using to kill yourself?					
4.	How much <u>access</u> do you have to any of these means?	None 0 Not at all	A little  1 A little	Partial 2 Partially	A lot  3  Mostly	Complete 4 Totally
5.	How completely have you <u>decided</u> on any means you might use to kill yourself?	0	1	2	3	4
	Location					
6.	How seriously have you thought about any locations you might use in your plan(s) to kill yourself?	0	1	2	3	4
	6.a. How many locations have you thought about?	None	A little	Partial	A lot	Complete
7.	How much <u>access</u> do you have to any of these locations?	0 Not at all	1 A little	2 Partially	3 Mostly	4 Totally
8.	How completely have you <u>decided</u> on any locations you might use to kill yourself?	0	1	2	3	4
	Date					
9.	How seriously have you thought about any timeframes and / or any specific dates during which you might try to kill yourself?	0	1	2	3	4
	9.a. How many different timeframes and / or specific dates have you thought about?					
	Unpublished work © 2011 - 2014 Jennifer M (	Giddens. All F	Rights Reser	rved.		
	☐ Patient Rated ☐ Clinician Rated Clinician Initials: Patient ID: Date:	Developed by		neehan and Je 20/14	ennifer M G SPTS Pag	

10.	How completely have you <u>decided</u> on any timeframes and / or any specific dates during which you might try to kill yourself?	Not at all	A little 1	Partially 2	Mostly 3	Totally 4
	Intent					
11.	How seriously do you <u>intend</u> to <u>make any plans</u> to kill yourself?	0	1	2	3	4
	11.a. How many different plans do you intend to make to kill yourself?				<u> </u>	
12.	How seriously do you <u>intend</u> to <u>act</u> on any plans to kill yourself?	0	1	2	3	4
	12.a. How many different plans do you intend to use to kill yourself?					
13.	How seriously do you <u>intend</u> to <u>die</u> from acting on any plans to kill yourself?	0	1	2	3	4
	Incomplete Preparations					
14.	How seriously have you thought about any tasks you would like to complete before you try to kill yourself? Examples of tasks include, but are not limited to, writing a suicide note, giving away personal property, arranging for a pet to be taken care of, settling financial affairs, or following through on commitments.	0	1	2	3	4
	14.a. How many tasks have you thought about?					
15.	How <u>emotionally prepared</u> are you <u>to act</u> on any plans to kill yourself?	0	1	2	3	4
16.	How <u>complete</u> are the <u>final preparations</u> to kill yourself?	0	1	2	3	4
	Involvement of Others					
17.	How seriously have you thought about involving others in your plan(s) to kill yourself? This includes, but is not limited to harming or injuring others during a suicide attempt, suicide by cop, plans to make a suicide attempt in a public place, suicide pacts, or other social, cultural, or religious expectation that increases the likelihood of an attempt.	0	1	2	3	4
	17.a. How many people have you thought about involving?					
18.	How <u>important</u> is the <u>involvement of others</u> in your plan(s) to kill yourself?	0	1	2	3	4
19.	How <u>seriously do you intend</u> to <u>involve others</u> in your plan(s) to kill yourself?	0	1	2	3	4
20.	Do you <u>intend</u> to <u>seriously injure or kill someone else</u> in the process of killing yourself?  IF YES TO QUESTION 20, CONSIDER USING S-HTS or HPTS <sup>1</sup>		No		Yes	
	Unpublished work © 2011 - 2014 Jennifer M G	iddens. All F	lights Reser	ved.		

. - II a la company de la comp

<sup>1</sup> S-HTS = Sheehan - H	omicidality Tracking Sca	le. HPTS = Homicide	Plan Tracking Scale.	See General Direction	ns for more information
□ Patient Rated	☐ Clinician Rated Cl	inician Initials:	Developed b	y David V Sheehan and	Jennifer M Giddens
Patient ID:		Oate:	_	06/20/14	SPTS Page 3 of 7
		412	<u>)</u>		

21.c. How easily can you

							ow easily ca	-						
21.a. What methods have you thought about		.b. How much	-		<u> </u>		means for t		od?		-	mportant is	· ·	
using to kill yourself?	<u></u>	ded to use thi			No		Moderately		Not			nethod to k		?
(Please list consistent with response to 1.a.)	Notatall Ali			Totally	access		difficult		difficult	Not at all	A little	Partially		Totally
1.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
2.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
3.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
4.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
5.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
6.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
7.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
8.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
9.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
10.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
using to kill yourself? (Please list consistent with response to 3.a.)	dec Not at all A lis	ided to use th		Totally	No access	•	Moderately d <u>ifficul</u> t		Not difficult	Not at all	_	neans to kil Partially		Totally
1.	0 1		3	4	0	1	2	3	4	0	1	2	3	4
2.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
3.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
4.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
5.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
6.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
7.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
8.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
9.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
10.	0 1	2	3	4	0	1	2	3	4	0	1	2	3	4
	Initials:		ublished v		11 - 2014 J s Reserved		 ∕I Giddens.		Develop	ed by David		nan and Je		Giddens ge 4 of 7

413

23.a. What <u>locations</u> have you <u>thought about</u>		23.b. How	much have you		23.c. Ho	ow easily ca	n you <u>access</u> this	location?	2	3.d. How <u>im</u>	nportant is i	it for you to	o
using to kill yourself?			use this <u>location</u>		No		oderately A little			use this <u>loc</u>		•	
(Please list consistent with response to 6.a.)			artially Mostly	i			difficult difficu	lt difficult	Not at all	A little		Mostly T	otally
1.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
2.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
3.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
4.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
5.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
6.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
7.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
8.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
9.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
10.	0	1	2 3	4	0	1	2 3	4	0	1	2	3	4
24.a. What <u>timeframes or dates</u> have you <u>thought about</u> using to kill yourself?  (Please list consistent with response to 9.a.) No.	use	this <u>timefra</u>	ly Mostly Tot	>1 M	74.c. Ho Nonth Wee more) (1 - 4	eks Days		inutes Alrea 0 - 60) pass	ady ed Not a		ame or date	•	rself?
				႕ 누	러 늗	╡	3	<u></u> ⊢	╡╞	<b>=                                    </b>	╡╞	<b> </b>	┆┝═
2.	<del>                                     </del>			<b>-</b> -	1	= =	┥ ├─┤ ╎	ᆜ 누	d ⊨		╡┝	3	4
3.	0 :	1 2	3 4	1 (	1	2	3	4 1	0	1	2	3	4
4.	0 :	1 2	3 4	1 (	) 1	2	3	4 1	0	1	2	3	4
5.	0 :	1 2	3 4	1 (	) 1	2	3	4 1	0	1	2	3	4
6.	0	1 2	3	4	) 1	2	3	4 1	0	1	2	3	4
7.	0	1 2	3	4 (	) 1	2	3	4 1	0	1	2	3	4
8.	0	1 2	3	4	) 1	2	3	4 1	0	1	2	3	4
9.	0	1 2	3	1 (	) 1	2	3	4 1	0	1	2	3	4
10.	0	1 2	3	4	) 1	2	3	4 1	0	1	2	3	4
	n Initials: _ :		Unpublished	work © 201 All Rights		ennifer M (	Giddens.	Develop	ed by David 06/20/1			nifer M Gi SPTS Page	

25.	a. What <u>tasks</u> have you <u>thought about</u>		25.b. H	low much l	have you							25.d. H	ow <u>import</u>	ant is it for	r you to <u>co</u>	mplete_
	completing before you kill yourself?			to <u>complet</u>				•		is this <u>task</u> ?				efore you		
(Ple	ease list consistent with response to 14.a.)			Partially						Mostly	Totally	Not at all				
	1.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	2.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	3.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	4.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	5.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	6.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	7.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	8.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	9.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
	10.	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
										Not at all	A little	Partia	IIv M	ostly	Totally	
26.	How important is it for you to use any sp	<u>ecific me</u>	thod to	kill your	self?					0	1	2		3	4	
27.	How important is it for you to use any sp	ecific me	ans to k	ill yourse	elf?					0	1	2	] [	3	4	
28.	How important is it for you to use any sp	ecific loca	ation to	kill your	self?					0	1	2	] [	3	4	
29.	How important is it for you to use any sp	ecific tim	<u>eframe</u>	or date	to kill yo	urself?				0	1	2	] [	3	4	
30.	How important is it for you to complete a	all tasks b	efore y	ou kill yo	ourself?					0	1	2	] [	3	4	
	Time Spent In A Day with Any Suicidal Pl	lanning														
31.	Usual time spent planning for suicide in a	ı day:	hou	rs	minute	S.										
32.	Least amount of time spent planning for	suicide ir	a day:	ho	ours	minu	tes.									
33.	Most amount of time spent planning for	suicide ir	a day:	ho	ours	minu	tes.									
	□ Patient Rated □ Clinician Rated Clinician Patient ID: Date:	n Initials: _		Unpu	ıblished v		11 - 2014 Jo Reserved.		1 Gidden	s.	Develope	d by David 06/20/2		nan and Je		Giddens ge 6 of 7

Pleas	se be truthful:							
34.	Were you having <u>any</u> thoughts a of the above questions?	bout suicide while	answering <u>any</u>		No		Yes	_
35.	How <u>truthful</u> are your responses	s to <u>all</u> of the above	e questions?	Not at all	A little	Partially 2	Mostly 3	Totally 4
Pleas	se give the SPTS to your clinician.							
		SPTS	Scoring Sect	ion				
	I Scale Score answers for the following question	ons to create the to	otal score:					
1.	2 3	3 4	1	5		5	7.	
8.	9	10 1	11	12	:	13	14.	
15.	16	17 1	18	19				
Snec	ific Plan Scores			То	tal Score:		_ (Out of 76	5)
Spec	ilic Fian Scores				De	omain	Proc	luct
Rank		Specific Plan			Ca	tegory	(x Factor	) Score <sup>2</sup>
1	<u>.                                    </u>				<u> </u>			
3					1 -			
4								
5	5.				1			
6								
	5.							
7	·							
8	3.							
9	3.							
8	3.							
9	3.		For the c	linician:				
8 9 10 For t	7. 3. 0. 0.		For the c	linician: reviewed t	he above	data with ti	ne patient.	
8 9 10 For t	he patient:	th the clinician.	For the c				•	
9 10 For t	he patient:	th the clinician.	For the control of th	reviewed t			•	

□ Patient Rated □ Clinician Rated Clinician Initials: \_\_\_\_\_ Developed by David V Sheehan and Jennifer M Giddens

Patient ID: \_\_\_\_\_ Date: \_\_\_\_

06/20/14 SPTS Page 7 of 7

# Suicide Plan Tracking Scale (SPTS) Optional Items

## Over the past (timeframe):

## Method

36.	How important has each of the following been as a factor in your thoughts about any methods?					
	36.a. comfort / method not painful	Not at all	A little	Partially 2	Mostly 3	Totally 4
	36.b. easy access to means or location / practicality	0	1	2	3	4
	36.c. lethality	0	1	2	3	4
	36.d. other: please specify	0	1	2	3	4
	Means					
37.	How important has each of the following been as a factor in your thoughts about any <u>means</u> ?					
	37.a. comfort / means not painful	0	1	2	3	4
	37.b. easy access / practicality	0	1	2	3	4
	37.c. lethality	0	1	2	3	4
	37.d. special importance of means to yourself or to other(s)	0	1	2	3	4
	37.e other: please specify	0	1	2	3	4
	Location					
38.	How important has each of the following been as a factor in your thoughts about any <u>locations</u> ?					
	38.a. comfort / familiarity	0	1	2	3	4
	38.b. easy access / practicality	0	1	2	3	4
	38.c. assistance in method / means	0	1	2	3	4
	38.d. body being located	0	1	2	3	4
	38.e. body not being located	0	1	2	3	4
	38.f. other: please specify	0	1	2	3	4

Unpublished work  $\hbox{@ 2011}$  - 2014 Jennifer M Giddens. All Rights Reserved.

□ Patient Rated	□ Clinician Rated	Clinician Initials:	Developed by David V Sheehan	and Jennifer M Giddens
Patient ID:		Date:	06/20/14	SPTS - OP Page 1 of 2

### Date

39.	How important has each of the following been as a factor in you thoughts about any timeframes and / or any specific dates?	r				
	39.a. easy access to location	Not at all	A little	Partially 2	Mostly 3	Totally 4
	39.b. easy access to means	0	1	2	3	4
	39.c. the need to kill yourself or to plan to kill yourself sooner rather than later	0	1	2	3	4
	39.d. the anniversary of a particular event	0	1	2	3	4
	39.e. enough time to prepare for an attempt	0	1	2	3	4
	39.f. other: please specify	0	1	2	3	4
	Intent					
40.	How important has each of the following been as a factor in you intent to make any plans to kill yourself or to take action to kill yourself or to die from acting on any plans to kill yourself?	r				
	40.a. an impulse or urgent need to plan or to act or to die	0	1	2	3	4
	40.b. losing hope that your life would get better	0	1	2	3	4
	40.c. major changes in your life	0	1	2	3	4
	40.d. events outside of your control	0	1	2	3	4
	40.e. your memories	0	1	2	3	4
	40.f. other: please specify	0	1	2	3	4
	Role of Plan	Helps Keep Me Safe	Dok	На	akes it rder to	None of These
41.	Does having a plan partially or fully worked out help you keep yourself safe, make it more difficult to keep yourself safe, both, or none of these?	ivie Sale	Bot		o Me Safe	of filese
	Additional Notes	5				
	Unpublished work © 2011 - 2014 Jennifer M G	iddens. All Ri	ghts Reserv	ed.		

Developed by David V Sheehan and Jennifer M Giddens

06/20/14 SPTS - OP Page 2 of 2

□ Patient Rated □ Clinician Rated Clinician Initials: \_\_\_\_\_

## Conclusion

The SPTS allows clinicians to assess and monitor suicide planning in clinical, research, and other settings. The above 2014 version of the SPTS and the related documents in the following chapters provide clinicians, researchers, and those charged with the responsibility to assess and monitor suicide planning answers to frequently asked questions on the current version of the scale.

## 14.7

## **SPTS Related Documents**

#### Introduction

This chapter contains the directions and scoring and tracking log instructions, the tracking logs, and the training slides created for the Suicide Plan Tracking Scale (SPTS).

The Suicide Plan Tracking Scale directions and scoring and tracking log instructions assist clinicians in understanding how to use the scale, the definitions of terms used in the scale, what scores can be calculated from the answers to the scale, and the related tracking logs. The directions give an overview of how to use the scale and specific issues to focus on when administering the scale. This includes the need and rationale behind examining the response to the patient's rating of question 34 *prior* to reviewing the SPTS with the patient. Citing the first patient who used the scale, the directions highlight the struggle a patient may experience in honestly acknowledging the extent of their suicide planning. Ambiguous terms are defined. There are *examples* for the words "means", "method", and "tasks" to help clinicians understand and properly identify these components of suicide planning. The *scoring instructions* explain 15 scores recommended for use and give instructions on how to calculate them.

The *tracking log instructions* give an overview of the tracking logs and how to use them. The *tracking logs* allow a clinician to track the details of a patient's suicide planning over time and to see how a full plan might be constructed over weeks or months, even if not fully thought out during one timeframe. There are a total of 14 tracking logs for the SPTS. The *tracking log instructions* recommend which 3 of these logs should always be used and which logs are appropriate to match the needs of each patient or of each study. All the tracking logs and two completed examples are included. Below are the 2015 SPTS directions and scoring and tracking log instructions and tracking logs.

# Suicide Plan Tracking Scale (SPTS) General Directions for Clinicians

It is incredibly difficult for some patients to discuss details of suicide plans. One patient that was asked to self-rate this form for clinical evaluation purposes encountered considerable difficulty over the ensuing months in fully completing the scale. She described her experience in self-rating this form for her lifetime as follows:

"The very first time I attempted to complete the SPTS for my lifetime, I managed to answer questions 1 and 2 before feeling so overwhelmed by shame and guilt that I had to stop. A few hours later I was able to complete questions 3 through 7. Five hours and a nap after, I was able to complete questions 8 through 15. After an additional eight hours, I managed to complete questions 16 through 20. Attempting to answer these questions was so stressful that I was unable to complete all of the questions that day. It wasn't until months later when I used "in the past day" as the timeframe that I was able to complete all of the questions. It took more than seven months for me to actually answer all of the questions concerning my lifetime. While answering the questions I had no intention of sharing the answers with anyone, but it was still extremely difficult for me to be honest while completing the questions. After managing to do so, I felt so much shame and guilt at not being able to control my suicidality that I destroyed the hand written answers so that no one could possibly find them and understand the high number of attempts and vast number of plans I had made."

For this reason it is very important for you to develop a rapport with the patient and be reassuring to them prior to asking them to complete the scale (if patient-rated), while conducting the interview (if clinician-rated), and while reviewing the interview with the patient.

Use data either directly or indirectly from the patient, but please put great effort in attempting to elicit data directly from the patient.

It is preferred that the SPTS is patient-rated and then reviewed with the clinician and patient. If this is not possible, the SPTS can be clinician administered and then reviewed between the patient and clinician. Reviewing the SPTS with the patient helps to develop a rapport with the patient that may assist the patient in being more truthful and forthcoming in the future.

This scale was designed as an extension of the Sheehan-Suicidality Tracking Scale (S-STS). <u>The S-STS needs to be completed prior to the use of the SPTS</u>. The SPTS is to be used if a patient indicates any answer > 0 to any of questions 3 through 12 and / or 14 through 16 of the S-STS. If the patient is not available to complete the SPTS as scheduled, complete page 3 of the S-STS. The S-STS is available by contacting David V. Sheehan M.D. via email (dsheehan@health.usf.edu).

The SPTS was designed for the tracking of suicidal planning. Scores from this scale should not be used as any type of "risk assessment" or "threat assessment", but could be factored into a "clinician judgment of suicide risk".

The Directions for Patients <u>must</u> be given to and read and signed by the patient prior to the use of the SPTS.

In order to get a better overall view of the patient's perspective and planning the clinician needs to ask details in connection to answers for questions 17 through 25, questions 36 through 41, and any other questions the clinician deems appropriate.

It is important that all of questions 1 through 35 are asked. Some clinicians may be tempted to ignore questions 1.a and 2 if the answer to question 1 is "0". Not asking questions 1.a would preclude the clinician from knowing that a patient thought about 3 methods, because they were "Not at all" serious when they thought about it. Not asking question 2 would preclude the clinician from fully understanding the suicidal planning in the event a patient has previously decided upon a method. The same issue may be true of questions in other sections of the SPTS.

It is important to ask the questions as they are worded. An example of this is in questions 2, 5, and 8. (Question 2 reads "How completely have you decided on any methods you might use to kill yourself?".) These questions contain the phrase "you might use". This phrase was selected because other wording such as "you will use" or "you plan to use" may suggest to the patient that the question only pertains to them if they have completely decided to make a suicide attempt. It is very important to gather data concerning a patient's decision making about a method, means, or a location, along with other domains, even if the patient hasn't completely decided to make an attempt.

Various timeframes can be used for this scale. It is suggested that clinicians use the following timeframes: "in the past week", "in the past month", "since your last visit", "in the past year", "in the past 13 months", or "in your lifetime". In certain instances it may be helpful to use the following timeframes: "concerning the plan(s) you will most likely use", "concerning your most recent plan(s)", or "concerning your recent attempt". If using the "concerning your recent attempt" timeframe, please change the tense of the questions as appropriate.

If either of the answers to questions 15 or 16 are > 0, use your best clinical judgment in appropriately assisting the patient to keep themself safe.

If the answer to question 20 is "Yes", consider using the Sheehan-Homicidality Tracking Scale (S-HTS) and the Homicide Plan Tracking Scale (HPTS). The S-HTS is available by contacting either David V. Sheehan M.D. via email (dsheehan@health.usf.edu) or Ivan Sascha Sheehan Ph.D. via

email (isheehan@ubalt.edu) or on his website (ProfessorSheehan.com). The HPTS is available by contacting Jennifer M. Giddens via email at (jgiddens@mail.usf.edu).

If the answer to question 34 is "Yes", please understand that the answers for the previous questions may be skewed. If a patient is experiencing suicidal ideation while completing the scale they may be minimizing the answers in order to assist them to cope with their suicidal ideation. It is much less common than minimizing, but it is also possible that a patient might engage in exaggerating the particular answer to one or more questions in order to assist them in getting closer to the point of making an attempt.

If the answer to question 35 is < 4, there is a potential for all of the previous answers to be incorrect. There is a large social stigma connected with suicidality and it is difficult for patients to give details concerning their suicidality, including their suicidal planning. Some of the reluctance may result from a patient attempting to keep details from the clinician in order for them to maintain the ability to make an attempt. Although the clinician would prefer to obtain the truth from the patient, it is very important for the therapeutic rapport for the clinician to not be abrasive in attempting to gather this information. Question 35 was placed at the end of the scale to give the patient the option of alerting the clinician to the potential of incorrect answers without having to detail which answers were incorrect and which were truthful. It may be helpful for the clinician to take note of the answer to question 35 prior to reviewing the interview with the patient in order to look for inconsistencies between the answers and any additional statements made by the patient during the review.

All clinicians using this scale in any clinical trial should be properly trained using materials designed for the SPTS. This is to ensure a thorough understanding of the meaning behind and the application of all components of this scale.

### Suicide Plan Tracking Scale (SPTS) Definitions and Examples

means - Means are the tool(s) someone could use to kill themself. Examples of means include, but are not limited to, insulin and / or syringe with needle, plastic bag and / or tape, rope and / or ladder, oleander tea, frozen pond, gun and / or bullets, or scalpel.

method - Method is the way someone could kill themself. Examples of methods include, but are not limited to overdose, suffocation, hanging, poisoning, hypothermia, gunshot wound, or excessive blood loss.

tasks - Examples of tasks someone would like to complete before they try to kill themself include, but are not limited to, writing suicide note(s), giving away personal items, arranging for pet(s) to be taken care of, settling financial affairs, following through on commitments, attending previously scheduled medical or mental health appointment, arranging for family member(s) to be taken care of, preparing personal property to be given to charity, destroying items they do not want others to see or read, planning their funeral, preparing individual meals for their husband following their death, prepaying for their funeral, dividing personal property to be given to particular people, purchasing a cemetery plot, writing a will, or telling people they love them.

Unpublished work © 2011 - 2014 Jennifer M Giddens. All Rights Reserved.

### Suicide Plan Tracking Scale (SPTS) Scoring and Tracking Log Instructions

#### **Suggested SPTS Scoring:**

In some instances it may be helpful for a clinician to combine the answers to particular questions in order to more clearly understand the planning and mindset of the patient. There are fifteen scores that are suggested for use.

#### Total Score

Sum the answers to questions 1 through 19 (excluding 1.a, 3.a, 6.a, 9.a, 11.a, 12.a, 14.a, and 17.a).

#### 2. Specific Plan Domain Scores

Find transformed product scores for each method, means, location, date, and task listed in questions 21 through 25. List the information for the ten highest transformed product scores. See Example 1 in Highest Method Score below for transformed product score calculation instructions.

#### 3. Domains Considered Score

Sum the answers to questions 1, 3, 6, 9, and 14.

#### 4. Number of Each Domain Considered Score

Sum the answers to questions 1.a, 3.a, 6.a, 9.a, and 14.a.

#### 5. Domains Decided Score

Sum the highest score for questions (2 or 21.b), (5 or 22.b), (8 or 23.b), (10 or 24.b), and 25.b.

#### 6. Access / Immediacy Score

Sum the highest score for questions 15, 16, 21.c, (4 or 22.c), (7 or 23.c), 24.c, and 25.c.

#### 7. Intent Score

Sum the answers to questions 11, 12, and 13.

#### 8. Highest Method Score

Transform scores for questions 21.b, 21.c, and 21.d from 0 - 4 to 1 - 5, respectively (by adding 1). Transform the score for question 26 from 0 to 2, from 1 to 1.75, from 2 to 1.5, from 3 to 1.25, and from 4 to 1. Multiply the transformed scores for questions 21.1.b by 21.1.c by 21.1.d by 26, 21.2.b by 21.2.c by 21.2.d by 26, ... 21.10.b by 21.10.c by 21.10.d by 26. Select the highest answer for all rows (1 - 10). See Example 1 below.

#### Example 1:

Only rows 21.1 and 21.2 are completed

21.1.b	$4 \rightarrow 5$	21.2.b	$2 \rightarrow 3$
21.1.c	$2 \rightarrow 3$	21.2.c	$3 \rightarrow 4$
21.1.d	$2 \rightarrow 3$	21.2.d	$1 \rightarrow 2$
26	$0 \rightarrow 2$	26	$0 \rightarrow 2$
5 x 3 x 3 x	x 2 = 90	3 x 4 x 2 x	2 = 48

The Method Score for row 21.1 = 90

The Method Score for row 21.2 = 48

Row 21.1 = 90 Row 21.2 = 48

The Highest Method Score = 90

Please note: a lower row score or highest score for Method indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 9. <u>Highest Means Score</u>

Transform scores for questions 22.b, 22.c, and 22.d from 0 - 4 to 1 - 5, respectively (by adding 1). Transform the score for question 27 from 0 to 2, from 1 to 1.75, from 2 to 1.5, from 3 to 1.25, and from 4 to 1. Multiply the transformed scores for questions 22.1.b by 22.1.c by 22.1.d by 27, 22.2.b by 22.2.c by 22.2.d by 27, ... 22.10.b by 22.10.c by 22.10.d by 27. Select the highest answer for all rows (1 - 10). See Example 1 in the Highest Method Score.

Please note: a lower row score or highest score for Means indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 10. Highest Location Score

Transform scores for questions 23.b, 23.c, and 23.d from 0 - 4 to 1 - 5, respectively (by adding 1). Transform the score for question 28 from 0 to 2, from 1 to 1.75, from 2 to 1.5, from 3 to 1.25, and from 4 to 1. Multiply the transformed scores for questions 23.1.b by 23.1.c by 23.1.d by 28, 23.2.b by 23.2.c by 23.2.d by 28, ... 23.10.b by 23.10.c by 23.10.d by 28. Select the highest answer for all rows (1 - 10). See Example 1 in the Highest Method Score.

Please note: a lower row score or highest score for Location indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion..

#### 11. Highest Date Score

Transform scores for questions 24.b, 24.c, and 24.d from 0 - 4 to 1 - 5, respectively (by adding 1). Transform the score for question 29 from 0 to 2, from 1 to 1.75, from 2 to 1.5, from 3 to 1.25, and from 4 to 1. Multiply the transformed scores for questions 24.1.b by 24.1.c by 24.1.d by 29, 24.2.b by 24.2.c by 24.2.d by 29, ... 24.10.b by 24.10.c by 24.10.d by 29. Select the highest answer for all rows (1 - 10). See Example 1 in the Highest Method Score.

Please note: a lower row score or highest score for Date indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 12. Highest Task Score

Transform scores for questions 25.b, 25.c, and 25.d from 0 - 4 to 1 - 5, respectively (by adding 1). Transform the score for question 30 from 0 to 2, from 1 to 1.75, from 2 to 1.5, from 3 to 1.25, and from 4 to 1. Multiply the transformed scores for questions 25.1.b by 25.1.c by 25.1.d by 30, 25.2.b by 25.2.c by 25.2.d by 30, ... 25.10.b by 25.10.c by 25.10.d by 30. Select the highest answer for all rows (1 - 10). See Example 1 in the Highest Method Score.

Please note: a lower row score or highest score for Task indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

### 13. <u>Usual Time Spent Planning Daily Score</u>

The score for Question 31.

### 14. <u>Least Time Spent Planning Daily Score</u> The score for Question 32.

#### 15. <u>Most Time Spent Planning Daily Score</u> The score for Question 33.

#### **Suggested SPTS Tracking Logs:**

In some instances it may be helpful for a clinician to maintain a log of the answers to particular questions over the course of interactions with a patient. There are fourteen optional logs that are available for use depending upon the needs of the protocol under investigation. It is suggested that you use the Scoring Log, the Daily Time Spent Log, and the Domain Importance Log, at the very least.

#### Scoring Log

The "Scoring Log" tracks the scores for the Total Score, the Domains Considered Score, the Number of Each Domain Considered Score, the Domains Decided Score, the Access / Immediacy Score, the Intent Score, the Highest Method Score, the Highest Means Score, the Highest Location Score, the Highest Date Score, the Highest Task Score, and the Others Involved question 17. (See the SPTS Scoring and page 7 of the SPTS for the details on calculating these scores.) The "Scoring Log" enables clinicians to track these totals in one location in order to notice large changes over time.

#### 2. Daily Time Spent Log

The "Daily Time Spent Log" tracks the answers for questions 31, 32, and 33. The "Daily Time Spent Log" enables clinicians to track the scores for the Usual Time Spent Planning Daily Score, the Least Time Spent Planning Daily Score, and the Most Time Spent Planning Daily Score. A change or shift in any of the time spent answers is a signal that the patient's usual suicidal planning has changed and must be further investigated by the clinician to find the reason behind the change / shift.

#### 3. <u>Domain Importance Log</u>

The "Domain Importance Log" tracks the ranking of the specific categories of domains over time. The "Domain Importance Log" enables clinicians to track the relative importance of domains over time. A change or shift in the importance of domains is a signal that the patient's usual suicidal planning has changed and must be further investigated by the clinician to find the reason behind the change / shift. For some patients this is an indication of a more specific plan to take action. For other patients, this is an indication that the date they considered using has passed or their interest in a particular method, means, or location has passed.

#### 4. <u>Domains Considered Log</u>

The "Domains Considered Log" tracks the answers for questions 1, 3, 6, 9, and 14. The "Domains Considered Log" enables clinicians to track the amount of consideration the patient has given the five main domains of a suicide plan - the method, the means, the location, the timeframe or date, and the unfinished tasks.

#### 5. Number of Each Domain Considered Log

The "Number of Each Domain Considered Log" tracks the answers for questions 1.a, 3.a, 6.a, 9.a, and 14.a. The "Number of Each Domain Considered Log" enables clinicians to track changes in the number of methods, means, locations, timeframes or dates, and unfinished tasks considered by the patient.

#### 6. Domains Decided Log

The "Domains Decided Log" tracks the highest answers for questions (2 or 21.b), (5 or 22.b), (8 or 23.b), (10 or 24.b), and 25.b. The "Domains Decided Log" enables clinicians to track the completeness of any of the patient's decisions concerning the five main domains of a suicide plan.

#### 7. Access / Immediacy Log

The "Access / Immediacy Log" tracks the highest answers for questions 15, 16, 21.c, (4 or 22.c), (7 or 23.c), 24.c, and 25.c. The "Access / Immediacy Log" enables clinicians to track the preparedness of the patient to engage in a planned suicide attempt.

#### 8. Intent Log

The "Intent Log" tracks the answers for questions 11, 12, and 13. The "Intent Log" enables clinicians to track the suicidal intent of the patient.

#### 9. Method Log

The "Method Log" tracks the product of answers for each row of question 21. The "Method Log" enables clinicians to track the importance of methods the patient has thought about. Please note: a lower row score for Method indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 10. Means Log

The "Means Log" tracks the product of answers for each row of question 22. The "Means Log" enables clinicians to track the importance of means the patient has thought about. Please note: a lower row score for Means indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 11. Location Log

The "Location Log" tracks the product of answers for each row of question 23. The "Location Log" enables clinicians to track the importance of locations the patient has thought about. Please note: a lower row score for Location indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 12. Date Log

The "Date Log" tracks the product of answers for each row of question 24. The "Date Log" enables clinicians to track the importance of timeframes or dates the patient has thought about. Please note: a lower row score for Date indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 13. Task Log

The "Task Log" tracks the product of answers for each row of question 25. The "Task Log" enables clinicians to track the importance of tasks the patient has thought about. Please note: a lower row score for Task indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

#### 14. Optional Items Log

The "Optional Items Log" tracks the answers for the questions 36 through 41. The "Optional Items Log" tracks the answers for the optional questions about the method, means, location, date, intent, and the role of the patient's suicide plan.

## Suicide Plan Tracking Scale (SPTS) Scoring Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

#### See Scoring Instructions:

Date	Visit Number	Total	Domains Considered	Number of Each Domain Considered	Domains Decided	Access / Immediacy	Intent	Highest Method	Highest Means	Highest Location	Highest Date	Highest Task	Others Involved (17)	Clinician Initials
01/01/13	1	46	8	8	16	16	11		9	•	12		1	JG

If more than one Scoring Log is used, consider transferring the highest scores from the prior log(s) to the first row.

## Suicide Plan Tracking Scale (SPTS) Daily Time Spent Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

#### See Scoring Instructions:

Scotting mistractions.						
Date	Visit Number	Usual (31)	Least (32)	Most (33)	Clinician Initials	
01/01/13	1	0 h 30 m		2 h 30 m	JG	
, , ,						

Date	Visit Number	Usual (31)	Least (32)	Most (33)	Clinician Initials

If more than one Daily Time Spent Log is used, consider transferring the highest scores from the prior log(s) to the first row.

Data on 01/01/13 is an example.

A change or shift in any of the time spent answers is a signal that the patient's usual suicidal planning has changed and must be further investigated by the clinician.

## Suicide Plan Tracking Scale (SPTS) Daily Time Spent Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

#### See Scoring Instructions:

Scoring Instructions:					
Date	Visit	Usual	Least	Most	Clinician
	Number	(31)	(32)	(33)	Initials
01/01/13	1	0 h 30 m	0 h 5 m	2 h 30 m	JG
01/08/13	2	0 h 25 m	0 h 8 m	2 h 15 m	JG
01/15/13	3	1 h 20 m	0 h 4 m	2 h 0 m	JG
01/22/13	4	0 h 20 m	0 h 10 m	1 h 45 m	JG
01/29/13	5	0 h 45 m	0 h 5 m	5 h 20 m	JG
02/05/13	6	0 h 35m	0 h 6 m	2 h 30 m	JG
02/12/13	7	0 h 25 m	0 h 9 m	1 h 50 m	JG
02/19/13	8	0 h 20 m	0 h 5 m	2 h 5 m	JG
02/26/13	9	1 h 20 m	1 h 5 m	1 h 30 m	JG

Date	Visit Number	Usual (31)	Least (32)	Most (33)	Clinician Initials
	Number	(31)	(32)	(33)	IIIICIGIS

If more than one Daily Time Spent Log is used, consider transferring the highest scores from the prior log(s) to the first row.

Data on 01/01/13 is an example.

A change or shift in any of the time spent answers is a signal that the patient's usual suicidal planning has changed and must be further investigated by the clinician.

# Suicide Plan Tracking Scale (SPTS) Domains Considered Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

See Scoring Instructions:

				1	1	1	
Date	Visit	Method	Means	Location	Date	Task	Clinician
	Number	(1)	(3)	(6)	(9)	(14)	Initials
01/01/13	1	0	4	0	4	3	JG
				<u> </u>			

If more than one Domains Considered Log is used, consider transferring the highest scores from the prior log(s) to the first row.

## Suicide Plan Tracking Scale (SPTS) Number of Each Domain Considered Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

See Scoring Instructions:

Date	Visit	Method	Means	Location	Date	Task	Clinician
	Number	(1.a)	(3.a)	(6.a)	(9.a)	(14.a)	Initials
01/01/13	1	0	3	0	5	0	JG

If more than one Number of Each Domain Considered Log is used, consider transferring the highest scores from the prior log(s) to the first row. Data on 01/01/13 is an example.

## Suicide Plan Tracking Scale (SPTS) Domains Decided Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use the Highest Score (See Scoring Instructions):

istructions):	Visit	Method	Means	Location	Date	Task	Clinician
Date	Number	(2 or 21.b)	(5 or 22.b)	(8 or 23.b)	(10 or 24.b)	(25.b)	Initials
01/01/13	1	2	3	0	4	0	JG
		_					
					og(s) to the fir		

If more than one Domains Decided Log is used, consider transferring the highest scores from the prior log(s) to the first row.

# Suicide Plan Tracking Scale (SPTS) Intent Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

#### See Scoring Instructions:

scoring instructions:										
	Visit	To Plan	To Act	To Die	Clinician					
Date										
	Number	(11)	(12)	(13)	Initials					
01/01/13	1	3	3	0	JG					
, ,										

Data	Visit	To Plan	To Act	To Die	Clinician
Date	Number	(11)	(12)	(13)	Initials
		` .	, ,	` '	

If more than one Intent Log is used, consider transferring the highest scores from the prior log(s) to the first row.

## Suicide Plan Tracking Scale (SPTS) Access / Immediacy Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use the Highest Score (See Scoring Instructions):

st Score (See Sc			- 1.						-u
Date	Visit	Emotional	Complete	Method	Means	Location	Date	Task	Clinician
	Number	Preparation (15)	Preparation (16)	(21.c)	(4 or 22.c)	(7 or 23.c)	(24.c)	(25.c)	Initials
01/01/13	1	3	2	1	4	1	3	4	JG

If more than one Access / Immediacy Log is used, consider transferring the highest scores from the prior log(s) to the first row.

## Suicide Plan Tracking Scale (SPTS) Method Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use Product Score for each Method (See Scoring Instructions and Example Method Log):

Date	Visit Number						Clinici Initia

If more than one Method Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Method indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

## Suicide Plan Tracking Scale (SPTS) Example Method Log

Sponsor:NIMH	Patient Name:Sarah Stevens
Protocol Number:506348	Patient Number:2056

Use Product Score for each Method (See Scoring Instructions and Example Method Log):

Date	e l	Visit Number	hanging	overdose	cutting wrist	gunshot wound	drowning					Clinician Initials
01/01		1	20	30	12	•			•	•	•	JG
01/08		2	•	30	•	18	45					JG
01/15	/13	3	22.5			12	-	•	•	•		JG

If more than one Method Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Method indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

## Suicide Plan Tracking Scale (SPTS) Means Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use Product Score for each Means (See Scoring Instructions and Example Method Log):

Date	Visit Number						Clinici Initia

If more than one Means Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Means indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

## Suicide Plan Tracking Scale (SPTS) Location Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use Product Score for each Location (See Scoring Instructions and Example Method Log):

Date	Visit Number						Clinicia Initia

If more than one Location Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Location indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

## Suicide Plan Tracking Scale (SPTS) Date Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use Product Score for each Date (See Scoring Instructions and Example Method Log):

Date	Visit Number						Clinici Initia
		v transfarring					

If more than one Date Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Date indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

## Suicide Plan Tracking Scale (SPTS) Task Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

Use Product Score for each Task (See Scoring Instructions and Example Method Log):

Date	Visit Number						Clinicia Initial:

If more than one Task Log is used, consider transferring the highest scores from the prior log(s) to the first row.

A lower row score for Task indicates a higher importance to the patient. Items with a higher score merits further questioning and discussion.

### Suicide Plan Tracking Scale (SPTS) Domain Importance Log

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

List the 10 highest domain categories from page 7 of the SPTS (See Scoring Instructions):

Date	Visit Number	Ranking 1	Ranking 2	Ranking 3	Ranking 4	Ranking 5	Ranking 6	Ranking 7	Ranking 8	Ranking 9	Ranking 10	Clinician Initials
01/01/13	1	method	means	date	date	location	method	task	task	means	date	JG
						<u> </u>					04 /04 /42 :	

If more than one Domain Importance Log is used, consider transferring the highest scores from the prior log(s) to the first row.

Data on 01/01/13 is an example.

A change or shift in any of the importance of domains is a signal that the patient's usual suicidal planning has changed and must be further investigated by the clinician.

### Suicide Plan Tracking Scale (SPTS) Optional Items Log - Page 1

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

See Scoring Instructions:

ng instructions:																	
Date	Visit		Met	hod				Means					Loca	ation			Clinician
	Number		(36.b)		(36.d)				(37.d)	(37.e)	(38.a)	(38.b)			(38.e)	(38.f)	
01/01/13	1	2	1	0		0	2	3	1		0	2	3	1	1	•	JG

If more than one Optional Items Log is used, consider transferring the highest scores from the prior log(s) to the first row.

Page 1 of 2.

## Suicide Plan Tracking Scale (SPTS) Optional Items Log - Page 2

Sponsor:	Patient Name:
Protocol Number:	Patient Number:

#### See Scoring Instructions:

ictions:															
Data	Visit			Da	ite			Intent					Role	Clinician	
Date	Number	(39.a)	(39.b)	(39.c)	(39.d)	(39.e)	(39.f)	(40.a)	(40.b)	(40.c)	(40.d)	(40.e)	(40.f)	of Plan	Initials
01/01/13	1	0	2	4	1	3		3	4	1	2	1		Neither	JG

If more than one Optional Items Log is used, consider transferring the highest scores from the prior log(s) to the first row.

Page 2 of 2.

We developed a set of *training slides* to help train clinicians in the use of the SPTS. These slides summarize the use of the SPTS outside research settings. *Any clinician using the* SPTS *in a study or clinical trial must be trained by a rater-training agency or by a pharmaceutical company approved by the author of the SPTS*. The 2015 version of the S SPTS training slides will soon be available on the Harm Research Press website (<a href="http://www.HarmResearch.org">http://www.HarmResearch.org</a>). Training videos are in development at the time of this writing.

#### Conclusion

The directions, definitions and examples, and training slides help clinicians understand how to use the SPTS in clinical, research, and other settings. The domains of suicide planning can fluctuate or evolve over time. The scores and tracking logs enable clinicians to get both a more detailed understanding and a bigger picture of a patient's suicide planning. This helps clinicians more completely assess and monitor suicide planning.

### 14.8

#### Suicidality Modifiers Scale (SMS)

#### Introduction

The Suicidality Modifiers Scale (SMS) assesses factors that can influence some domains of suicidality. For each domain covered, it assesses:

- 1. the severity of each domain
- 2. the ability to experience / resist the domain
- 3. the loss of desire to experience / resist the domain
- 4. how much memories impacted the domain
- 5. how much events outside the patient's control impacted the domain
- 6. how much events within the patient's control impacted the domain.

What does the SMS probe that the other suicidality scales don't?

Suicide attempts in the young are frequently impulsive. Suicide attempts in the elderly are often associated with hopelessness. This scale uniquely investigates these and other domains association with suicidality in each subject. These domains are not necessarily all suicidal phenomena in and of themselves. However, they are acknowledged phenomena that can compound existing suicidal phenomena.

#### Use and Value

The SMS may be helpful in providing a deeper understanding of attacks of impulsive suicidality, the extent to which they are present, their effect on the patient, and the effect of memories and events on these impulse attacks (if any). This could provide more useful information about the nature of attacks of impulsive suicidality than the heretofore norm of using impulsive personality trait scales in suicidality. We have found

that impulse attacks as identified in this scale do not correlate with trait impulsivity in the individual in suicidal patients.

#### Use to Clinicians

The answers to items 4 through 6 above provide information on individualized target areas the clinician can focus on in understanding and assisting the patient to cope with the memories and events that impact each domain. We found that it sometimes provided an early warning sign of impending worsening of suicidality before it became apparent in other ways. This was particularly true of question 3 — "the loss of desire to hold back the impulse to plan or to act in any suicidal way". The change in the score on this question tends to precede other changes during deterioration. It also lags behind improvement in other areas and is one of the last questions in that domain to fully resolve.

#### Use to Researchers

It would be useful to study this scale in the context of Dialectical Behavioral Therapy (DBT) or Cognitive Behavioral Therapy (CBT) treatment study for subjects with suicidality. It could address whether these domains (questions 1 - 3) persist, even if the memories and events are no longer factors influencing the domain (questions 4 - 6).

### **Suicidality Modifiers Scale (SMS)**

### Impulsivity

	er the past (timeframe): <b>Topic</b> How strong was the impulse (urgent need) to <u>plan</u> or to <u>act</u> in <u>any</u> suicidal way?	Not at all	A little	Moderate 2	y Very	Extremely 4			
2.	Ability to Resist Suicidal Impulses How difficult was it to resist this impulse?	0	1	2	3	4			
3.	Desire to Resist Suicidal Impulses  How much did you lose the desire to resist this impulse?	0	1	2	3	4			
4.	<b>Memories Modifier</b> How much did your memories make you <b>lose the desire</b> to resist this impulse?	0	1	2	3	4			
5.	Events Modifier 1 How much did events outside your control make you lose the desire to resist this impulse?	0	1	2	3	4			
6.	Events Modifier 2 How much did events within your control make you lose the desire to resist this impulse?	0	1	2	3	4			
	Hopelessness								
Over the past (timeframe):									
1.	<b>Topic</b> How much did you lose hope that your life would get better?	0	1	2	3	4			
2.	Ability to Be Hopeful How difficult was it for you to be hopeful that your life would get better?	0	1	2	3	4			
3.	<b>Desire to Be Hopeful</b> How much did you <b>lose the desire</b> to be hopeful that your life would get better?	0	1	2	3	4			
4.	Memories Modifier  How much did your memories make you lose the desire to be hopeful that your life would get better?	0	1	2	3	4			
5.	Events Modifier 1  How much did events outside your control make you lose the desire to be hopeful that your life would get better?	0	1	2	3	4			
6.	Events Modifier 2 How much did events within your control make you lose the desire to be hopeful that your life would get better?	0	1	2	3	4			

### **Suicidality Modifiers Scale (SMS)**

### Loss of Enjoyment

Ove	er the past (timeframe): <b>Topic</b>	Not at all	Λ little	Moderate	v Verv	Extremely
1.	How much did you lose your ability to enjoy things or to feel happiness and joy in your life?	0	1	2	3	4
2.	Ability to Enjoy How difficult was it for you to feel this happiness and joy?	0	1	2	3	4
3.	<b>Desire to Enjoy</b> How much did you <b>lose the desire</b> to experience this happiness and joy?	0	1	2	3	4
4.	Memories Modifier  How much did your memories make you lose the desire to experience this happiness and joy?	0	1	2	3	4
5.	Events Modifier 1 How much did events outside your control make you lose the desire to experience this happiness and joy?	0	1	2	3	4
6.	Events Modifier 2  How much did events within your control make you lose the desire to experience this happiness and joy?	0	1	2	3	4
	Overwhelmed Feeling					
Ove	er the past (timeframe):  Topic					
1.	How overwhelmed have you felt?	0	1	2	3	4
2.	Ability to Resist Overwhelmed Feeling How difficult was your struggle with this overwhelmed feeling?	0	1	2	3	4
3.	<b>Desire to Resist Overwhelmed Feeling</b> How much did you <b>lose the desire</b> to struggle with this overwhelmed feeling?	0	1	2	3	4
4.	Memories Modifier  How much did your memories make you lose the desire to struggle with this overwhelmed feeling?	0	1	2	3	4
5.	Events Modifier 1  How much did events outside your control make you lose the desire to struggle with this overwhelmed feeling?	0	1	2	3	4
6.	Events Modifier 2  How much did events within your control make you lose the desire to struggle with this overwhelmed feeling?	0	1	2	3	4

#### Conclusion

The SMS assesses the presence of some domains that compound suicidality. It investigates factors that can influence these domains of suicidality. The SMS may be particularly helpful in assessing impulsive suicidality and hopelessness in a way that is very sensitive to change and may provide an early warning sign of impending worsening of suicidality before it becomes apparent in other ways.

### 14.9

#### Suicidal Impulse Attack Scale (SIAS)

#### Introduction

What does the SIAS probe that the other suicidality scales don't?

The Suicidal Impulse Attack Scale (SIAS) assesses the components of a suicidal impulse attack. These components are the:

- 1. need or impulse for the patients to kill themselves sooner rather than later
- 2. need or impulse for the patients *to plan* to kill themselves sooner rather than later
- 3. patients thoughts about killing themselves or of being better off dead
- 4. associated physical symptoms

#### **Purpose**

The SIAS is specifically designed for use as a very brief measure of components within a suicidal impulse attack. Because the suicidal impulse attack events are relatively brief compared to chronic suicidality, an instrument is needed to quickly measure these events over very short periods of time in anti-suicidality impulse attack treatments. For example, in acute ketamine infusion treatment studies, if the interval between assessments is very short, there is not enough time to administer any of the standard validated suicidality scales to assess those short intervals. The SIAS may serve as a brief assessment to capture the severity of the core phenomena of the suicidal impulse attack over very short periods of time.

#### Clinical and Research Use

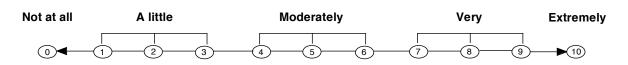
The primary application of the SIAS is most likely to be in Impulse Attack Suicidality Disorder (IASD) rather than in other suicidality disorders. It allows a clinician to determine if a patient with IASD is responding to treatment. The scale allows clinicians and researchers to assess the severity of the essential components of suicidal impulse attacks and to monitor these components over time. Using this scale to build a database on suicidal impulse attacks across a large sample of such individuals is likely to help identify patterns that were not heretofore observed. The use of the SIAS in conjunction with the Suicidality Modifiers Scale (SMS) may help identify patterns in how the domains of the SMS do or do not influence subsequent suicidal impulse attacks.

### Suicidal Impulse Attack Scale (SIAS)

In the past (timeframe: past 10 minutes / 20 minutes / 1 day / 1 week / 1 month):

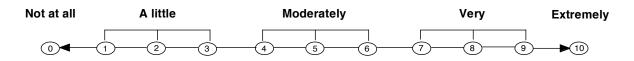


How strong was the need or impulse to kill yourself sooner rather than later:



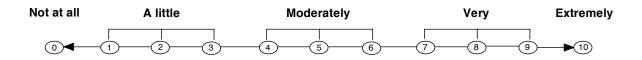
### **Suicidal Impulse Planning**

How strong was the need or impulse to plan to kill yourself sooner rather than later:



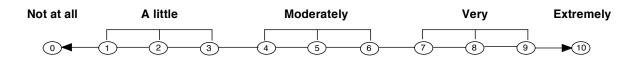
#### **Suicidal Ideation**

How seriously did you think about killing yourself or that you would be better off dead:



### **Physical Symptoms**

How much were you bothered by any physical symptoms:



#### Conclusion

The SIAS is a very brief assessment of the components of a suicidal impulse attack. The SIAS may be helpful in measuring a patient's response to treatment. It can also be used in rapid onset of action studies for anti-suicidality treatments.

#### 14.10

#### Visit Face Sheet

#### Introduction

At the beginning of visits or consultations with health care providers, the patient and the clinician may have different agendas. To focus the clinician's attention on the core problems and questions that patients bring to these meetings, it is prudent to provide a face sheet such as the example below to allow the patient to identify the main problems and questions they would like their physician to help them with at todays visit. For example, the clinician may assume that the patient has come for a follow up visit to monitor their response to an antidepressant treatment. However, the patient may be coming to the visit because they want the clinician to complete a form to help them get food stamps and to get them to write a report for their divorce lawyer so that they will not loose custody of their children on mental health grounds. Regrettably after the clinician has gone through their usual Major Depressive Disorder follow up procedures, the patient may bring up these two additional requests at the very end of the allotted time for the visit. If the clinician had known about these issues from the very beginning, they may have allocated the time for the visit in a different way.

To help us meet your needs today, please outline briefly the main problems or questions that you would like your physician to help you with at today's visit.

For problems you would prefer not to mention in writing just write the words "ask me" opposite any of the 4 problems below.

1.	
1.	
ļ	
4	
2.	
İ	
<b></b>	
3.	
Ο.	
ļ	
<u> </u>	
1	
4.	
ļ	
ļ	

## Conclusion

The visit face sheet can assist the patient in communicating their needs for the visit to their clinician. This assists the clinician in better managing their time with the patient.

## 14.11

## Mini International Neuropsychiatric Interview (MINI) for Suicidality Disorder Studies

and

Mini International Neuropsychiatric Interview (MINI) for Psychotic and Suicidality Disorder Studies

#### Introduction

The following sections contain copies of the standard version of the Mini International Neuropsychiatric Interview (MINI) and the MINI for Psychotic Disorders. Both are versions 7.0.1 for DSM-5. We have added a module for the differential diagnosis of all the Suicidality Disorders outlined in chapter 6.1. This module (Module Z) is optional and not part of the standard MINI. However, when doing research studies on Suicidality Disorders Module Z provide a clinical operational guide to identify which of the several suicidality disorder phenotypes to which each subject should be assigned. This may be helpful for those doing clinical trials with suicidality as the primary target of treatment and for those investigating genetic and other biomarkers in suicidality. We expect with the accumulation of better genetic and other biomarkers of suicidality that these phenotypes will need to be modified as we reach a confluence in our understanding between the clinical features and the genetic and other biomarkers associated with suicidality. In the meantime, the current phenotypes have heuristic clinical value.

If you wish to jump straight to the Suicidality Disorders Module (Module Z) please click here.

If you wish to jump straight to the following chapter and not scroll through either the MINI or the Suicidality Disorders Module please click here.

## M.I.N.I.

# MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW FOR SUICIDALITY DISORDERS STUDIES

**English Version 7.0.1** 

For

DSM-5

© Copyright 1992-2016 Sheehan DV

All rights reserved. No part of this document may be reproduced or transmitted in any form, or by any means, electronic or mechanical, including photocopying, or by any information storage or retrieval system, without permission in writing from Dr. Sheehan. Individual researchers, clinicians and students working in nonprofit or publicly owned settings (including universities, nonprofit hospitals, and government institutions) may make paper copies of a M.I.N.I. instrument for their **personal** clinical and research use, but **not** for institutional use, or for any financial profit or gain. Any use involving financial gain requires a license agreement from the copyright holder and payment of a per use license fee.

#### **DISCLAIMER**

Our aim is to assist in the assessment and tracking of patients with greater efficiency and accuracy. Before action is taken on any data collected and processed by this program, it should be reviewed and interpreted by a licensed clinician.

This program is not designed or intended to be used in the place of a full medical and psychiatric evaluation by a qualified licensed physician – psychiatrist. It is intended only as a tool to facilitate accurate data collection and processing of symptoms elicited by trained personnel. It is not a diagnostic test.

• • • • • • • • • • • • • • • • • • • •		
Patient Name:	Patient Number:	
Date of Birth:	Time Interview Began:	
Interviewer's Name:	Time Interview Ended:	
Date of Interview:	Total Time:	

Da	te of Interview:	Total Time:				
	MODULES	TIME FRAME	MEETS CRITERIA	DSM-5	ICD-10	PRIMARY DIAGNOSIS
Α	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)	₫			
		Past				
	AAA IOD DEDDECCIVE DICODDED	Recurrent		205 20 205 25 5	<b>500</b>	_
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks)		296.20-296.26 Single	F32.x	
		Past	0	296.20-296.26 Single	F32.x	0
		Recurrent	L	296.30-296.36 Recurrent	F33.x	
В	SUICIDALITY	Current (Past Month)				
		Lifetime attempt	□	☐ Low ☐ Moderate ☐ H	igh	
	SUICIDE BEHAVIOR DISORDER	Current		(In Past Year)		
		In early remission		(1 - 2 Years Ago)		
С	MANIC EPISODE	Current				
		Past				
	HYPOMANIC EPISODE	Current				
		Past		Not Explored		
	BIPOLAR I DISORDER	Current		296.41-296.56	F31.0F31.76	
		Past		296.41-296.56	F31.0- F31.76	
	BIPOLAR II DISORDER	Current		296.89	F31.81	
		Past		296.89	F31.81	
	BIPOLAR DISORDER UNSPECIFIED	Current		296.40/296.50	F31.9	
		Past		296.40/296.50	F31.9	
	BIPOLAR I DISORDER WITH PSYCHOTIC FEATURES	Current		296.44/296.54	F31.2/31.5	
		Past		296.44/296.54	F31.2/31.5	
D	PANIC DISORDER	Current (Past Month)		300.01	F41.0	
		Lifetime		300.01	F40.0	
Ε	AGORAPHOBIA	Current		300.22	F40.00	
F	SOCIAL ANXIETY DISORDER (Social Phobia)	Current (Past Month)		300.23	F40.10	
G	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)	О	300.3	F42	
Н	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)		309.81	F43.10	
ı	ALCOHOL USE DISORDER	Past 12 Months		303.9	F10.10-20	
J	SUBSTANCE USE DISORDER (Non-alcohol)	Past 12 Months		304.0090/305.2090	F11.1x-F19.288	
K	PSYCHOTIC DISORDERS	Lifetime	О	297.3/297.9/	F20.81-F29	0
				293.81/298.83/298.89		
		Current	_	297.3/297.9/ 293.81/298.83/298.89	F20.81-F29	_
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime	0	296.24/296.34-296.44 296.54	F31.2/F32.2/F33	3.3
		Current		296.24/296.34/296.44/296	.54F31.2/F32.2/F33	3.3
L	ANOREXIA NERVOSA	Current (Past 3 Months)		307.1	F50.01-02	
M	BULIMIA NERVOSA	Current (Past 3 Months)	_	307.51	F50.2	
MB	BINGE-EATING DISORDER	Current (Past 3 Months)		307.51	F50.8	
N	GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)		300.02	F41.1	
0	MEDICAL, ORGANIC, DRUG CAUSE RULED OUT		□ No	☐ Yes ☐ Uncertain		
Р	ANTISOCIAL PERSONALITY DISORDER	Lifetime	О	301.7	F60.2	□
	IDENTIFY THE PRIMARY DIAGNOSIS BY CHECK (Which problem troubles you the most or do					

#### **GENERAL INSTRUCTIONS**

The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-5 and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization). The results of these studies show that the M.I.N.I. has similar reliability and validity properties, but can be administered in a much shorter period of time (mean  $18.7 \pm 11.6$  minutes, median 15 minutes) than the above referenced instruments. Clinicians can use it, after a brief training session. Lay interviewers require more extensive training.

#### INTERVIEW:

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

#### **GENERAL FORMAT:**

The M.I.N.I. is divided into modules identified by letters, each corresponding to a diagnostic category.

- •At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.
- •At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

#### **CONVENTIONS:**

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « **bold** » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them (→) indicate that one of the criteria necessary for the diagnosis or diagnoses is not met. In this case, the interviewer should go to the end of the module, circle « NO » in all the diagnostic boxes and move to the next module.

When terms are separated by a slash (/) the interviewer should read only those symptoms known to be present in the patient (for example, questions J2b or K6b).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

#### **RATING INSTRUCTIONS:**

All questions must be rated. The rating is done at the right of each question by circling either YES or NO. Clinical judgment by the rater should be used in coding the responses. Interviewers need to be sensitive to the diversity of cultural beliefs in their administration of questions and rating of responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.

The clinician should be sure that each dimension of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives).

Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. has questions that investigate these issues.

For any questions, suggestions, need for a training session or information about updates of the M.I.N.I., please contact: David V Sheehan, M.D., M.B.A.

University of South Florida College of Medicine

tel: +1 813-956-8437

e-mail: dsheehan@health.usf.edu

3

#### A. MAJOR DEPRESSIVE EPISODE

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO IN THE DIAGNOSTIC BOX, AND MOVE TO THE NEXT MODULE)

A1	а	Were you <u>ever</u> depressed or down, or felt sad, empty or hopeless most of the day, nearly every day, for two weeks?  IF NO, CODE NO TO <b>A1b</b> : IF <b>YES</b> ASK:	NO	YES
	b	<u>For the past two weeks,</u> were you depressed or down, or felt sad, empty or hopeless most of the day, nearly every day?	NO	YES
A2		Were you <u>ever</u> much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks?	NO	YES
		IF NO, CODE NO TO A2b: IF YES ASK:		
	b	In the <u>past two weeks</u> , were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time?	NO	YES
		IS <b>A1a</b> OR <b>A2a</b> CODED <b>YES</b> ?	<b>→</b> NO	YES

A3 IF **A1b** OR **A2b** = **YES**: EXPLORE THE **CURRENT** AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE IF **A1b** AND **A2b** = **NO**: EXPLORE **ONLY** THE MOST SYMPTOMATIC **PAST** EPISODE

	Over that two week period, when you felt depressed or uninterested:	Past 2	Weeks	Past E	pisode
а	Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by $\pm 5\%$ of body weight or $\pm 8$ lb or $\pm 3.5$ kg, for a 160 lb/70 kg person in a month)? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES
b	Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES	NO	YES
С	Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day? Did anyone notice this?	NO	YES	NO	YES
d	Did you feel tired or without energy almost every day?	NO	YES	NO	YES
е	Did you feel worthless or guilty almost every day?	NO	YES	NO	YES
	IF YES, ASK FOR EXAMPLES. LOOK FOR DELUSIONS OF FAILURE, OF INADEQUACY, OF RUIN OR OF GUILT, OR OF NEEDING PUNISHMENT OR DELUSIONS OF DISEASE OR DEATH OR NIHILISTIC OR SOMATIC DELUSIONS.  THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. Current Episode  No Yes  Past Episode No Yes				
f	Did you have difficulty concentrating, thinking or making decisions almost every day?	NO	YES	NO	YES
g	Did you repeatedly think about death (FEAR OF DYING DOES NOT COUNT HERE), or have any thoughts of killing yourself, or have any intent or plan to kill yourself? Did you attempt suicide? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES
	Did these symptoms cause significant distress or problems at home, at work, at school, socially, in your relationships, or in some other important way, and are they a change from your previous functioning?	NO	YES	NO	YES

Α4

AS		months, without any significant depression or any significant loss of interest?	N/A NO	YES
		ARE <b>5</b> OR MORE ANSWERS <b>(A1-A3)</b> CODED <b>YES</b> AND IS <b>A4</b> CODED YES	NO	YES
		AND	MAJOR DEP EPISO	
	13	S "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?		
	S	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	CURRENT PAST	
	I	F <b>A5</b> IS CODED <b>YES,</b> CODE <b>YES</b> FOR RECURRENT.	RECURRENT	
A6	a F	How many episodes of depression did you have in your lifetime?		
	E	Between each episode there must be at least 2 months without any significant depressi	on.	

## **B. SUICIDALITY**

	In the meet month did you.			Points
	In the past month did you:			
B1	Have any accident? This includes taking too much of your medication accidentally. IF NO TO B1, SKIP TO B2; IF YES, ASK B1a:	NO	YES	0
B1a	Plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?	NO	YES	0
	IF NO TO B1a, SKIP TO B2: IF YES, ASK B1b:			
B1b	Intend to die as a result of any accident?	NO	YES	0
B2	Think (even momentarily) that you would be better off dead or wish you were dead or needed to be dead?	NO	YES	1
В3	Think (even momentarily) about harming or of hurting or of injuring yourself - with at least some intent or awareness that you might die as a result - or think about suicide (i.e. about killing yourself)?	NO	YES	6
	IF NO TO B2 + B3, SKIP TO B4. OTHERWISE ASK:			
	Frequency Intensity			
	Occasionally			
B4	Hear a voice or voices telling you to kill yourself or have dreams with any suicidal content?  If YES, mark either or both:  was it a voice or voices?  was it a dream?	NO	YES	4
B5	Have a suicide method in mind (i.e. how)?	NO	YES	8
В6	Have a suicide means in mind (i.e. with what)?	NO	YES	8
В7	Have any place in mind to attempt suicide (i.e. where)?	NO	YES	8
В8	Have any date/timeframe in mind to attempt suicide (i.e. when)?	NO	YES	8
В9	Think about any task you would like to complete before trying to kill yourself? (e.g. writing a suicide note)	NO	YES	8
B10	Intend to act on thoughts of killing yourself?  If YES, mark either or both:  did you intend to act at the time?  did you intend to act at some time in the future?	NO	YES	8
B11	Intend to die as a result of a suicidal act?  If YES, mark either or both:   did you intend to die by suicide at the time?  did you intend to die by suicide at some time in the future?	NO	YES	8
B12	Feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  If YES, mark either or both:  was this to kill yourself?  was this to plan to kill yourself?  was this provoked?	NO elf?	YES	8
	IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED ASK: "5 minutes before this Impulse, could you have predicted it would occur at that time?"			

B13	Have difficulty resisting these impulses?	NO	YES	8
B14	Take any active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)? This includes times when you were going to kill yourself, but were interrupted or stopped yourself, before harming yourself.  IF NO TO B14, SKIP TO B15.	NO	YES	
B14a	Take active steps to prepare to kill yourself, but you did not start the suicide attempt?	NO	YES	9
B14b	Take active steps to prepare to kill yourself, but then <b>you stopped yourself just before</b> harming yourself ("aborted").	NO	YES	10
B14c	Take active steps to prepare to kill yourself, but then someone or something stopped you just before harming yourself ("interrupted")?	NO	YES	11
B15	Injure yourself on purpose without intending to kill yourself?	NO	YES	0
B16	Attempt suicide (to kill yourself)? IF NO TO B16, SKIP TO B17.	NO	YES	
B16a	Start a suicide attempt (to kill yourself), but then <b>you decided to stop</b> and did not finish the attempt?	NO	YES	12
B16b	Start a suicide attempt (to kill yourself), but then <b>you were interrupted</b> and did not finish the attempt?	NO	YES	13
B16c	Went through with a suicide attempt (to kill yourself), <b>completely</b> as you meant to? A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.  IF NO, SKIP TO B17:	NO	YES	14
	Hope to be rescued / survive   Expected / intended to die			
B17	TIME SPENT PER DAY WITH ANY SUICIDAL IMPULSES, THOUGHTS OR ACTIONS:  Usual time spent per day: hours minutes.  Least amount of time spent per day: hours minutes.  Most amount of time spent per day: hours minutes.			
	In your lifetime:			
B18	Did you ever make a suicide attempt (try to kill yourself)?  If YES, how many times?  If YES, when was the last suicide attempt?  Current: within the past 12 months  In early remission: between 12 and 24 months ago  In remission: more than 24 months ago	NO	YES	4
	"A suicide attempt is any self injurious behavior, with at least some intent (> 0) to die as a rethe individual intended to kill him-or herself, at least to some degree, can be explicit or infectircumstance. For example, it is defined as a suicide attempt if it is clearly not an accident of the act could be lethal, even though denying intent." (FDA Guidance for Industry Suicidal Id Document 2012 and C-CASA definition). Posner K et al. Am J Psychiatry 2007; 164 (7): 1035 <a href="http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/">http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/</a>	erred from the or if the indivi- leation and B	e behavior dual thinks	
B19	How likely are you to try to kill yourself within the next 3 months on a scale of 0-100% ANY LIKELIHOOD > 0% ON B19 SHOULD BE CODED YES	% NO	YES	13

NO YES IS AT LEAST 1 OF THE ABOVE (EXCEPT B1) CODED YES? SUICIDALITY IF YES, ADD THE TOTAL POINTS FOR THE ANSWERS (B1-B19) CHECKED 'YES' AND SPECIFY THE SUICIDALITY SCORE CATEGORY AS INDICATED IN THE DIAGNOSTIC BOX: 1-8 points Low INDICATE WHETHER THE SUICIDALITY IS CURRENT (PAST MONTH) OR A LIFETIME SUICIDE ATTEMPT OR 9-16 points Moderate BOTH BY MARKING THE APPROPRIATE BOXES OR BY LEAVING EITHER OR BOTH OF THEM UNMARKED. ≥ 17 points High CURRENT = ANY POSITIVE RESPONSE IN B1a THROUGH B16c OR ANY TIME SPENT IN B17. LIFETIME ATTEMPT = B18 CODED YES. LIKELY IN THE NEAR FUTURE = B19 CODED YES. **CURRENT** MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURRENT LIFETIME ATTEMPT AND NEAR FUTURE SUICIDALITY IN THE SPACE BELOW: LIKELY IN NEAR FUTURE

IS **B18** CODED YES?

#### AND A YES RESPONSE TO

Was the suicidal act started when the subject was not in a state of confusion or delirium?

#### AND A YES RESPONSE TO

Was the suicidal act done without a political or religious purpose?

IF YES, SPECIFY WHETHER THE DISORDER IS CURRENT, IN EARLY REMISSION OR IN REMISSION.

NO	YES
SUICIDAL BEH DISORDE	
Current In early remission In remission	

## **C. MANIC AND HYPOMANIC EPISODES**

	(➡ MEANS: GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN MANIC AND HYPOMANIC DIAGNOSTIC BOXES, AND MOVE TO NEXT MODULE)							
		Do you have any family history of manic-depressive illness or bipolar disorder, or any family member who had mood swings treated with a medication like lithium, sodium valproate (Depakote) or lamotrigine (Lamictal)?  THIS QUESTION IS NOT A CRITERION FOR BIPOLAR DISORDER, BUT IS ASKED TO INCREASE THE CLINICIAN'S VIGILANCE ABOUT THE RISK FOR BIPOLAR DISORDER.  IF YES, PLEASE SPECIFY WHO:	N	0	YES			
C1	a	Have you <b>ever</b> had a period of time when you were feeling 'up' or 'high' or 'hyper' and so active or full of energy or full of yourself that you got into trouble, - or that other people thought you were not your usual self? (Do not consider times when you were intoxicated on drugs or alcohol.)  IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT YOU MEAN BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS: By 'up' or 'high' or 'hyper' I mean: having elated mood; increased energy or increased activity; needing less sleep having rapid thoughts; being full of ideas; having an increase in productivity, motivatio creativity, or impulsive behavior; phoning or working excessively or spending more mo	; n,	0 \	/ES			
	b	Are you currently feeling 'up' or 'high' or 'hyper' or full of energy?	N	0 Y	/ES			
C2	a	Have you <b>ever</b> been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified?	N	O Y	/ES			
		IF NO, CODE NO TO C2b: IF YES ASK:						
	b	Are you currently feeling persistently irritable?	N	0 Y	/ES			
		IS C1a OR C2a CODED YES?	N	0 Y	/ES			
C3	Ov Wi	IF C1b OR C2b = YES: EXPLORE THE CURRENT EPISODE FIRST AND THEN THE MOST SYMPTOMATIC PAST E  IF C1b AND C2b = NO: EXPLORE ONLY THE MOST SYMPTOMATIC PAST EPISODE  HEN EXPLORING THE CURRENT EPISODE, PREFACE EACH QUESTION AS FOLLOWS:  YET THE PAST FEW days including today, when you felt high and full of energy or irritable  HEN EXPLORING THE PAST EPISODE, PREFACE EACH QUESTION AS FOLLOWS:	e, did you:					
	Ov	ver a period of a few days in the past, when you felt most high and most full of energy	or most irrita	able, did	d you:			
		Curren	nt Episode	<u>Past l</u>	<u>Episode</u>			
	а	Feel that you could do things others couldn't do, or that you were an especially important person? If YES, ASK FOR EXAMPLES.  THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA.  Current Episode No Yes Past Episode No Yes	YES	NO	YES			

NO

NO

YES

YES

b Need less sleep (for example, feel rested after only a few hours sleep)?

		Curren	t Episode	Past Ep	<u>oisode</u>
С	Talk too much without stopping, or felt a pressure to keep talking?	NO	YES	NO	YES
d	Notice your thoughts going very fast or running together or racing or moving very quickly from one subject to another?	NO	YES	NO	YES
е	Become easily distracted so that any little interruption could distract you?	NO	YES	NO	YES
f	Have a significant increase in your activity or drive, at work, at school, socially or sexually or did you become physically or mentally restless? This increase in activity may be with or without a purpose.	NO	YES	NO	YES
g	Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)?	NO	YES	NO	YES
C3 sum	MARY: WHEN RATING CURRENT EPISODE:  IF C1b IS NO, ARE 4 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?  IF C1b IS YES, ARE 3 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?	NO	YES	NO	YES
	WHEN RATING PAST EPISODE:  IF C1a IS NO, ARE 4 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?  IF C1a IS YES, ARE 3 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?				
	code YES only if the above $3$ or $4$ symptoms occurred during the same time period.				
	RULE: ELATION/EXPANSIVENESS REQUIRES ONLY THREE C3 SYMPTOMS, WHILE IRRITABLE MOOD ALONE REQUIRES 4 OF THE C3 SYMPTOMS.				
C4	What is the longest time these symptoms lasted (most of the day nearly every ASSESS THIS DURATION FROM THE VERY START TO THE VERY END OF SYMPTOMS, NOT JUST THE				
	a) 3 consecutive days or less				
	b) 4, 5 or 6 consecutive days or more				
	c) 7 consecutive days or more				
C5	Were you hospitalized for these problems?	NO	YES	NO	YES
	IF YES, CIRCLE YES IN MANIC EPISODE FOR THAT TIME FRAME AND GO TO C7.				
C6	Did these symptoms cause significant problems at home, at work, socially, in your relationships, at school or in some other important way?	NO	YES	NO	YES
C7	Were these symptoms associated with a clear change in the way that you previously functioned and that was different from the way that you usually are	NO e?	YES	NO	YES
	Are ${f C3}$ summary and ${f C7}$ and ${f (C4c}$ or ${f C5}$ or ${f C6}$ or any psychotic feature in ${f K1}$ throu coded ${f Yes}$	Gн <b>К8</b> )	NO		YES
	AND		MA	NIC EPI	SODE
	IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?		CURREN PAST	NT	
	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.		1 /31		

	Is <b>C3</b> summary coded <b>YES</b> and are <b>C5</b> and <b>C6</b> coded <b>n0</b> and <b>C7</b> coded <b>YES</b> , and is either <b>C4b</b> or <b>C4c</b> coded <b>yes?</b> AND	НҮРО	EPISODE	
	IS "RULE OUT ORGANIC CAUSE ( <b>O2</b> SUMMARY)" CODED <b>YES</b> ?  AND  ARE ALL PSYCHOTIC FEATURES IN K1 THROUGH K8 CODED <b>NO</b> ?	CURRENT	□ NC	
	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	PAST	□ NO	
	IF YES TO CURRENT MANIC EPISODE, THEN CODE CURRENT HYPOMANIC EPISODE AS NO.		☐ YES	S T EXPLORED
	IF YES TO PAST MANIC EPISODE, THEN CODE PAST HYPOMANIC EPISODE AS NOT EXPLORED.			
	ARE <b>C3</b> SUMMARY AND <b>C4a</b> CODED <b>YES</b> AND IS <b>C5</b> CODED <b>NO</b> ?	НҮРОЛ	MANIC S	SYMPTOMS
	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	CURRENT		10
	IF <b>YES</b> TO CURRENT MANIC EPISODE OR HYPOMANIC EPISODE, THEN CODE CURRENT HYPOMANIC SYMPTOMS AS <b>NO.</b>		□ Y	ΈS
	IF <b>YES</b> TO PAST MANIC EPISODE OR YES TO PAST HYPOMANIC EPISODE, THEN CODE PAST HYPOMANIC SYMPTOMS AS <b>NOT EXPLORED.</b>	PAST	□ <b>Y</b>	O 'ES OT EXPLORED
C8	<ul> <li>a) IF MANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK: Did you have 2 or more of these (manic) episodes lasting 7 days or more (C4c) in yo lifetime (including the current episode if present)?</li> <li>b) IF MANIC OR HYPOMANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK: Did you have 2 or more of these (hypomanic) episodes lasting 4 days or more (C4b) in your lifetime (including the current episode)?</li> </ul>	ur		YES
	in your lifetime (including the current episode)?  c) IF THE PAST "HYPOMANIC SYMPTOMS" CATEGORY IS CODED POSITIVE ASK: Did you have these hypomanic symptoms lasting only 1 to 3 days (C4a) 2 or more ti in your lifetime, (including the current episode if present)?	mes		YES

## **D. PANIC DISORDER**

( $\Rightarrow$  Means: go to the diagnostic box, circle NO and move to the next module)

			<b>→</b>	
D1	а	Have you, on more than one occasion, had spells or attacks when you <b>suddenly</b>	NO	YES
		felt anxious, very frightened, uncomfortable or uneasy, even in situations		
		where most people would not feel that way?	<b>→</b>	
	b	Did the spells surge to a peak within 10 minutes of starting?	NO	YES
		Did the spens sarge to a peak within 10 minutes of starting.	110	123
			_	
D2		At any time in the past, did any of those spells or attacks come on unexpectedly	<b>→</b> NO	YES
02		or occur in an unpredictable or unprovoked manner?	110	123
		The state of the s		
D3		Have you ever had one such attack followed by a month or more of persistent	NO	YES
		concern about having another attack, or worries about the consequences of the attack -		
		or did you make any significant change in your behavior because of the attacks (e.g., avoiding		
		unfamiliar situations, or avoiding leaving your house or shopping alone, or doing things		
		to avoid having a panic attack or visiting your doctor or the emergency room more frequently)?		
D4		During the worst attack that you can remember:		
		•		
	а	Did you have skipping, racing or pounding of your heart?	NO	YES
				V-50
	b	Did you have sweating or clammy hands?	NO	YES
	С	Were you trembling or shaking?	NO	YES
	C	Were you trembing or snaking:	NO	1123
	d	Did you have shortness of breath or difficulty breathing or a smothering sensation?	NO	YES
	e	Did you have a choking sensation or a lump in your throat?	NO	YES
				V-5
	f	Did you have chest pain, pressure or discomfort?	NO	YES
	g	Did you have nausea, stomach problems or sudden diarrhea?	NO	YES
	Б	bla you have haused, stomach problems of sudden didifficus	110	123
	h	Did you feel dizzy, unsteady, lightheaded or feel faint?	NO	YES
	i	Did you have hot flushes or chills?	NO	YES
	j	Did you have tingling or numbness in parts of your body?	NO	YES
	k	Did things around you feel strange, unreal, detached or unfamiliar, or did	NO	YES
	K	you feel outside of or detached from part or all of your body?	110	123
		, , , , , , , , , , , , , .		
	1	Did you fear that you were losing control or going crazy?	NO	YES
	m	Did you fear that you were dying?	NO	YES
D5		ARE BOTH <b>D3</b> , AND <b>4</b> OR MORE <b>D4</b> ANSWERS, CODED <b>YES</b> ?	<b>→</b> NO	YES
טט		ARE BOTH D3, AND 4 OR MORE D4 ANSWERS, CODED 163:	NO	PANIC DISORDER
				LIFETIME
D6		In the past month did you have persistent concern about having another attack,	NO	YES
_ •		or worry about the consequences of the attacks,		PANIC DISORDER
		or did you change your behavior in any way because of the attacks?		CURRENT

IS EITHER <b>D5</b> OR <b>D6</b> CODED <b>YES</b> ,	NO	YES
AND	PANIC DI	SORDER
IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?	LIFETIME	
SPECIFY IF THE EPISODE IS CURRENT AND / OR LIFETIME.	CURRENT	

## E. AGORAPHOBIA

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

			APHOBIA RRENT	
	IS <b>E6</b> CODED <b>YES?</b>	NO	YES	
<b>E</b> 6	Did these symptoms cause significant distress or problems at home, at work, socially, at school or in some other important way?	<b>→</b> NO	YES	
5	Did this avoidance, fear or anxiety persist for at least 6 months?	<b>→</b> NO	YES	
<b>4</b>	Is this fear or anxiety excessive or out of proportion to the real danger in the situation?	<b>→</b> NO	YES	
Ξ3	Do you fear these situations so much that you avoid them, or suffer through them, or need a companion to face them?	→ NO	YES	
2	Do these situations almost always bring on fear or anxiety?	<b>→</b> NO	YES	
	ARE 2 OR MORE OF THE ABOVE SITUATIONS CODED YES?	<b>→</b> NO	YES	
E1	Do you feel anxious or uneasy in places or situations where help might not be available or escape might be difficult if you had a panic attack or panic-like or embarrassing symptoeing in a crowd, or standing in a line (queue), being in an open space or when crossing a bridge, being in an enclosed space, when you are alone away from home, or alone at home, or traveling in a bus, train or car or using public transportation?	toms, like:  NO	YES	

## F. SOCIAL ANXIETY DISORDER (Social Phobia)

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

F1	In the past month, did you have persistent fear and significant anxiety at being watched being the focus of attention, or of being humiliated or embarrassed or rejected?  This includes things like speaking in public, eating in public or with others, writing while someone watches, performing in front of others or being in social situations.	<b>→</b> I, NO	YES
	EVANABLES OF SUCH SOCIAL SITUATIONS TYPICALLY INCLUDE		
	EXAMPLES OF SUCH SOCIAL SITUATIONS TYPICALLY INCLUDE  • INITIATING OR MAINTAINING A CONVERSATION		
	THE STATE OF THE MINISTRAL PROPERTY.		
	<ul><li>PARTICIPATING IN SMALL GROUPS,</li><li>DATING,</li></ul>		
	,		
	SI EARING TO ACTIONET FIGURES,		
	ATTENDING FARTES,		
	TOBLE STEAMING,		
	Extinte in trivial of orners,		
	TEMORITOR OF CITERS,		
	<ul> <li>URINATING IN A PUBLIC WASHROOM, ETC.</li> </ul>	<b>→</b>	
F2	Do these social situations almost always bring on fear or anxiety?	NO	YES
F3	Do you fear these social situations so much that you avoid them, or suffer	<b>→</b> NO	YES
	through them, or need a companion to face them?		
		<b>→</b>	
F4	Is this social fear or anxiety excessive or unreasonable in these social situations?	NO	YES
F5	Did this social avoidance, fear or anxiety persist for at least 6 months?	<b>→</b> NO	YES
F6	Did these social fears cause significant distress or interfere with your ability to function at work, at school or socially or in your relationships or in some other important way?	<b>→</b> NO	YES
	·	NO	YES
	is <b>F6</b> coded <b>yes</b>		
	and	SOCIAL ANXIETY DISORDER (Social Phobia) CURRENT	
	IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?		
	NOTE TO INTERVIEWER: PLEASE SPECIFY IF THE SUBJECT'S FEARS ARE RESTRICTED TO SPEAKING OR PERFORMING IN PUBLIC.	RESTRICTED TO	O PERFORMANCE

## **G. OBSESSIVE-COMPULSIVE DISORDER**

( $\Rightarrow$  means: go to the diagnostic box, circle NO and move to the next module)

G1a	In the past month, have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? - (For example, the idea that you were dirty, contaminated or had germs, <b>or</b> fear of contaminating others, <b>or</b> fear of harming someone even though it disturbs or distresses you, or fear you would act on some impulse, <b>or</b> fear or superstitions that you would be responsible for things going wrong, <b>or</b> obsessions with sexual thoughts, images or impulses, <b>or</b> religious obsessions.)	NO ↓ SKIP TO	YES G3a
G1b	In the past month, did you try to suppress these thoughts, impulses, or images or to neutralize or to reduce them with some other thought or action? -	NO ↓ SKIP TO	YES <b>G3</b> a
	(DO NOT INCLUDE SIMPLY EXCESSIVE WORRIES ABOUT REAL LIFE PROBLEMS. DO NOT INCLUDE OBSESSIONS DIRECTLY RELATED TO HOARDING, HAIR PULLING, SKIN PICKING, BODY DYSMORPHIC DISORDER, EATING DISORDERS, SEXUAL DEVIATIONS, PATHOLOGICAL GAMBLING, OR ALCOHOL OR DRUG ABUSE BECAUSE THE PATIENT MAY DERIVE PLEASURE FROM THE ACTIVITY AND MAY WANT TO RESIST IT ONLY BECAUSE OF ITS NEGATIVE CONSEQUENCES.)		
G2	Did they keep coming back into your mind even when you tried to ignore or get rid of them?	NO	YES
G3a	In the past month, did you feel driven to do something repeatedly in response to an obsession or in response to a rigid rule, like washing or cleaning excessively, counting or checking things over and over, or repeating or arranging things, or other superstitious rituals?	NO	YES
G3b	Are these rituals done to prevent or reduce anxiety or distress or to prevent something bad from happening and are they excessive or unreasonable?	NO	YES
	ARE ( <b>G1</b> a AND <b>G1</b> b AND <b>G2</b> ) OR ( <b>G3</b> a AND <b>G3</b> b) CODED <b>YES</b> ?	<b>→</b> NO	YES
G4	In the past month, did these obsessive thoughts and/or compulsive behaviors cause significant distress, or interfere with your ability to function at home, at work, at school or socially or in your relationships or in some other important way or did they take more than one hour a day?  and	_	YES .C.D. RRENT
	IS "RULE OUT ORGANIC CAUSE ( <b>O2</b> SUMMARY)" CODED <b>YES?</b> (CHECK FOR ANY <b>OC</b> SYMPTOMS STARTING WITHIN 3 WEEKS OF AN INFECTION)  SPECIFY THE LEVEL OF INSIGHT AND IF THE EPISODE IS TIC-RELATED.	INSIGHT: GOOD OR POOR ABSENT DELUSIO	NAL _
		TIC-RELAT	ED $\square$

## H. POSTTRAUMATIC STRESS DISORDER

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

H1		Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury or sexual violence to you or someone else?	<b>→</b> NO	YES
		EXAMPLES OF TRAUMATIC EVENTS INCLUDE: SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, WAR, OR NATURAL DISASTER, WITNESSING THE VIOLENT OR SUDDEN DEATH OF SOMEONE CLOSE TO YOU, OR A LIFE THREATENING ILLNESS.	_	
H2		Starting after the traumatic event, did you repeatedly re-experience the event in an unwanted mentally distressing way, (such as in recurrent dreams related to the event, intense recollections or memories, or flashbacks or as if the event was recurring) or did you have intense physical or psychological reactions when you were reminded about the event or exposed to a similar event?	NO	YES
Н3		In the past month:		
	а	Did you persistently try to avoid thinking about or remembering distressing details or feelings related to the event ?	NO	YES
	b	Did you persistently try to avoid people, conversations, places, situations, activities or things that bring back distressing recollections of the event?	NO <b>→</b>	YES
		ARE 1 OR MORE H3 ANSWERS CODED YES?	NO	YES
H4		In the past month:		
	a	Did you have trouble recalling some important part of the trauma? (but not because of or related to head trauma, alcohol or drugs).	NO	YES
	b	Were you constantly and unreasonably negative about yourself or others or the world?	NO	YES
	С	Did you constantly blame yourself or others in unreasonable ways for the trauma?	NO	YES
	d	Were your feelings always negative (such as fear, horror, anger, guilt or shame)?	NO	YES
	e	Have you become much less interested in participating in activities that	NO	YES
		were meaningful to you before?		
	f	were meaningful to you before?  Did you feel detached or estranged from others?	NO	YES
	f g		NO NO	YES YES
		Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction		
H5		Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?	NO <b>→</b>	YES
H5		Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?  ARE 2 OR MORE H4 ANSWERS CODED YES?	NO <b>→</b>	YES
Н5	g	Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?  ARE 2 OR MORE H4 ANSWERS CODED YES?  In the past month:	NO → NO	YES

Were you more easily startled?	NO	YES
Did you have more difficulty concentrating?	NO	YES
Did you have more difficulty sleeping?	NO	YES
ARE <b>2</b> OR MORE <b>H5</b> ANSWERS CODED <b>YES</b> ?	<b>→</b> NO	YES
Did all these problems start after the traumatic event and last for more than one month	<b>→</b> ? NO	YES
During the past month, did these problems cause significant distress, or interfere with your ability to function at home, at work, at school or socially or in your relationships or in some other important way? and  IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?  SPECIFY IF THE CONDITION IS ASSOCIATED WITH DEPERSONALIZATION, DEREALIZATION OR WITH DELAYED EXPRESSION.	STRESS CUF	ION 🗆
	Did you have more difficulty sleeping?  ARE 2 OR MORE H5 ANSWERS CODED YES?  Did all these problems start after the traumatic event and last for more than one month  During the past month, did these problems cause significant distress, or interfere with your ability to function at home, at work, at school or socially or in your relationships or in some other important way?  and  IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?  SPECIFY IF THE CONDITION IS ASSOCIATED WITH DEPERSONALIZATION, DEREALIZATION OR	Did you have more difficulty concentrating?  NO  Did you have more difficulty sleeping?  NO  ARE 2 OR MORE H5 ANSWERS CODED YES?  NO  Did all these problems start after the traumatic event and last for more than one month?  NO  During the past month, did these problems cause significant distress, or interfere with your ability to function at home, at work, at school or socially or in your relationships or in some other important way?  and  IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?  WE DEPERSONAL DEREALIZATION OR  DELAYED EX

## I. ALCOHOL USE DISORDER

(➡ MEANS: GO TO DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

1		In the past 12 months, have you had 3 or more alcoholic drink 3 hour period, - on 3 or more occasions?	:s, - within a	<b>→</b> NO	YES
2		In the past 12 months:			
	а	During the times when you drank alcohol, did you end up drin you planned when you started?	king more than	NO	YES
	b	Did you repeatedly want to reduce or control your alcohol use Did you try to cut down or control your alcohol use, but failed IF YES TO EITHER, CODE YES.		NO	YES
	С	On the days that you drank, did you spend substantial time ob alcohol, drinking, or recovering from the effects of alcohol?	taining	NO	YES
	d	Did you crave or have a strong desire or urge to use alcohol?		NO	YES
	е	Did you spend less time meeting your responsibilities at work, or at home, because of your repeated drinking?	at school,	NO	YES
	f	If your drinking caused problems with your family or other pedid you still keep on drinking?	ople,	NO	YES
	g	Were you intoxicated more than once in any situation where y at risk, for example, driving a car, riding a motorbike, using ma		NO	YES
	h	Did you continue to use alcohol, even though it was clear that had caused or worsened psychological or physical problems?	the alcohol	NO	YES
	i	Did you reduce or give up important work, social or recreation because of your drinking?	al activities	NO	YES
	j	Did you need to drink a lot more in order to get the same effe started drinking or did you get much less effect with continue		NO	YES
	k1	When you cut down on heavy or prolonged drinking did you h	ave any of the following:	NO	YES
		<ol> <li>increased sweating or increased heart rate,</li> <li>hand tremor or "the shakes"</li> <li>trouble sleeping</li> <li>nausea or vomiting</li> <li>hearing or seeing things other people could not see or hear or having sensations in your skin for no apparent reason</li> <li>agitation</li> <li>anxiety</li> <li>seizures</li> </ol>			
	1.2	IF YES TO 2 OR MORE OF THE ABOVE 8, CODE k1 AS YES.	o or to ovoid boing home are 2	NO	VEC
	K2	Did you drink alcohol to reduce or avoid withdrawal symptom	s or to avoid being hung-over?	NO	YES

ARE  ${f 2}$  OR MORE  ${f I2}$  ANSWERS FROM  ${f I2a}$  THROUGH  ${f 12J}$  AND  ${f 12K}$  SUMMARY CODED YES?

NO YES

**ALCOHOL USE DISORDER** 

**PAST 12 MONTHS** 

SPECIFIERS FOR ALCOHOL USE DISORDER:

MILD = 2-3 OF THE I2 SYMPTOMS MODERATE = 4-5 OF THE I2 SYMPTOMS SEVERE = 6 OR MORE OF THE I2 SYMPTOMS

IN EARLY REMISSION = CRITERIA NOT MET FOR BETWEEN 3 & 12 MONTHS IN SUSTAINED REMISSION = CRITERIA NOT MET FOR 12 MONTHS OR MORE (BOTH WITH THE EXCEPTION OF CRITERION d. – (CRAVING) ABOVE).

IN A CONTROLLED ENVIRONMENT = WHERE ALCOHOL ACCESS IS RESTRICTED

SPECIFY IF:					
MILD  MODERATE  SEVERE					
IN EARLY REMISSION  IN SUSTAINED REMISSION  IN A CONTROLLED ENVIRONMENT					

## J. SUBSTANCE USE DISORDER (NON-ALCOHOL)

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

		Now I am going to show you / read to you a list of street drugs or medicines.	_	
J1	а	In the past 12 months, did you take any of these drugs more than once, to get high, to feel elated, to get "a buzz" or to change your mood?	NO NO	YES
		CIRCLE EACH DRUG TAKEN:		
		Stimulants: amphetamines, "speed", crystal meth, "crank", Dexedrine, Ritalin, diet pills.		
		Cocaine: snorting, IV, freebase, crack, "speedball".		
		Opiates: heroin, morphine, Dilaudid, opium, Demerol, methadone, Darvon, codeine, Percodan,	Vicodin,	OxyContin.
		Hallucinogens: LSD ("acid"), mescaline, peyote, psilocybin, STP, "mushrooms", "ecstasy", MDA,	MDMA.	
		Dissociative Drugs: PCP (Phencyclidine, "Angel Dust", "Peace Pill", "Hog"), or ketamine ("Specia	ıl K").	
		Inhalants: "glue", ethyl chloride, "rush", nitrous oxide ("laughing gas"), amyl or butyl nitrate ("p	oppers").	
		Cannabis: marijuana, hashish ("hash"), THC, "pot", "grass", "weed", "reefer".		
		Sedatives, Hypnotics or Anxiolytics: Quaalude, Seconal ("reds"), Valium, Xanax, Librium, Ativar	, Dalmane	e, Halcion,
		barbiturates, Miltown, GHB, Roofinol, "Roofies".		
		Miscellaneous: steroids, nonprescription sleep or diet pills. Cough Medicine? Any others?		
		SPECIFY THE MOST USED DRUG(S):	_	
		WHICH DRUG(S) CAUSE THE BIGGEST PROBLEMS?	_	
		FIRST EXPLORE THE CRITERIA BELOW FOR THE DRUG CLASS CAUSING THE BIGGEST PROBLEMS AND THE ONE MOST LIKELY TO MEET CRI	ΓERIA	
		FOR SUBSTANCE USE DISORDER. IF SEVERAL DRUG CLASSES HAVE BEEN MISUSED, EXPLORE AS MANY OR AS FEW AS REQUIRED BY THE	PROTOCOL.	
J2		Considering your use of (NAME OF DRUG / DRUG CLASS SELECTED), in the past 12 months:		
	a	During the times when you used the drug, did you end up using more (NAME OF DRUG / DRUG CLASS SELECTED) than you planned when you started?	NO	YES
	b	Did you repeatedly want to reduce or control your (NAME OF DRUG / DRUG CLASS SELECTED) use? Did you try to cut down or control your (NAME OF DRUG / DRUG CLASS SELECTED) use, but failed? IF YES TO EITHER, CODE YES.	NO	YES
	С	On the days that you used more (NAME OF DRUG / DRUG CLASS SELECTED), did you spend substantial time obtaining (NAME OF DRUG / DRUG CLASS SELECTED), using it, or recovering from the its effects?	NO	YES
	d	Did you crave or have a strong desire or urge to use (NAME OF DRUG / DRUG CLASS SELECTED)?	NO	YES
	е	Did you spend less time meeting your responsibilities at work, at school, or at home, because of your repeated (NAME OF DRUG / DRUG CLASS SELECTED) use?	NO	YES
	f	If your (NAME OF DRUG / DRUG CLASS SELECTED) use caused problems with your family or other people, did you still keep on using it?	NO	YES
	g	Did you use the drug more than once in any situation where you or others were physically at risk, for example, driving a car, riding a motorbike, using machinery, boating, etc.?	NO	YES
	h	Did you continue to use (NAME OF DRUG / DRUG CLASS SELECTED), even though it was clear that the (NAME OF DRUG / DRUG CLASS SELECTED) had caused or worsened psychological or physical problems?	NO	YES

i	Did you reduce or give up important work, social or recreational ac because of your (NAME OF DRUG / DRUG CLASS SELECTED) use?	tivities	NO	YES
j	Did you need to use (NAME OF DRUG / DRUG CLASS SELECTED) a lot more in or same effect that you got when you first started using it or did you gwith continued use of the same amount?	get much less effect	NO	YES
	THIS CRITERION IS CODED NO IF THE MEDICATION IS PRESCRIBED AND USED UNDER	RVISION.		
k1	When you cut down on heavy or prolonged use of the drug did you have any of the following withdrawal symptoms:  IF YES TO THE REQUIRED NUMBER OF WITHDRAWAL SYMPTOMS FOR EACH CLASS, CODE J2k1 AS YES.  THIS CRITERION IS CODED NO IF THE MEDICATION IS PRESCRIBED AND USED UNDER APPROPRIATE MEDICAL SUPE		NO	YES
	Sedatives, Hypnotics or Anxiolytics (2 or more withdrawal sympto	ms)		
	1. increased sweating or increased heart rate			
	2. hand tremor or "the shakes"			
	3. trouble sleeping			
	4. nausea or vomiting			
	5. hearing or seeing things other people could not see or hear			
	or having sensations in your skin for no apparent reason			
	6. agitation			
	7. anxiety			
	8. seizures			
	Opiates (3 or more withdrawal symptoms)			
	1. feeling depressed			
	2. nausea or vomiting			
	3. muscle aches			
	4. runny nose or teary eyes			
	5. dilated pupils, goose bumps or hair standing on end			
	or sweating			
	6. diarrhea			
	7. yawning			
	8. hot flashes			
	9. trouble sleeping			
	Stimulants and Cocaine (2 or more withdrawal symptoms)			
	1. fatigue			
	2. vivid or unpleasant dreams			
	3. difficulty sleeping or sleeping too much			
	4. increased appetite			
	5. feeling or looking physically or mentally slowed down			
	Cannabis (3 or more withdrawal symptoms)			
	1. irritability, anger or aggression			
	2. nervousness or anxiety			
	3. trouble sleeping			
	4. appetite or weight loss			
	5. restlessness			
	6. feeling depressed			
	7. significant discomfort from one of the following:			
	"stomach nain" tramors or "shakes" sweating hot flashes			

chills, headaches.

k2 Did you use (NAME OF DRUG / DRUG CLASS SELECTED) to reduce or avoid withdrawal symptoms?

NO YES

J2k SUMMARY: IF YES TO J2k1 OR J2k2, CODE YES

NO YES

ARE **2** OR MORE **J2** ANSWERS FROM **J2a** THROUGH **J2k SUMMARY** CODED **YES**? (**J2**k1 AND **J2**k2 TOGETHER COUNT AS ONE AMONG THESE CHOICES)

NO YES

SUBSTANCE (Drug or Drug Class Name) USE DISORDER

**PAST 12 MONTHS** 

SPECIFIERS FOR SUBSTANCE USE DISORDER:

MILD = 2-3 OF THE J2 SYMPTOMS MODERATE = 4-5 OF THE J2 SYMPTOMS SEVERE = 6 OR MORE OF THE J2 SYMPTOMS

IN EARLY REMISSION = CRITERIA NOT MET FOR BETWEEN 3 & 12 MONTHS IN SUSTAINED REMISSION = CRITERIA NOT MET FOR 12 MONTHS OR MORE (BOTH WITH THE EXCEPTION OF CRITERION d. – (CRAVING) ABOVE).

IN A CONTROLLED ENVIRONMENT = WHERE SUBSTANCE / DRUG ACCESS IS RESTRICTED

SPECIFY IF:					
MILD MODERATE SEVERE					
IN EARLY REMISSION IN SUSTAINED REMISSION IN A CONTROLLED ENVIRON	□ □ MENT □				

#### K. PSYCHOTIC DISORDERS AND MOOD DISORDER WITH PSYCHOTIC FEATURES

ASK FOR AN EXAMPLE OF EACH QUESTION ANSWERED POSITIVELY. CODE **YES** ONLY IF THE EXAMPLES CLEARLY SHOW A DISTORTION OF THOUGHT OR OF PERCEPTION OR IF THEY ARE NOT CULTURALLY APPROPRIATE. THE PURPOSE OF THIS MODULE IS TO EXCLUDE PATIENTS WITH PSYCHOTIC DISORDERS. THIS MODULE NEEDS EXPERIENCE.

Now I am going to ask you about unusual experiences that some people have.

K1	а	Have you ever believed that people were spying on you, or that someone was plotting against you, or trying to hurt you?  NOTE: ASK FOR EXAMPLES TO RULE OUT ACTUAL STALKING.	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K2	а	Have you ever believed that someone was reading your mind or could hear your thoughts, or that you could actually read someone's mind or hear what another person was thinking?	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
К3	а	Have you ever believed that someone or some force outside of yourself put thoughts in your mind that were not your own, or made you act in a way that was not your usual self? Have you ever felt that you were possessed?  CLINICIAN: ASK FOR EXAMPLES AND DISCOUNT ANY THAT ARE NOT PSYCHOTIC.	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K4	а	Have you ever believed that you were being sent special messages through the TV, radio, internet, newspapers, books, or magazines or that a person you did not personally know was particularly interested in you?	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K5	а	Have your relatives or friends ever considered any of your beliefs odd or unusual? INTERVIEWER: ASK FOR EXAMPLES. ONLY CODE YES IF THE EXAMPLES ARE CLEARLY DELUSIONAL IDEAS NOT EXPLORED IN QUESTIONS K1 TO K4, FOR EXAMPLE, RELIGIOUS, DEATH, DISEASE OR SOMATIC DELUSIONS, DELUSIONS OF GRANDIOSITY, JEALOUSY OR GUILT, OR OF FAILURE, INADEQUACY, RUIN, OR DESTITUTION, OR NIHILISTIC DELUSIONS.	NO	YES
	b	IF YES: do they currently consider your beliefs strange or unusual?	NO	YES
К6	а	Have you ever heard things other people couldn't hear, such as voices?	NO	YES
		<b>IF YES TO VOICE HALLUCINATION:</b> Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO	YES
	b	IF YES TO K6a: have you heard sounds / voices in the past month?	NO	YES
		<b>IF YES TO VOICE HALLUCINATION:</b> Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO	YES

23

Κ/	а	other people couldn't see?  CLINICIAN: CHECK TO SEE IF THESE ARE CULTURALLY INAPPROPRIATE.	NO	YES
	b	IF YES: have you seen these things in the past month?	NO	YES
		CLINICIAN'S JUDGMENT		
К8	а	DID THE PATIENT EVER IN THE PAST EXHIBIT DISORGANIZED, INCOHERENT OR DERAILED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS?	NO	YES
К8	b	IS THE PATIENT CURRENTLY EXHIBITING INCOHERENCE, DISORGANIZED OR DERAILED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS?	NO	YES
К9	а	DID THE PATIENT EVER IN THE PAST EXHIBIT DISORGANIZED OR CATATONIC BEHAVIOR?	NO	YES
К9	b	IS THE PATIENT CURRENTLY EXHIBITING DISORGANIZED OR CATATONIC BEHAVIOR?	NO	YES
K10	а	DID THE PATIENT EVER IN THE PAST HAVE NEGATIVE SYMPTOMS, E.G. SIGNIFICANT REDUCTION OF EMOTIONAL EXPRESSION OR AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION)?	NO	YES
K10	b	ARE NEGATIVE SYMPTOMS OF SCHIZOPHRENIA, E.G. SIGNIFICANT REDUCTION OF EMOTIONAL EXPRESSION OR AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION), PROMINENT DURING THE INTERVIEW?	NO	YES
K11	а	ARE 1 OR MORE « a » QUESTIONS FROM K1a TO K7a, CODED YES?		
		AND IS EITHER:		
		MAJOR DEPRESSIVE EPISODE, (CURRENT, RECURRENT OR PAST)  OR  MANIC OR HYPOMANIC EPISODE, (CURRENT OR PAST) CODED YES?		
		AND		
		HOW LONG HAS THE MOOD EPISODE LASTED? HOW LONG HAS THE PSYCHOTIC EPISODE LASTED? IF SUCH A MOOD EPISODE IS PRESENT, CODE YES TO K11a ONLY IF THE MOOD DISTURBANCE IS PRESENT FOR THE MAJORITY OF THE TOTAL DURATION OF THE ACTIVE AND RESIDUAL PERIODS OF THE PSYCHOTIC SYMPTOMS. OTHERWISE CODE NO.	NO → K13	YES
		IF NO TO K11a AND THE TOTAL DURATION OF THE MOOD EPISODE IS LESS THAN THE TOTAL DURATION OF THE PSYCHOTIC EPISODE, THEN CIRCLE NO IN BOTH 'MOOD DISORDER WITH PSYCHOTIC FEATURES' DIAGNOSTIC BOXES AND MOVE TO K13.		

b You told me earlier that you had period(s) when you felt (depressed/high/persistently irritable).

Were the beliefs and experiences you just described (SYMPTOMS CODED YES FROM K1a TO K7a) restricted exclusively to times when you were feeling depressed/high/irritable?

IF THE PATIENT EVER HAD A PERIOD OF AT LEAST 2 WEEKS OF HAVING THESE BELIEFS OR EXPERIENCES (PSYCHOTIC SYMPTOMS) WHEN THEY WERE NOT DEPRESSED/HIGH/IRRITABLE, CODE NO TO THIS DISORDER.

IF THE ANSWER IS NO TO THIS DISORDER GROUPING, ALSO CIRCLE NO TO K12 AND MOVE TO K13

NO YES

**MOOD DISORDER WITH**PSYCHOTIC FEATURES

**LIFETIME** 

K12 a ARE 1 OR MORE « b » QUESTIONS FROM K1b TO K7b CODED YES AND IS EITHER:

MAJOR DEPRESSIVE EPISODE (CURRENT)

OR

MANIC OR HYPOMANIC EPISODE (CURRENT) CODED YES?

IF THE ANSWER IS YES TO THIS DISORDER (LIFETIME OR CURRENT), CIRCLE NO TO K13 AND K14 AND MOVE TO THE NEXT MODULE.

NO YES

**MOOD DISORDER WITH**PSYCHOTIC FEATURES

**CURRENT** 

K13 ARE 1 OR MORE « b » QUESTIONS FROM K1b TO K8b, CODED YES?

AND

ARE 2 OR MORE « b » QUESTIONS FROM K1b TO K10b, CODED YES?

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1-MONTH PERIOD?

AND

IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?

NO YES

PSYCHOTIC DISORDER
CURRENT

K14 IS K13 CODED YES

OR

(ARE 1 OR MORE « a » QUESTIONS FROM K1a TO K8a, CODED YES?

AND

ARE 2 OR MORE « a » QUESTIONS FROM K1a TO K10a, CODED YES

AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1-MONTH PERIOD?

AND

IS "RULE OUT ORGANIC CAUSE [O2 SUMMARY]" CODED YES?)

NO YES

PSYCHOTIC DISORDER
LIFETIME

487

#### L. ANOREXIA NERVOSA

( $\Rightarrow$  means: go to the diagnostic box, circle NO, and move to the next module)

L1	а	How tall are you?		☐ ft	☐ ☐ in.
					Ст
	b	What was your lowest weight in the past 3 months?			☐ ☐ Ib
					☐ ☐ kg
	С	IS PATIENT'S WEIGHT EQUAL TO OR BELOW THE THRESHOLD CORRESPONDING TO HIS / HER HEIGHT? (SEE TABLE BELOW)		<b>→</b> NO	YES
		In the past 3 months:		_	
L2		In spite of this low weight, have you tried not to gain weight or to restrict your food intal	ke?	₩ NO	YES
L3		Have you intensely feared gaining weight or becoming fat, even though you were under	weight?	NO	YES
L4	а	Have you considered yourself too big / fat or that part of your body was too big / fat?		NO	YES
	b	Has your body weight or shape greatly influenced how you felt about yourself?		NO	YES
	С	Have you thought that your current low body weight was normal or excessive?		NO	YES
L5		ARE 1 OR MORE ITEMS FROM <b>L4</b> CODED <b>YES</b> ?		NO	YES
					_
		IS <b>L5</b> CODED <b>YES</b> ?	NO		YES
			ANOREXIA NERVOSA CURRENT		

#### HEIGHT / WEIGHT TABLE CORRESPONDING TO A BMI THRESHOLD OF 17.0 Kg/m<sup>2</sup>

Height/Weight														
ft/in	4'9	4'10	4'11	5'0	5'1	5'2	5'3	5'4	5'5	5'6	5'7	5'8	5'9	5'10
lb	79	82	84	87	90	93	96	99	102	106	109	112	115	119
cm	145	147	150	152	155	158	160	163	165	168	170	173	175	178
kg	36	37	38.5	39.5	41	42.5	43.5	45.5	46.5	48	49	51	52	54
Heigh	ıt/Weigh	t												
ft/in	5'11	6'0	6'1	6'2	6'3									
lb	122	125	129	133	136									
cm	180	183	185	188	191									
kg	55	57	58.5	60	62									

The weight thresholds above are calculated using a body mass index (BMI) equal to or below 17.0 kg/m² for the patient's height using the Center of Disease Control & Prevention BMI Calculator. This is the threshold guideline below which a person is deemed underweight by the DSM-5 for Anorexia Nervosa.

## M. BULIMIA NERVOSA

(→ MEANS: GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN THE 4 BULIMIA SECTION DIAGNOSTIC BOXES, AND MOVE TO BINGE EATING DISORDER)

M1 M2	In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period?  During these binges, did you feel that your eating was out of control?	→ NO → NO	YES
M3	In the last 3 months, did you have eating binges as often as once a week?	<b>→</b> NO	YES
M4	Did you do anything to compensate for, or to prevent a weight gain, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications? Did you do this as often as once a week?	<b>→</b> NO	YES
	CODE YES TO M3 ONLY IF THE ANSWER TO BOTH THESE M3 QUESTIONS IS YES.		
M4a	Number of Episodes of Inappropriate Compensatory Behaviors per Week?		
	Number of Days of Inappropriate Compensatory Behaviors per Week?		
M5	Does your body weight or shape greatly influence how you feel about yourself?	<b>→</b> NO	YES
M6	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO ↓ Skip t	YES o M8
M7	Do these binges occur only when you are under (lb/kg)? INTERVIEWER: WRITE IN THE ABOVE PARENTHESIS THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.	NO	YES
M8	IS <b>M5</b> CODED <b>YES</b> AND IS EITHER <b>M6</b> OR <b>M7</b> CODED <b>NO</b> ?	NO	YES
			A <i>NERVOSA</i> RRENT
	IS M7 CODED YES?	NO	YES
		ANOREXIA NERVOSA Binge Eating/Purging Type CURRENT	

DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?			
AND	NO	YES	
ARE M2 AND M4 CODED NO?	ANOREXIA NERVOSA Restricting Type CURRENT		
SPECIFIERS OF EATING DISORDER:	SPECIFY IF:		
MILD = 1-3 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS  MODERATE = 4-7 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS  SEVERE = 8-13 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS	MILD MODE SEVE	RATE	

**EXTREME** 

#### MB. BINGE EATING DISORDER

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO IN THE DIAGNOSTIC BOX, AND MOVE TO THE NEXT MODULE)

SEVERE = 8-13 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS

EXTREME = 14 OR MORE EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS

MB1	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO	<b>→</b> YES
MB2	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR BULIMIA NERVOSA?	NO	→ YES
MB3	M2 IS CODED YES	<b>→</b> NO	YES
MB4	M3 IS CODED YES	<b>→</b> NO	YES
MB5	M4 IS CODED YES	NO	→ YES
	In the last 3 months during the binging did you:		
MB6a	Eat more rapidly than normal?	NO	YES
MB6b	Eat until you felt uncomfortably full?	NO	YES
MB6c	Eat large amounts of food when you were not hungry?	NO	YES
MB6d	Eat alone because you felt embarrassed about how much you were eating?	NO	YES
MB6e	Feel guilty, depressed or disgusted with yourself after binging?	NO	YES
	ARE 3 OR MORE <b>MB6</b> QUESTIONS CODED YES?	<b>→</b> NO	YES

MB7 MB8	Does your binging distress you a lot?  Number of Binge Eating Episodes per Week?  Number of Binge Eating Days per Week?	<b>→</b> NO	YES		
	IS MB7 CODED YES?	NO BINGE-EATI CUR		'ES ORDER	
	SPECIFIERS OF EATING DISORDER:  MILD = 1-3 EPISODES OF BINGE EATING PER WEEK  MODERATE = 4-7 EPISODES OF BINGE EATING PER WEEK	SPECIFY IF:  MILL  MODE	D		
	SEVERE = 8-13 EPISODES OF BINGE EATING PER WEEK EXTREME = 14 OR MORE EPISODES OF BINGE EATING PER WEEK	SEVER EXTRE			

#### N. GENERALIZED ANXIETY DISORDER

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

	1A	ID IS "RULE OUT ORGANIC CAUSE ( <b>02</b> SUMMARY)" CODED YES?	CUI	ORDER RRENT
N4	to	o these anxieties and worries significantly disrupt your ability to work, function socially or in your relationships or in other important areas of our life or cause you significant distress?		YES  ZED ANXIETY
		ARE 3 OR MORE N3 ANSWERS CODED YES?	<b>→</b> NO	YES
	f	Have difficulty sleeping (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES
	e	Feel irritable?	NO	YES
	d	Have difficulty concentrating or find your mind going blank?	NO	YES
	С	Feel tired, weak or exhausted easily?	NO	YES
	b	Have muscle tension?	NO	YES
	a	When you were anxious over the past 6 months, did you, most of the time:  Feel restless, keyed up or on edge?	NO	YES
N3		FOR THE FOLLOWING, CODE <b>NO</b> IF THE SYMPTOMS ARE CONFINED TO FEATURES OF ANY DISORDER EXPLORED PRIOR TO THIS POINT.  When you were anytous over the past 6 months, did you most of the time.		
N2		Do you find it difficult to control the worries?	<b>→</b> NO	YES
		ARE THE PATIENT'S ANXIETY AND WORRIES RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT?	NO	<b>→</b> YES
	b	Are these anxieties and worries present most days?	<b>→</b> NO	YES
N1	а	Were you excessively anxious or worried about several routine things, over the past 6 months?  IN ENGLISH, IF THE PATIENT IS UNCLEAR ABOUT WHAT YOU MEAN, PROBE BY ASKING (Do others think that you are a worrier or a "worry wart"?) AND GET EXAMPLES.	NO G	YES
			•	

IF THE PATIENT CODES POSITIVE FOR ANY CURRENT DISORDER OR A MAJOR DEPRESSIVE EPISODE OR A MANIC OR A HYPOMANIC EPISODE ASK:

	Just before these symptoms began:			
O1a	Were you taking any drugs or medicines or in withdrawal from any of these?	□ No	□ Yes	☐ Uncertain
O1b	Did you have any medical illness?	□ No	□ Yes	☐ Uncertain
O2	IF O1a OR O1b IS CODED YES, IN THE CLINICIAN'S JUDGMENT, IS EITHER LIKELY TO BE A DIRECT CAUSE OF THE PATIENT'S DISORDER? IF NECESSARY, ASK ADDITIONAL OPEN-ENDED QUESTIONS.	□ No	□ Yes	☐ Uncertain
O2 SU	MMARY: HAS AN "ORGANIC" / MEDICAL / DRUG RELATED CAUSE BEEN RULED OUT?	□ No	☐ Yes	Uncertain

IF **O2** IS YES, THEN **O2** SUMMARY IS NO. IF **O2** IS NO, THEN **O2** SUMMARY IS YES. OTHERWISE IT IS UNCERTAIN.

## P. ANTISOCIAL PERSONALITY DISORDER

(➡ MEANS: GO TO THE DIAGNOSTIC BOX AND CIRCLE NO)

P1		Before you were 15 years old, did you:		
	а	repeatedly skip school or run away from home overnight or stayed out at night against your parent's rules?	NO	YES
	b	repeatedly lie, cheat, "con" others, or steal or break into someone's house or car?	NO	YES
	С	start fights or bully, threaten, or intimidate others?	NO	YES
	d	deliberately destroy things or start fires?	NO	YES
	e	deliberately hurt animals or people?	NO	YES
	f	force someone into sexual activity?	NO <b>→</b>	YES
		ARE <b>2</b> OR MORE <b>P1</b> ANSWERS CODED <b>YES</b> ?	NO	YES
		DO NOT CODE <b>YES</b> TO THE BEHAVIORS BELOW IF THEY ARE EXCLUSIVELY POLITICALLY OR RELIGIOUSLY MOTIVATED.		
P2		Since you were 15 years old, have you:		
	а	done things that are illegal or would be grounds to get arrested, even if you didn't get caught (for example destroying property, shoplifting, stealing, selling drugs, or committing a felony)?	NO	YES
	b	often lied or "conned" other people to get money or pleasure, or lied just for fun?	NO	YES
	С	been impulsive and didn't care about planning ahead?	NO	YES
	d	been in physical fights repeatedly or assaulted others (including physical fights with your spouse or children)?	NO	YES
	е	exposed others or yourself to danger without caring?	NO	YES
	f	repeatedly behaved in a way that others would consider irresponsible, like failing to pay for things you owed, deliberately being impulsive or deliberately not working to support yourself?	NO	YES
	g	felt no guilt after hurting, mistreating, lying to, or stealing from others, or after damaging property?	NO	YES

NO YES

ANTISOCIAL PERSONALITY
DISORDER
LIFETIME

ARE 3 OR MORE P2 QUESTIONS CODED YES?

## MOOD DISORDERS: DIAGNOSTIC ALGORITHM

Consult Modules:	A Major Depre C (Hypo)manic K Psychotic Dis				
MODULE K:					
1a IS <b>K11b</b> CODED YE 1b IS <b>K12a</b> CODED YE		NO NO	YES YES		
MODULES A and C:		Current	Past		
	a CIRCLE YES IF A DELUSIONAL IDEA IS IDENTIFIED IN <b>A3e</b> OR IN ANY PSYCHOTIC FEATURE IN <b>K1</b> THROUGH <b>K7</b>				
	SIONAL IDEA IS IDENTIFIED FEATURE IN <b>K1</b> THROUGH <b>K</b>		YES	<u></u>	
and is Manic Episode code and is Hypomanic Episode and	e coded NO (current and past)?	past)?		MDD	R DEPRESSIVE DISORDER  current past
Specify:	ause (O2 Summary)" code			With Psy Current Past	ychotic Features
<del>-</del>	<b>Features</b> Current: If 1b o Features Past: If 1a or 2a				

d	Is a Manic Episode coded YES (current or past)? and	BIPOLAI DISORDI		
	Is "Rule out Organic Cause (O2 Summary)" coded YES?			
	Specify:	Bipolar I Disorder Single Manic Episod	current	past 
	<ul> <li>If the Bipolar I Disorder is current or past or both</li> </ul>			
		With Psychotic	Featur	es
	<ul> <li>With Single Manic Episode: If Manic episode (current or past) = YES and MDE (current and past) = NO</li> </ul>	Current Past		
	• With Psychotic Features Current: If 1b or 2a (current) or 2b (current) = YES	Most Recent	-	?
	With Psychotic Features Past: If 1a or 2a (past) or 2b (past) = YES	Manic Depressed		
		Hypomanic		
	<ul> <li>If the most recent episode is manic, depressed,</li> </ul>	Unspecified		
	or hypomanic or unspecified (all mutually exclusive)	Onspecifica	_	
	Most Recent Episode Unspecified if the Past Manic Episode is coded YES	Most Recent	-	?
		Mild		
	AND	Moderate		
	, <del>.</del>	Severe		
	(If any current C3 symptoms are coded YES and current C3 Summary is coded NO)			
	OR			
	(If current C3 Summary is coded YES			
	AND If current Manic Episode diagnostic box is coded NO current)			
e	Is Major Depressive Episode coded YES (current or past)			
C	and	BIPOLAF		
	Is Hypomanic Episode coded YES (current or past)  and	DISORD	:K	
	Is Manic Episode coded NO (current and past)?  and	Bipolar II Disorder	current	past
	Is "Rule out Organic Cause (O2 Summary)" coded YES?	Most Recent	Enicode	
	Specify:	Wost Recent	-pisoue	•
	If the Bipolar Disorder is <b>current</b> or <b>past</b> or both	Hypomanic Depressed		
	If the most recent mood episode is <b>hypomanic</b> or <b>depressed</b> (mutually exclusive)	Hypomanic Unspecified		
		Most Recent	Episode	?
	<ul> <li>Most Recent Episode Unspecified if the Past Manic / Hypomanic Episode is coded YES</li> </ul>	Mild		
	AND	Moderate Severe		
	(If any current C3 symptoms are coded YES and current C3 Summary is coded NO)			
	OR			
	(If current C3 Summary is coded YES			
	AND If current Hypomanic Episode diagnostic box is coded NO current)			

Is MDE coded NO (current and past)  and	BIPOLAR DISORDER UNSPECIFIED	
Is Manic Episode coded NO (current and past) and	current pas	it
Is C4b coded YES for the appropriate time frame and	Bipolar Disorder 🔲 📮	1
Is C8b coded YES?	Unspecified	
or		
Is Manic Episode coded NO (current and past)  and		
Is Hypomanic Episode coded NO (current and past) and		
Is C4a coded YES for the appropriate time frame and		
Is C8c coded YES?		
Specify if the Bipolar Disorder Unspecified is <b>current</b> or <b>past</b> or b	ooth.	

# **Z. SUICIDALITY DISORDERS CLASSSIFICATION INTERVIEW**

# In your lifetime did you:

Z1	Have any accident? This includes taking too much of your medication accidentally. IF NO TO Z1, SKIP TO Z2; IF YES, ASK Z1a:	NO	YES
Z1a	Plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?	NO	YES
	IF NO TO Z1a, SKIP TO Z2: IF YES, ASK Z1b:		
Z1b	Intend to die as a result of any accident?	NO	YES
Z2	Think (even momentarily) that you would be better off dead or wish you were dead or needed to be dead?	NO	YES
Z3	Think (even momentarily) about harming or of hurting or of injuring yourself - with at least some intent or awareness that you might die as a result - or think about suicide (i.e. about killing yourself)?	NO	YES
Z4	Hear a voice or voices telling you to kill yourself or have dreams with any suicidal content? If YES, was it either or both:   was it a voice or voices?   was it a dream?	NO	YES
<b>Z</b> 5	Have a suicide method in mind (i.e. how)?	NO	YES
<b>Z</b> 6	Have a suicide means in mind (i.e. with what)?	NO	YES
<b>Z</b> 7	Have any place in mind to attempt suicide (i.e. where)?	NO	YES
Z8	Have any date/timeframe in mind to attempt suicide (i.e. when)?	NO	YES
<b>Z</b> 9	Think about any task you would like to complete before trying to kill yourself? (e.g. writing a suicide note)	NO	YES
Z10	Intend to act on thoughts of killing yourself?	NO	YES
Z11	Intend to die as a result of a suicidal act?	NO	YES
Z12	Feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  If YES, mark either or both:   was this largely unprovoked?   was this provoked?	NO	YES
	IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED ASK: "5 minutes before this Impulse, could you have predicted it would occur at that time?"		
Z13	Take any active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)? This includes times when you were going to kill yourself, but were interrupted or stopped yourself, before harming yourself.  IF NO TO Z13, SKIP TO Z14.	NO	YES
Z13a	Take active steps to prepare to kill yourself, but you did not start the suicide attempt?	NO	YES
Z13b	Take active steps to prepare to kill yourself, but then <b>you stopped yourself just before</b> harming yourself ("aborted").	NO	YES
Z13c	Take active steps to prepare to kill yourself, but then someone or something stopped you just before harming yourself ("interrupted")?	NO	YES
Z14	Injure yourself on purpose without intending to kill yourself?	NO	YES
M.I.N.I	. 7.0.1 (January 6, 2016) (1/6/16) 497		

Z15	Attempt suicide (to kill yourself)? IF NO TO Z15, SKIP TO Z16.		NO	YES
Z15a	Start a suicide attempt (to kill yourself), but then <b>you decided to stop</b> and did not finish the attempt?		NO	YES
Z15b	Start a suicide attempt (to kill yourself), but then <b>you were interrupted</b> and did not finish the attempt?		NO	YES
Z15c	Went through with a suicide attempt (to kill yourself), <b>completely</b> as you meant to? A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.		NO	YES
	A suicide attempt is any (set of) behavior(s), whether incomplete or completed, perceived lethal connected with any level of intent* to die that does not result in a fatality. The behavior actual harm to the patient and the (set of) behavior(s) may be incomplete due to an interpatient's body or existence or may be incomplete due to the patient aborting the alread behavior(s) before it (they) are fully executed. The intent to die can be inferred by a real should not always be assumed unless the evidence is compelling. Not all self-injury is sufficient at the time of initiation of the suicide attempt. * Intent is defined as the states them towards a specific action.	havior <i>m</i> rruption y started sonable g icidal. Th	by event by event , perceiv group of his intent	esult in any ts outside the red lethal experts, but t to die refers to
Z16	ARE ALL THE LIFETIME SUICIDALITY MODULE QUESTIONS (Z1a THROUGH Z13c) AND (Z15 THROUGH Z15c CODED ${f no}$ ?		NO	YES
	is Z16 coded no?	NO		YES
		LIFE	TIME S	UICIDALITY
	IF LIFETIME SUICIDALITY IS CODED NO, END THIS MODULE HERE.	LIFE	TIME S	UICIDALITY
	IF LIFETIME SUICIDALITY IS CODED NO, END THIS MODULE HERE.  IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.	LIFE	TIME S	UICIDALITY
<b>Z17</b>	,	Yes	TIME S	UICIDALITY
<b>Z17</b>	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE:	Yes	TIME S	UICIDALITY
<b>Z17</b>	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE:  a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?	Yes	TIME S	UICIDALITY
<b>Z17</b>	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE:  a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?  b. OBSESSIVE COMPULSIVE DISORDER?	Yes	TIME S	UICIDALITY
Z17	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE: a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?  b. OBSESSIVE COMPULSIVE DISORDER?  c. POSTTRAUMATIC STRESS DISORDER?  d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS? THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES. USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION,	Yes	TIME S	UICIDALITY
<b>Z17</b>	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE:  a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?  b. OBSESSIVE COMPULSIVE DISORDER?  c. POSTTRAUMATIC STRESS DISORDER?  d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS?  THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES.  USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION, AND LABORATORY RESULTS (E.G. DRUG SCREENS, GGT, MCV).	Yes	TIME S	UICIDALITY
Z17	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.  DOES THE PATIENT HAVE:  a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?  b. OBSESSIVE COMPULSIVE DISORDER?  c. POSTTRAUMATIC STRESS DISORDER?  d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS? THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES. USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION, AND LABORATORY RESULTS (E.G. DRUG SCREENS, GGT, MCV).	Yes	TIME S	UICIDALITY

#### Z. IMPULSE ATTACK SUICIDALITY DISORDER

( MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS IASD MODULE, CODE THE IMPULSE ATTACK SUICIDALITY EPISODE AS NO. THEN FOLLOW THE CODING INSTRUCTIONS FOR THE NON SUICIDAL PHYSICAL SYMPTOM ATTACKS BEFORE CODING IT.)

Z	18	Have you ever had a sudden urge or impulse or urgent need to make a suicide attempt, or to plan a suicide attempt?	<b>→</b> NO	YES
Z	19	Did these attacks or impulses usually surge to a peak with in 10 minutes of starting?	NO	YES
Z	20	At any time in the past, did any of those attacks or impulses, come on unexpectedly, or occur in an unpredictable or unprovoked manner?  IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED ASK: "5 minutes before this Impulse, could you have predicted it would occur at that time?"	<b>→</b> NO	YES

#### During the worst suicidal impulse attack that you can remember:

	During the worst suicidal impulse attack that you can remember:		
Z21	Prodromal Aura a. At first, did everything around you suddenly appear different from the way it normally does?	NO	YES
	b. At first, did you feel as if you were loosing control?	NO	YES
	c. At first, did the loss of control feeling and the awareness of things appearing different, last between 30 seconds and 5 minutes?	NO	YES
	Z21 SUMMARY: ARE Z21a AND Z21b AND Z21c ALL CODED YES?	NO	YES
Z22	Physical Symptoms a. Did you have a sensation of external pressure on your upper central forehead?	NO	YES
	b. Did you feel outside of, or detached from, part or all of your body, <b>o</b> r did you feel that things around you were strange, detached or unfamiliar, <b>or</b> did you have difficulty recalling what happened for a block of time, even though there was no loss of consciousness?	NO	YES
	c. Did you have a sudden onset of pain, in the middle of your back, surrounding your spine?	NO	YES
	d. Did you have skipping or racing of your heart, or feel these sensations in your neck arteries?	NO	YES
	e. Did you have difficulty or more effort, in breathing or interrupted breathing, or slow, shallow breathing?	NO	YES
	f. Did you have an interruption in swallowing or an increased frequency of swallowing, or a sensation of prolonged swallowing, or repetitive swallowing?	NO	YES
	g. Did you have chest pain, pressure, or discomfort?	NO	YES
	h. Did you have a headache at the front of your head?	NO	YES
	Z22 SUMMARY: DID 2 OR MORE OF THE Z22a THROUGH Z22h SYMPTOMS OCCUR WITHIN THE SAME 10 MINUTES?	NO	YES

Z23	Pre Awareness I	Need to Be	Dead Sensatio	n

Z24

Z25

Z26

3	Pre Awareness Need to Be Dead Sensation  a. Did you have an unusual sensation, that you have learned from experience, to associate with a need to be dead? This sensation may or may not be followed, by an awareness of a need to be dead, or a suicidal impulse.	NO	YES
l	Sensory a. Were all sensations muffled or muted?	NO	YES
	b. Did you suddenly become aware of things close to you that could be used to attempt suicide?	NO	YES
	c. Did time become distorted or slowed down?	NO	YES
	Z24 SUMMARY: IS EITHER Z24a OR Z24b OR Z24c CODED YES?	NO	YES
5	Gambit a. Did resting the urge to plan a suicide attempt lead into an urge to act on the suicidal impulse?	NO	YES
	b. Did resisting the urge to plan or the urge to act, result in an increase in the suicidal and (associated) physical symptoms?	NO	YES
	c. Did giving into the urge to plan a suicide attempt or to act on suicidal impulses result in a reduction of suicidal and (associated) physical symptoms?	NO	YES
	Z25 SUMMARY: ARE (Z25a OR Z25b) AND Z25c CODED YES?	NO	YES
5	Hours After the Suicidal Impulse a. Did you feel exhausted hours after the suicidal impulse attack?	NO	YES
	b. Were you very sleepy hours after the suicidal impulse attack?	NO	YES
	c. Did you have aches in parts of your body, that earlier in the impulse attack, felt detached from you?	NO	YES
	d. Did you have diarrhea hours after the suicidal impulse attack?	NO	YES

#### Z27 **Days After**

a. Did you have more	depression in the da	ys after the suicidal impu	lse attack?	NO
----------------------	----------------------	----------------------------	-------------	----

Z26 SUMMARY: IS EITHER Z26a OR Z26 b OR Z26c OR Z26c CODED YES?

b. Did you deliberately think about, plan, prepare, or take action to make a		
suicide attempt in the days after the suicidal impulse attack?	NO	YES

С	c. Did you have a craving for fatty or calcium-rich foods, about a week after		
	the suicidal impulse attack?	NO	YES

Z27 SUMMARY: IS EITHER Z27a OR Z27b OR Z27c CODED YES? NO YES

#### Z28 Minimization

a. Did you feel a need at multiple points during and after the suicidal impulse attack,		
to minimize the symptoms to yourself, in an attempt to cope with them?	NO	YES

b. Did you feel a need at multiple points during and after the suicidal impulse attack, to minimize the symptoms to others, because they might overreact or not understand? NO YES

NO YES Z28 SUMMARY: IS EITHER Z28a OR Z28b CODED YES?

500

NO

YES

YES

Z29 ARE THE SUMMARIES OF Z22 AND Z24 AND Z25 AND Z26 ALL CODED YES?

ARE THE SUMMARIES OF EITHER Z22 OR Z24 OR Z26 CODED NO?

NO YES

YES

YES

IS EITHER Z29 OR Z30 CODED YES?

Z30

IF Z20 IS CODED YES, CODE EPISODE AS USIA PHYSICAL & IDEATION SUBTYPE.

IF Z30 IS CODED YES, CODE EPISODE AS USIA IDEATION ONLY SUBTYPE.

CLARIFICATIONS FOR CODING DIRECTIONS IN Z29 AND Z30:

**Z21** SUMMARY IS USUALLY PRESENT, BUT MAY BE DIFFICULT FOR SOME PATIENTS TO ACCURATELY PERCEIVE IN THE EARLY YEARS OF THE DISORDER. HENCE IT IS NOT MANDATORY IN THE CALCULATIONS FOR THE IIMPULSE ATTACK SUICIDALITY EPISODE.

THE Z23 CRITERION IS NOT MANDATORY, BECAUSE IT IS SO BRIEF, AND SINCE IT OCCURS IN THE CONTEXT OF OTHER MORE INTENSE SYMPTOMS, IT MAY BE DIFFICULT FOR SOME PATIENTS TO IDENTIFY AND TO RECALL.

THE **Z27** CRITERION IS NOT MANDATORY, BECAUSE PATIENTS MAY NOT MAKE THE CONNECTION BETWEEN THE IMPULSE ATTACK AND THE SYMPTOMS THEY EXPERIENCE IN THE DAYS FOLLOWING THE ATTACK.

THE Z28 CRITERION IS NOT MANDATORY, BECAUSE SOME PATIENTS DO NOT MINIMIZE THEIR SYMPTOMS.

WHEN IMPULSE ATTACK SUICIDALITY DISORDER GOES INTO PARTIAL REMISSION, SOME PATIENTS HAVE ATTACKS LIMITED TO THE CHARACTERISTIC PHYSICAL SYMPTOMS (CRITERIA Z22 AND Z24 AND Z26), BUT WITHOUT ANY OVERY SUICIDAL IDEATION, IMPULSES, OR BEHAVIORS. THEY DESCRIBE THESE ATTACKS AS BEING ALMOST IDENTICAL TO THE USIA ATTACKS, BUT THESE PHYSICAL SYMPTOMS OCCUR IN THE ABSENCE OF ANY SUICIDALITY.

TO CAPTURE THE PRESENCE OF SUCH ATTACKS, CODE NON SUICIDAL PHYSICAL SYMPTOM ATTACK EPISODE AS YES, IF THE PATIENT DESCRIBES SUCH ATTACKS.

OTHERWISE CODE NO.

IS IMPULSE ATTACK SUICIDALITY EPISODE CODED YES?

NO

NO

IMPULSE ATTACK
SUICIDALITY
EPISODE

USIA Physical & Ideation subtype

**USIA Ideation Only subtype** 

NO YES

NON SUICIDAL
PHYSICAL SYMPTOM
ATTACK EPISODE

NO YES

IMPULSE ATTACK
SUICIDALITY DISORDER

# **Specifiers for Impulse Attack Suicidality Disorder**

(▶ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SPECIFIER)

#### Z31 Most Recent Episode

During the most recent attack:		
a. Did you have the suicidal impulse?	NO YES	
b. Did you have the typical associated physical symptoms?	NO YES	
c. Was the most recent attack?		
☐ unexpected (i.e. came on for no apparent reason)		
☐ expected (i.e. occurred as a direct and immediate response to a stressor)		
IF Z31a AND Z31b ARE CODED YES AND Z31c IS CODED AS UNEXPECTED, THEN CODE THE MOST RECENT EPSISODE AS USIA PHYSICAL & IDEATION SUBTYPE.  IF Z31a IS CODED YES AND Z31b IS CODED NO AND Z31c IS CODED AS UNEXPECTED, THEN CODE THE MOST RECENT EPSISODE AS USIA IDEATION ONLY SUBTYPE.  IF Z31a AND Z31b ARE CODED YES AND Z31c IS CODED AS UXPECTED, THEN CODE THE MOST RECENT EPSISODE AS EXPECTED SUICIDAL IMPULSE ATTACK EPISODE.	MOST RECENT IMPULSE ATTACK SUICIDALITY EPISODE  USIA Physical & Ideation subtype  USIA Ideation Only subtype  Expected Suicidal Impulse Attack	٥

If Z31a is coded no and Z31b is coded yes, then code the most recent epsisode as non suicidal physical symptom attack.

NO YES

NON SUICIDAL
PHYSICAL SYMPTOM
ATTACK EPISODE

#### Z32 Symptom Pattern

a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	NO	YES
b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	NO	YES
d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	→ NO	YES
g. How long have the times without any suicidal impulses, thoughts, or acts lasted?		
☐ it is always less than 3 months		
☐ it is always more than 3 months		
☐ it varies (sometimes less than 3 months, sometimes more than 3 months)		

IF Z32b AND Z32f ARE CODED YES
THEN CODE THE SYMPTOM PATTERN AS PERSISTENT.

IE Z32d IS CODED YES

IF Z32d IS CODED YES
AND Z32e AND Z32f ARE CODED NO,
AND Z32g IS CODED LESS THAN 3 MONTHS,
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING.

IF Z32d IS CODED YES
AND Z32e AND Z32f ARE CODED NO,
AND Z32g IS CODED MORE THAN 3 MONTHS,
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING.

IF Z32d IS CODED YES

AND Z32e AND Z32f ARE CODED NO,

AND Z32g IS CODED AS "IT VARIES",

THEN CODE THE SYMPTOM PATTERN AS RECURRENT, NO APPARENT CYCLING.

IF Z32e IS CODED YES AND Z32c IS CODED NO, OR

IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW CYCLING OR RECURRENT, NO APPARENT CYCLING
THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

# IMPULSE ATTACK SUICIDALITY DISORDER SYMPTOM PATTERN

Persistent

Recurrent, Rapid Cycling

Recurrent, Slow Cycling

Recurrent, No Apparent Cycling

Fresh Onset

	Did the su	nicidal impulse attack occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z34	Age of Or	set		
	a. How ol	d were you when you had the first suicidal impulse attack? years of age		
	Did the	MEN WITH CHILDREN ONLY: suicidal impulse attack first occur within 3 months following the birth of our children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z34b IS YES, CHECK THIS CATEGORY		
Z35	Current L	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

**Timeframes** 

Z33

#### **Z. PSYCHOTIC SUICIDALITY DISORDERS**

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS PSYCHOTIC SUICIDALITY DISORDERS MODULE, CODE THE PSYCHOTIC SUICIDALITY EPISODE AS NO.)

Z36	IS Z17a CODED YES?	<b>→</b> NO	YES
Z37	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of a voice or voices telling you to kill yourself?	NO <b>→ z38</b>	YES
	b. Tell me about <b>these</b> voices and what they said.  CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ONLY CODE  THE RESPONSE TO <b>Z37b</b> AS YES, IF THE EXAMPLES PROVIDED ARE HALLUCINATIONS. OTHERWISE CODE NO	. NO <b>→ z38</b>	YES
	c. Did you have <b>these</b> suicidal impulses, thoughts, or acts on 3 or more separate occasion clinician: By "These suicidal implulses, thoughts, or acts" we mean here the suicidal impulses, thoughts, or acts that a direct result of a hallucination.	ns?	YES
Z38	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of believing, that for some reason, you needed to kill yourself?	<b>→</b> NO	YES
	b. Tell me about <b>these</b> reasons.  CLINICIAN: REVIEW ALL THE REASONS WITH THE PATIENT, AND ONLY CODE THE RESPONSE TO <b>Z38b</b> AS YES IF THE EXAMPLES ARE CLEARLY DELUSIONAL. OTHERWISE CODE NO.	s, <b>→</b> NO	YES
	c. Did you have <b>these</b> suicidal impulses, thoughts, or acts on 3 or more separate occasion clinician: By "These suicidal implulses, thoughts, or acts" we mean here the suicidal impulses, thoughts, or acts that a direct result of a delusion.	ns?	YES
	IF (Z37a AND Z37b) OR (Z38a AND Z38b) ARE CODED YES, THEN CODE PSYCHOTIC SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.	NO PSYCHOTIC	YES SUICIDALITY
			SODE

IF (Z37a AND Z37b AND Z37c) OR (Z38a AND Z38b AND Z38c) ARE CODED YES, THEN CODE PSYCHOTIC SUICIDALITY DISORDER AS YES. OTHERWISE CODE NO.

NO YES

PSYCHOTIC SUICIDALITY

DISORDER

#### **Specifiers for Psychotic Suicidality Disorder**

# Did the psychotic suicidality occur: Current: within the past 2 weeks Recent Past: between 2 weeks ago and 1.5 years ago Past: more than 1.5 years ago

#### Z40 Disorder Involved

**Timeframes** 

Z39

SPECIFY PRECISELY WHICH DISORDER IS ASSOCIATED WITH THE PSYCHOTIC SUICIDALITY FEATURES IDENTIFIED IN THIS MODULE.

# DISORDER ASSOCIATED WITH THIS PSYCHOTIC SUICIDALITY DISORDER

Which Mood Disorder with Psychotic Features?	
Major Depressive Disorder	
Bipolar ! Disorder	۵
Bipolar !I Disorder	
Which Psychotic Disorder?	
Schizophrenia	
Schizoaffective Disorder	
Schizoaffective Disorder Schizophreniform Disorder	<u> </u>

Z41	Age of On	set		
	a. How old	d were you when you had the first psychotic suicidality? years of age		
	Did the	MEN WITH CHILDREN ONLY: osychotic suicidality first occur within 3 months following the birth of our children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z41b IS YES, CHECK THIS CATEGORY		
Z42	Current Le	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC – RESPONSE, BUT NOT YET REMISSION ( $\geq 50\%$ RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC – REMISSION, BUT NOT YET RECOVERED ( $\leq 100\%$ RESPONSE, FOR $< 3$ MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

#### Z. OBSESSIVE COMPULSIVE SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS OBSESSIVE COMPULSIVE SUICIDALITY DISORDER MODULE, CODE THE OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AS NO.)

Z43	IS Z17b CODED YES?	<b>→</b> NO	YES
Z44	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of one of the obsessive thoughts or compulsive rituals you described to me earlier?		
	CLINICIAN: REFRESH THE PATIENT'S MEMORY WITH INFORMATION ABOUT THEIR OBSESSIONS AND / OR COMPULSIONS IDENTIFIED EARLIER IN MODULE G.	<b>→</b> NO	YES
	b. Tell me how <b>these</b> suicidal impulses, thoughts, or acts are connected to your obsessions or compulsions.		
	CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE ATTACKS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.		
	CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF AN IMPULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM A <b>TRUE</b> OBSESSION OR COMPULSION.	<b>→</b> NO	YES
Z45	a. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
	b. Did you have <b>these</b> suicidal impulses, thoughts, or acts connected to obsessions or compulsions, on 3 or more separate occasions?	NO	YES
	IF Z44a AND Z44b ARE CODED YES, THEN CODE OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.	NO	YES
	THEN GOOD GOOD OLD VE SOUGH ALTH ET SOOD AND TEST OF THE THINGS COOL THO		E COMPULSIVE LITY EPISODE

IF OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AND IF  ${\sf Z45b}$  are both coded yes, then code obsessive compulsive suicidality disorder as yes. Otherwise code no.

NO YES

OBSESSIVE COMPULSIVE
SUICIDALITY DISORDER

#### **Specifiers for Obsessive Compulsive Suicidality Disorder**

Z46

**Timeframes** 

	Did the obsessive compulsive suicidality occur:	
	☐ Current: within the past 2 weeks	
	☐ Recent Past: between 2 weeks ago and 1.5 years ago	
	☐ Past: more than 1.5 years ago	
Z47	Age of Onset	
	a. How old were you when you had the first obsessive compulsive suicidality? years of age	
	b. FOR WOMEN WITH CHILDREN ONLY:  Did the obsessive compulsive suicidality first occur within 3 months following the birth of one of your children?  NO YES	
	☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5	
	$\ \square$ Latency Childhood onset: $6$ through the age of $11$	
	☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17	
	☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24	
	☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64	
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE	
	□ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION <b>Z47b</b> IS YES, CHECK THIS CATEGORY	
Z48	Current Level of Symptoms	
	☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE)	
	☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)	
	$\Box$ STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)	
	☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)	

# Z. POSTTRAUMATIC STRESS DISORDER INDUCED SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS POSTTRAUMATUC STRESS DISORDER INDUCED SUICIDALITY DISORDER MODULE, CODE THE POSTTRAUMATUC STRESS DISORDER INDUCED SUICIDALITY EPISODE AS NO.)

ou ever have any suicidal impulse, thought, or act, as a direct result PTSD symptoms that you described to me earlier?  AN: REFRESH THE PATIENT'S MEMORY WITH INFORMATION ABOUT THEIR PTSD SYMPTOMS ED EARLIER IN MODULE G.  The how these suicidal impulses, thoughts, or acts are connected are PTSD symptoms.  AN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT ICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE IS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.  ES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF ULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM PTSD.	→ NO	YES
me how these suicidal impulses, thoughts, or acts are connected our PTSD symptoms.  AN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT ICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE IS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.  ES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF	<b>→</b>	
AN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT ICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE IS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.	<b>→</b> NO	YES
ICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE IS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.  ES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF	<b>→</b> NO	YES
	<b>→</b> NO	YES
these suicidal impulses, thoughts, or acts come and gone episodic pattern? By episodic I mean, that you have had periods lasting 1 day are, without any suicidality.	<b>→</b> NO	YES
ou have <b>these</b> suicidal impulses, thoughts, or acts connected to PTSD, more separate occasions?	NO	YES
AND Z50b ARE CODED YES,  DE PTSD INDUCED SUICIDALITY EPISODE AS YES OTHERWISE CODE NO	NO	YES
DE LIST INDUCED SUICIDALITY EL SUDE AS 1ES. O'MENWISE CODE NO.	DISORD	JMATIC STRESS PER INDUCED LITY EPISODE
		AND Z50b ARE CODED YES,  DE PTSD INDUCED SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.  POSTTRAL DISORD

IF PTSD INDUCED SUICIDALITY EPISODE AND IF Z51b are both coded Yes, then code PTSD induced suicidality disorder as Yes. Otherwise code No.

NO YES

POSTTRAUMATIC STRESS
DISORDER INDUCED
SUICIDALITY DISORDER

# Specifiers for Posttraumatic Stress Disorder Induced Suicidality Disorder

Z52	Timefram	es		
	Did the PT	SD induced suicidality occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z53	Age of On	set		
	a. How old	d were you when you had the first PTSD induced suicidality? years of age		
	Did the F	MEN WITH CHILDREN ONLY: PTSD induced suicidality first occur within 3 months following the birth of our children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z53b IS YES, CHECK THIS CATEGORY		
Z54	Current Le	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

# **Z. SUBSTANCE INDUCED SUICIDALITY DISORDERS**

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS SUBSTANCE INDUCED SUICIDALITY DISORDERS MODULE, CODE THE SUBSTANCE INDUCED SUICIDALITY EPISODE AS NO.)

<b>Z</b> 55	IS Z17d CODED YES?	<b>→</b> NO	YES
<b>Z</b> 56	a. Which drugs or medications or substances did you use?		
	Which of these drugs or medications or substances are most likely to be related to your suicidal impulses, thoughts, or acts?		
	b. How long was the interval between the drug use and the onset of the suicidal impulses, thoughts, or acts.		
	CLINICIAN: PATIENTS MAY HAVE SUICIDALITY WITHIN MINUTES OF AN INGESTION OF A SUBSTANCE ("INTOXICATION") OR WITHIN 5 HALF LIVES OF STOPPING A SUBSTANCE ("WITHDRAWAL"). USING YOUR KNOWLEDGE OF PHARMACOLOGY AND DRUG HALF LIVES, ESTIMATE BASED ON THE SUBSTANCES USED BY EACH PATIENT WHETHER THE SUICIDALITY OCCURRED:		
	C. DURING THE INGESTION PHASE OF THE SUBSTANCE / MEDICATION		
	d.   AS PART OF THE WITHDRAWAL PHASE FROM THE SUBSTANCE / MEDICATION (WITHIN 5 HALF LIVES)		
	e.   NEITHER DURING THE INGESTION OR WITHDRAWAL PHASES		
	f.   AS A RESULT OF STOPPING AN ANTISUICIDAL MEDICATION TREATMENT		
	CHECK ALL THAT APPLY.		_
	Z56 SUMMARY: ARE (Z56e AND Z56f) CHECKED AND ARE (Z56c AND Z56d) UNCHECKED?	NO	YES
Z57	<ul> <li>a. Have these suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.</li> </ul>	<b>→</b> NO	YES
	b. Did you have <b>these</b> suicidal impulses, thoughts, or acts connected to ingestion or withdrawal of a substance, on 3 or more separate occasions?	NO	YES

IF Z56c or Z56d are checked, then code substance induced suicidality episode as yes. Otherwise code no.

NO YES

SUBSTANCE INDUCED SUICIDALITY EPISODE

IF (Z56c or Z56d) are checked, and Z57b is coded yes, then code substance induced suicidality disorder as yes. Otherwise code no.

NO YES

SUBSTANCE INDUCED SUICIDALITY DISORDER

# **Specifiers for Substance Induced Suicidality Disorder** Z58 **Timeframes** Did the substance induced suicidality occur: ☐ Current: within the past 2 weeks ☐ Recent Past: between 2 weeks ago and 1.5 years ago ☐ Past: more than 1.5 years ago Z59 Substance(s) Which substance(s) are most likely to be related to the Substance Induced Suicidality Disorder in this case: **Time of Onset** Z60 IF Z56c is checked, code time of onset as "onset during ingestion phase". IF Z56D IS CHECKED, CODE TIME OF ONSET AS "ONSET DURING WITHDRAWAL PHASE". Z61 Age of Onset a. How old were you when you had the first substance induced suicidality? \_\_\_\_\_ years of age b. FOR WOMEN WITH CHILDREN ONLY: Did the substance induced suicidality first occur within 3 months following the birth of one of your children? YES NO ☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5 ☐ LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11 ☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17 ☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24 ☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64 ☐ LATE ADULT ONSET: 65 YEARS AND ABOVE POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z61b IS YES, CHECK THIS CATEGORY Z62

#### **Current Level of Symptoms**

STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)
STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)
STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)
RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

# Z. MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDER MODULE, CODE THE MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AS NO.)

Z63 IS Z17e CODED YES? NO YES Z64 a. Did you ever have any suicidal impulse, thought, or act, as a direct result of having a medical illness or a neurological condition? NO YES b. Which medical illness / neurological condition caused this? c. Tell me how these suicidal impulses, thoughts, or acts are connected to your medical illness / neurological condition. CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE ATTACKS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER. CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF AN IMPULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM A MEDICAL ILLNESS / NEUROLOGICAL CONDITION. NO YES d. Did you have the suicidal impulses, thoughts, or acts persist even after the NO YES medical illness / neurological condition resolved? Z65 a. Have these suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality. NO YES b. Did you have **these** suicidal impulses, thoughts, or acts connected to your YES medical illness / neurological condition, on 3 or more separate occasions? NO IF (Z64a AND Z64c) ARE BOTH CODED YES, AND Z64d IS NO, NO YES THEN CODE MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO. **MEDICAL ILLNESS** / NEUROLOGICAL

IF MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AND IF Z65b are both coded yes, then code medical illness / neurological condition induced suicidality disorder as yes. Otherwise code no.

NO YES

CONDITION INDUCED SUICIDALITY EPISODE

MEDICAL ILLNESS /
NEUROLOGICAL
CONDITION INDUCED
SUICIDALITY DISORDER

Specifiers for Medical Illness / Neurological Condition Induced Suicidality Disorder

	Did the medical illness / neurological condition induced suicidality occur:		
	☐ Current: within the past 2 weeks		
	☐ Recent Past: between 2 weeks ago and 1.5 years ago		
	☐ Past: more than 1.5 years ago		
Z67	Medical Illness / Neurological Condition		
	Which medical illness / neurological condition(s) is most likely to be related to the Medical Illness Induced Suicidality Disorder in this case:	s / Neu	rological Conditio
Z68	Age of Onset		
	a. How old were you when you had the first medical illness / neurological condition induced suicidality? years of age		
	<ul><li>b. FOR WOMEN WITH CHILDREN ONLY:</li><li>Did the medical illness / neurological condition induced suicidality first occur within 3 months following the birth of one of your children?</li></ul>	NO	YES
	☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
	$\square$ LATENCY CHILDHOOD ONSET: $6$ THROUGH THE AGE OF $11$		
	☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
	☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
	☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE		
	□ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z68b IS YES, CHECK THIS CATEGORY		
Z69	Current Level of Symptoms		
	☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE)		
	☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
	☐ STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
	☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

Z66

**Timeframes** 

# Z. MOOD DISORDER INDUCED SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS MOOD DISORDER INDUCED SUICIDALITY DISORDER MODULE, CODE THE MOOD DISORDER INDUCED SUICIDALITY EPISODE AS NO.)

<b>Z</b> 70	IS Z17f CODED YES?	<b>-</b>	<b>→</b>	YES
Z71	a. Did it ever cross your mind that you get depressed because your suicidal impulses, thoughts, or acts interfere with your life, rather than the other way around?		NO → <b>z72</b>	YES
	b. Tell me why you think the suicidal impulses, thoughts, or acts causes your depression.			
Z72	Did you ever have any depressed mood as a direct result of your suicidal impulses, thoughts, or acts?			
	CLINICIAN: IF $Z71a$ is coded yes and $Z72$ is coded no, ask the patient to explain this apparent discrepancy. Recode the response to $Z72$ if necessary.	٨	NO	YES
Z73	Did you ever have any suicidal impulses, thoughts, or acts as a direct result of your depression or Bipolar Disorder?	٨	NO	YES
	CLINICIAN: IF EITHER Z72 OR Z73 ARE CODED NO, SKIP TO THE INSTRUCTIONS ON DIAGNOSTIC BOXES AT THE END OF THIS MOOD DISORDER INDUCED DISORDER MODULE.  IF Z72 AND Z73 ARE BOTH CODED YES, THEN ASK:			
Z74	What % of the suicidal impulses, thoughts, or acts are a direct result of you depression o	or Bipolar D	)isorde:	r?
	CLINICIAN: GET THE PATIENT'S PERSPECTIVE ON THIS, NOT YOUR INTERPRETATION OF WHAT YOU THINK IT	SHOULD BE.		%
	IF (Z71a AND Z72) ARE BOTH CODED YES, AND Z74 IS $\leq$ 50%, THEN CODE AS PRIMARY SUICIDALITY DISORDER WITH SECONDARY MOOD DISTURBANCE. OTHERWISE CODE NO.	NO		YES
	IF (Z71a AND Z72) ARE BOTH CODED YES, AND Z74 IS > 50%, THEN CODE AS PRIMARY MOOD DISORDER WITH SECONDARY MOOD DISORDER INDUCED SUICIDALITY DISORDER. OTHERWISE CODE NO.	INDU		DISORDER FUICIDALITY RDER
	if Z73 is coded no,		Mood Dis	isorder Induced order:
	THEN CODE NO TO MOOD DISORDER INDUCED SUICIDALITY DISORDER.	Prin	mary	٥
	,	Sec	condary	

# **Specifiers for Mood Disorder Induced Suicidality Disorder**

	(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SP	ECIFIER)		
Z75	Symptom Pattern			
	a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	N	IO YES	
	b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifeting	ne? N	IO YES	
	c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	Ν	IO YES	
	d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	H.	IO YES	
	e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetime	e? N	O YES	
	f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	<b>-</b>	O YES	
	g. How long have the times without any suicidal impulses, thoughts, or acts lasted?			
	☐ it is always less than 3 months			
	☐ it is always more than 3 months			
	$\ \square$ it varies (sometimes less than 3 months, sometimes more than 3 months)			
	IF Z75b AND Z75f ARE CODED YES THEN CODE THE SYMPTOM PATTERN AS PERSISTENT.	INDU	OD DISORI CED SUICID	ALITY
	IF Z75d IS CODED YES AND Z75e AND Z75f ARE CODED NO, AND Z75g IS CODED LESS THAN 3 MONTHS,	DISOI	RDER SYMI PATTERN	РТОМ
	THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING.	Persistent		٥
	IF Z75d IS CODED YES AND Z75e AND Z75f ARE CODED NO, AND Z75g IS CODED MORE THAN 3 MONTHS, THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING.	Recurrent,	Rapid Cycling	
	IF 275d IS CODED YES	Recurrent,	Slow Cycling	٥
	AND Z75e AND Z75f ARE CODED NO, AND Z75g IS CODED AS "IT VARIES", THEN CODE THE SYMPTOM PATTERN AS RECURRENT, NO APPARENT CYCLING.	Recurrent,	No Apparent (	Cycling 🖵
	if Z75e is coded yes and Z75c is coded no,	Fresh Onse	t	۵
	OR			

CYCLING OR RECURRENT, NO APPARENT CYCLING THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW

	Did the m	ood disorder induced suicidal impulses, thoughts, or acts occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z77	Disorder	Involved		
		ICH MOOD DISORDER IS ASSOCIATED WITH THE MOOD DISORDER INDUCED SUICIDALITY DENTIFIED IN THIS MODULE.	MOOD DISORDER ASSOCIATED WITH T MOOD DISORDER INDUCED SUICIDALI DISORDER	THIS R
			Major Depressive Disorder	
			Bipolar I Disorder	
			Bipolar II Disorder	
			Other (specify):	0
Z78	Age of Or	iset		
		d were you when you had the first mood disorder induced impulses, thoughts, or acts? years of age		
	Did the	MEN WITH CHILDREN ONLY: mood disorder induced suicidal impulses, thoughts, or acts first occur months following the birth of one of your children?	NO YES	
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z78b IS YES, CHECK THIS CATEGORY		
Z79	Current L	evel of Symptoms		

Z76

**Timeframes** 

Ш	STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)
	STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)
	STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)
	RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

#### Z. LIFE EVENT INDUCED SUICIDALITY DISORDER

( MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS LIFE EVENT INDUCED SUICIDALITY DISORDER MODULE, CODE THE LIFE EVENT INDUCED SUICIDALITY EPISODE AS NO.)

Z80 IS Z17g CODED YES? NO YES

Tell me about the significant life stressor(s), to which you attribute your suicidal impulses, thoughts, or acts.

CLINICIAN: REVIEW ALL THE EXAMPLES GIVEN, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, ACTIONS) ARE CLEARLY A DIRECT RESULT OF THESE STRESSORS, AND NOT AUTONOMOUS EVENTS OF SUICIDAL IMPULSES, THOUGHTS, OR ACTS, FOR WHICH THE PATIENT IS TRYING TO FIND AN EXPLANATION. REACTION TO STRESSORS THAT ARE CLEARLY OUT OF PROPORTION TO THE REALITY AND GRAVITY OF THE STRESSOR, MAY INDICATE THE NEED TO CONSIDER ANOTHER SUICIDALITY DISORDER. THE REASONABLE PERSON'S JUDGEMENT TEST, SHOULD APPLY WHEN DETERMINING, IF THE STRESSOR IS SUFFICIENTLY GRAVE TO JUSTIFY THE OBSERVED SUICIDALITY.

CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE, IS CLEARLY DIRECTLY ATTRIBUTIBLE TO THE STRESSOR(S) IDENTIFIED.

NO YES

IF Z81 is coded yes, then code as life event induced suicidality disorder as yes. Otherwise code no.

NO YES

LIFE EVENT INDUCED SUICIDALITY DISORDER

#### **Specifiers for Life Event Induced Suicidality Disorder**

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SPECIFIER)

Z82	Symptom	Pattern
-----	---------	---------

a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	NO	YES
b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	NO	YES
d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	<b>→</b> NO	YES
g. How long have the times without any suicidal impulses, thoughts, or acts lasted?		
☐ it is always less than 3 months		
☐ it is always more than 3 months		
☐ it varies (sometimes less than 3 months, sometimes more than 3 months)		

IF Z82b AND Z82f ARE CODED YES
THEN CODE THE SYMPTOM PATTERN AS PERSISTENT.

IF Z82d IS CODED YES
AND Z82e AND Z82f ARE CODED NO,
AND Z82g IS CODED LESS THAN 3 MONTHS,
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING.

IF Z82d IS CODED YES
AND Z82e AND Z82f ARE CODED NO,
AND Z82g IS CODED MORE THAN 3 MONTHS,
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING.

IF Z82d IS CODED YES

AND Z82e AND Z82f ARE CODED NO,

AND Z82g IS CODED AS "IT VARIES",

THEN CODE THE SYMPTOM PATTERN AS RECURRENT, NO APPARENT CYCLING.

IF Z82e IS CODED YES
AND Z82c IS CODED NO,
OR

IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW CYCLING OR RECURRENT, NO APPARENT CYCLING
THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

# SUICIDALITY DISORDER SYMPTOM PATTERN

Persistent
ersistent

n	D I C	- 12 mm
Recurrent.	Rapid C	vciing

#### Recurrent, No Apparent Cycling

#### Fresh Onset

# **Specifiers for Life Event Induced Suicidality Disorder**

Z83

**Timeframes** 

	Did the su	uicidal impulses, thoughts, or acts caused by a stressful life event occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z84	Age of Or	nset		
		d were you when you had the first suicidal impulses, thoughts, or acts by a stressful life event? years of age		
	Did the 3 month	MEN WITH CHILDREN ONLY: suicidal impulses, thoughts, or acts caused by a stressful life event first occur within as following the birth of one of your children? If you consider the birth of your child essful life event which caused you to feel suicidal then answer this question as yes.	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z84b IS YES, CHECK THIS CATEGORY		
Z85	Current L	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

#### Z. SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS SECTION. THEN CODE **BOTH** THE SUICIDALITY **EPISODE**, NOT ELSEWHERE CLASSIFIED AND SUICIDALITY **DISORDER**, NOT ELSEWHERE CLASSIFIED MODULE AS NO.)

Z86 IS ANY OTHER SUICIDALITY DISORDER ENDORSED UP TO THIS POINT?

NO YES

CLINICIAN: IF NO OTHER SUICIDALITY DISORDER IS CODED YES UP TO THIS POINT, THEN REEVALUATE WHETHER THE EXISTING SUICIDALITY IDENTIFIED IN THE LIFETIME SUICIDALITY MODULE QUESTIONS (Z1A THROUGH Z13C) AND (Z15 THROUGH Z15C) MIGHT BELONG IN ONE OF THE PRIOR SUICIDALITY DISORDERS. OTHERWISE CODE YES TO SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED. THEN ASK:

a. Have your suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.

**→** NO

YES

b. Did you have **these** suicidal impulses, thoughts, or acts, on 3 or more separate occasions?

NO YES

IF Z86 IS CODED NO,

THEN CODE SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED AS YES. OTHERWISE CODE NO.

NO

YES

SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED

IF SUICIDALITY EPISODE, NOT OTHERWISE CLASSIFIED IS CODED YES
AND
IF 79.79 AND 79.7h ARE CODED YES

 ${\tt IF~Z87a~AND~Z87b~ARE~CODED~YES,}\\$ 

THEN CODE SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED AS YES. OTHERWISE CODE NO.

NO

YES

SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED

63

# Specifiers for Suicidality Disorder, Not Elsewhere Classified

Z88	Timeframes
	Did the suicidal impulses, thoughts, or acts occur:
	☐ Current: within the past 2 weeks
	☐ Recent Past: between 2 weeks ago and 1.5 years ago
	☐ Past: more than 1.5 years ago
Z89	Age of Onset
	a. How old were you when you had the first suicidal impulses, thoughts, or acts? years of age
	b. FOR WOMEN WITH CHILDREN ONLY: Did the suicidal impulses, thoughts, or acts first occur within 3 months following the birth of one of your children?  NO YES
	$\square$ Early Childhood onset: 0 through the age of 5
	$\square$ Latency Childhood onset: 6 through the age of $11$
	$\square$ Adolescent onset: 12 through the age of 17
	$\square$ Early adult onset: 18 through the age of 24
	$\square$ mid adult onset: 25 through the age of 64
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE
	$\square$ postpartum onset: if the answer to question Z89b is yes, check this category
Z90	Current Level of Symptoms
	☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE)
	$\Box$ STILL SYMPTOMATIC − RESPONSE, BUT NOT YET REMISSION ( $\geq$ 50% RESPONSE, BUT < 70% RESPONSE)
	□ STILL SYMPTOMATIC – REMISSION, BUT NOT YET RECOVERED ( $\leq 100\%$ RESPONSE, FOR $< 3$ MONTHS)
	☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

Patient Name:	Patient Number:	
Date of Birth:	Time Interview Began:	
Interviewer's Name:	Time Interview Ended:	
Date of Interview:	Total Time:	

	MODULES	TIME FRAME	MEETS CRITERIA	MOST RECENT EPISODE	MEETS CRITERIA	* PRIMARY DIAGNOSIS
Z	SUICIDALITY	Lifetime				
	IMPULSE ATTACK SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _	USIA Physical & Ideation Subtype Only USIA Ideation Only Subtype Expected Suicidal Impulse Attack Non-Suicidal Physical Symptom Attack	0	0 0
	PSYCHOTIC SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			_ _ _
	OBSESSIVE COMPULSIVE SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)				0
	PTSD INDUCED SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _			<u> </u>
	SUBSTANCE INDUCED SUICIDALITY DISORDERS	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _			_ _ _
	MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDERS	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0
	MOOD DISORDER INDUCED SUICIDALITY DISORDERS Major Depressive Disorder Bipolar I Disorder Bipolar II Disorder	Current (2 weeks) Recent Past Past (> 1.5 years ago)	0			0
	LIFE EVENT INDUCED SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			_ _ _
	SUICIDALITY DISORDERS, NOT ELSEWHERE CLASSIFIED	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0

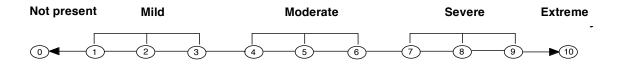
<sup>\*</sup> PRIMACY IS USUALLY DETERMINED BY WHICH DISORDER IS THE DOMINANT CLUSTER IN THE PATEINT'S PRESENTATION OF SYMPTOMS AND / OR WHICH CAME FIRST IN THE PATIENT'S NATURAL HISTORY.

#### **OPTIONAL ASSESSMENT MEASURES TO TRACK CHANGES OVER TIME**

#### **A: CROSS CUTTING MEASURES**

#### **SEVERITY OF SYMPTOM**

Use this scale to rate the severity of your symptom in the score column in the table below:



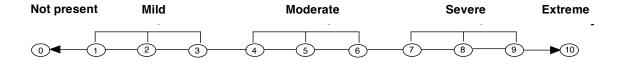
# **Assessment of Symptoms That Cut Across Disorders**

	Symptom Name	Score
1	Depression	
2	Anger	
3	Mania (feeling up or high or hyper or full of energy with racing thoughts)	
4	Anxiety	
5	Physical (somatic) symptoms	
6	Suicidal thoughts (having ANY thoughts of killing yourself)	
	Hearing sounds or voices others can't hear or fearing someone can hear or read	
7	your thoughts or believing things others don't accept as true e.g. that people	
	are spying on you or plotting against you or talking about you (Psychosis)	
8	Sleep problems	
9	Memory problems	
10	Repetitive thoughts or behaviors	
11	Feeling things around you are strange, unreal, detached or unfamiliar, or	
11	feeling outside or detached from part or all of your body (Dissociation)	
12	Ability to function at work, at home, in your life, or in your relationships	
12	(Personality functioning)	
13	Overusing alcohol or drugs	

# **B: DISABILITY / FUNCTIONAL IMPAIRMENT**

# **SEVERITY OF DISABILITY / IMPAIRMENT**

Use this scale to rate in the score column of the table below, how much your symptoms have disrupted your ability to function in the following areas of your life:



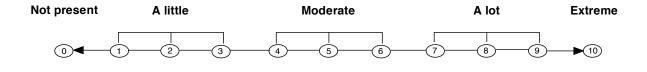
# Assessment of Impairment of Functioning /Disability

	Domain Name	
1	Work or school work	
2	Social life or leisure activities (like hobbies or things you do for enjoyment)	
3	Family life and / or home responsibilities	
4	Ability to get along with people	
5	Personal and social relationships	
6	Ability to understand and to communicate with others	
7	Ability to take care of yourself (washing, showering, bathing, dressing properly, brushing teeth, laundry, combing / brushing hair, eating regularly)	
8	Made you disruptive or aggressive towards others	
9	Financially (ability to manage your money)	
10	Ability to get around physically	
11	Spiritual or religious life	
12	How much did your condition have an impact on other people in your family?	

#### C: CROSS CUTTING DOMAINS FOR SUICIDLITY DISORDERS ONLY

#### **ASSOCIATION OF DOMAIN WITH SUICIDALITY**

Use this scale to rate in the score column of the table below, how much your suicidality Is associated with each of the following domains:



# **Assessment of Suicidality Cross Cutting Domains**

	Domain Name	Score
1	with hopelessness	
2	motivated by a wish to avoid a future loss that the subject feels is essential to their wish to live (e.g. love, good health)	
3	with bereavement / reunification intent	
4	with obsessive compulsive features	
5	with "overwhelmed state" features	
6	with psychotic features	
7	with anhedonia / depressive / melancholic features	
8	with anger / aggressive features	
9	with serious / terminal illness	
10	with anxiety / tension	
11	with sleep disturbance	
12	with seasonal pattern	
13	with depersonalization / derealization / dissociative features	
14	with non-suicidal self-injury	
15	with social / political motivation or sanction	
16	with religious motivation or sanction	
17	with martyrdom motivation or sanction	
18	with motivation to control another or others	
19	with motivation to use suicidality to communicate a message	
20	with homicidal features	
21	with impairment in work, school, social life, leisure activities, family life or home responsibilities	

#### REFERENCES

- 1. Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar G: The Mini International Neuropsychiatric Interview (M.I.N.I.): The Development and Validation of a Structured Diagnostic Psychiatric Interview. J. Clin Psychiatry, 1998;59(suppl 20): 22-33.
- 2. Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Janavs J, Weiller E, Bonara LI, Keskiner A, Schinka J, Knapp E, Sheehan MF, Dunbar GC. Reliability and Validity of the MINI International Neuropsychiatric Interview (M.I.N.I.): According to the SCID-P. European Psychiatry. 1997; 12:232-241.
- 3. Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Sheehan K, Janavs J, Dunbar G. The MINI International Neuropsychiatric Interview (M.I.N.I.) A Short Diagnostic Structured Interview: Reliability and Validity According to the CIDI. European Psychiatry. 1997; 12: 224-231.
- 4. Amorim P, Lecrubier Y, Weiller E, Hergueta T, Sheehan D: DSM-III-R Psychotic Disorders: procedural validity of the Mini International Neuropsychiatric Interview (M.I.N.I.). Concordance and causes for discordance with the CIDI. European Psychiatry. 1998; 13:26-34.

#### **ACKNOWLEDGEMENTS**

The author wishes to acknowledge the valuable contributions made to the earlier versions of the MINI for DSM III-R and DSM IV by: 1. Yves Lecrubier, my close collaborator (now deceased) on the initial development of the MINI for DSM III-R, the DSM IV and ICD-10.

- 2. Juris Janavs, Emanuelle Weiller, Christer Allgulander, Kathy Harnett-Sheehan, Roxy Baker, Michael Sheehan, Chris Gray, Thierry Hergueta, N. Kadri, David Baldwin, Christian Even, Rosario Hidalgo, Marelli Soto-Colon, Ossama Osman.
- 3. Patricia Amorim for her extensive work on the development of the expanded version of the Psychotic Disorders Module and algorithms for DSM III-R. We have evolved her model further in the MINI for Psychotic Disorders 7 and in the MINI Plus 7 for DSM-5.
- 4. Executive Scientific committee for the MINI 6.0.0:

Christer Allgulander, Stockholm, Sweden

A. Carlo Altamura, Milano, Italy

Cyril Hoschl, Praha, Czech Republic

George Papadimitriou, Athens, Greece

Hans Ågren, Göteborg, Sweden

Hans-Jürgen Möller, München, Germany

Hans-Ulrich Wittchen, Dresden, Germany

István Bitter, Budapest, Hungary

Jean-Pierre Lépine, Paris, France

Jules Angst, Zurich, Switzerland

Julio Bobes, Oviedo, Spain

Luciano Conti, Pisa, Italy

Marelli Colon-Soto MD, Puerto Rico, United States

Michael Van Ameringen MD, Toronto, Canada

Rosario Hidalgo MD, Tampa, United States

Siegfried Kasper, Vienna, Austria

Thomas Schlaepfer, Bonn, Germany

- 5. Mapi and the many academic translation teams internationally who collaborated in ensuring that quality translations became available in over 70 languages or language variants. Mapi (<a href="http://www.mapigroup.com">http://www.mapigroup.com</a>) is now the official translation and linguistic validation service for all variants of the MINI.
- 6. Individual clinicians and patients who over the years made countless suggestions to help improve the accuracy and clinical value to the MINI: JM Giddens for her advice on the MINI 7 version of the Suicidality Module, Dr. Michael Van Ameringen for assistance with the ADHD module, and Dr P Powers for her advice on the modules on Anorexia Nervosa and Bulimia.
- 7. A validation study of this instrument was made possible, in part, by grants from SmithKlineBeecham and the European Commission.

### M.I.N.I. PLUS

The shaded modules below are additional modules available in the MINI PLUS beyond what is available in the standard MINI. The un-shaded modules below are in the standard MINI.

These MINI PLUS modules can be inserted into or used in place of the standard MINI modules, as dictated by the specific needs of any study.

	MODULES	TIME FRAME			
Α	MAJOR DEPRESSIVE EPISODE	Current (2 weeks) Past Recurrent			
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks) Past Recurrent			
	MDE WITH MELANCHOLIC FEATURES MDE WITH CATATONIC FEATURES MDE WITH ATYPICAL FEATURES	Current (2 weeks) Current (2 weeks) Current (2 weeks)			
	MAJOR DEPRESSIVE DISORDER WITH PSYCHOTIC FEATURES	Current Past			
	MINOR DEPRESSIVE DISORDER (DEPRESSIVE DISORDER UNSPECIFIED)	Current (2 weeks) Past Recurrent			
	MOOD DISORDER DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	SUBSTANCE INDUCED MOOD DISORDER	Current (2 weeks) Past			
AY	PERISITENT DEPRESSIVE DISORDER	Current			
В	SUICIDALITY	Current (Past Month)		a. a a	
	SUICIDE BEHAVIOR DISORDER	Lifetime attempt Current In early remission	0	□ Low □ Moderate □ High (In Past Year) (1 - 2 Years Ago)	
С	MANIC EPISODE	In remission Current Past	L)	(> 2 Years Ago)	
	HYPOMANIC EPISODE	Current Past			
	BIPOLAR I DISORDER	Current Past			
	BIPOLAR II DISORDER	Current Past			
	BIPOLAR DISORDER UNSPECIFIED	Current Past			
	BIPOLAR I DISORDER WITH PSYCHOTIC FEATURES	Current Past			
	MANIC EPISODE DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	HYPOMANIC EPISODE DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	SUBSTANCE INDUCED MANIC EPISODE	Current (2 weeks) Past			

70

	SUBSTANCE INDUCED HYPOMANIC EPISODE	Current (2 weeks) Past
	MOOD DISORDER UNSPECIFIED	Lifetime
D	PANIC DISORDER	Current (Past Month) Lifetime
	ANXIETY DISORDER WITH PANIC ATTACKS DUE TO A GENERAL MEDICAL CONDITION	Current
	SUBSTANCE INDUCED ANXIETY DISORDER WITH PANIC ATTACKS	Current
E	AGORAPHOBIA	Current
F	SOCIAL ANXIETY DISORDER (Social Phobia)	Current (Past Month) Generalized Non-Generalized
FA	SPECIFIC PHOBIA	Current
G	OBSESSIVE-COMPULSIVE DISORDER (OCD)	Current (Past Month)
	OCD DUE TO A GENERAL MEDICAL CONDITION	Current
	SUBSTANCE INDUCED OCD	Current
H HL	POSTTRAUMATIC STRESS DISORDER POSTTRAUMATIC STRESS DISORDER	Current (Past Month) Lifetime
I	ALCOHOL USE DISORDER	Past 12 Months
IL	ALCOHOL USE DISORDER	Lifetime
J	SUBSTANCE DEPENDENCE (Non-alcohol) SUBSTANCE ABUSE (Non-alcohol)	Past 12 Months Past 12 Months
JL	SUBSTANCE USE DISORDER (Non-alcohol)	Lifetime
K	PSYCHOTIC DISORDERS	Lifetime Current
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime
	MOOD DISORDER WITH PSYCHOTIC FEATURES	Current
	SCHIZOPHRENIA	Current Lifetime
	SCHIZOAFFECTIVE DISORDER	Current Lifetime
	SCHIZOPHRENIFORM DISORDER	Current Lifetime
	BRIEF PSYCHOTIC DISORDER	Current Lifetime
	DELUSIONAL DISORDER	Current Lifetime
	PSYCHOTIC DISORDER DUE TO A GENERAL MEDICAL CONDITION	Current Lifetime
	SUBSTANCE INDUCED PSYCHOTIC DISORDER	Current Lifetime

	PSYCHOTIC DISORDER UNSPECIFIED	Current Lifetime
L	ANOREXIA NERVOSA	Current (Past 3 Months)
	ANOREXIA NERVOSA, BINGE EATING/PURGING TYPE	Current
	ANOREXIA NERVOSA, RESTRICTING TYPE	Current
М	BULIMIA NERVOSA	Current (Past 3 Months)
	BULMIA NERVOSA, PURGING TYPE	Current
	BULMIA NERVOSA, NON-PURGING TYPE	Current
МВ	BINGE-EATING DISORDER	Current (Past 3 Months)
N	GENERALIZED ANXIETY DISORDER (GAD)	Current (Past 6 Months)
	GAD DUE TO A GENERAL MEDICAL CONDITION SUBSTANCE INDUCED GAD	Current
0	SOMATIZATION DISORDER	Current Lifetime
Р	HYPOCHONDRIASIS	Current
Q	BODY DYSMORPHIC DISORDER	Current
R	PAIN DISORDER	Current
S	CONDUCT DISORDER	Current (past 12 months)
т	ATTENTION DEFICIT/ HYPERACTIVITY DISORDER	Current (Past 6 months) (Children /Adolescents)
	ADHD COMBINED	
	ADHD INATTENTIVE	
	ADHD HYPERACTIVE / IMPULSIVE	
TA	ATTENTION DEFICIT/ HYPERACTIVITY DISORDER	Current (Past 6 months) (Adults)
	ADHD COMBINED	
	ADHD INATTENTIVE	
	ADHD HYPERACTIVE / IMPULSIVE	
U	PREMENSTRUAL DYSPHORIC DISORDER	Current
V	MIXED ANXIETY DEPRESSIVE DISORDER	Current
W	ADJUSTMENT DISORDERS	Current
Х	MEDICAL. ORGANIC. DRUG CAUSE RULED OUT	

X MEDICAL, ORGANIC, DRUG CAUSE RULED OUT

Y ANTISOCIAL PERSONALITY DISORDER Lifetime

For Schizophrenia and psychotic disorder studies and for psychotic disorder subtyping in clinical settings, use the MINI for Psychotic Disorders instead of the standard MINI. For many clinical settings this level of psychotic disorder subtyping detail is not necessary.

For children and adolescents, use the MINI Kid or the MINI Kid Parent of the MIN Kid for Psychotic Disorders. A computerized version of the MINI is available from Medical Outcomes Systems <a href="https://www.medical-outcomes.com">https://www.medical-outcomes.com</a>

# M.I.N.I.

# MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW FOR **PSYCHOTIC** AND **SUICIDALITY DISORDERS** STUDIES

### MINI INTERNATIONAL NEUROPSYCHIATRIC INTERVIEW

**English Version 7.0.1** 

For

DSM-5

### © Copyright 1992-2016 Sheehan DV

All rights reserved. No part of this document may be reproduced or transmitted in any form, or by any means, electronic or mechanical, including photocopying, or by any information storage or retrieval system, without permission in writing from Dr. Sheehan. Individual researchers, clinicians and students working in nonprofit or publicly owned settings (including universities, nonprofit hospitals, and government institutions) may make paper copies of a M.I.N.I. instrument for their **personal** clinical and research use, but **not** for institutional use, or for any financial profit or gain. Any use involving financial gain requires a license agreement from the copyright holder and payment of a per use license fee.

#### **DISCLAIMER**

Our aim is to assist in the assessment and tracking of patients with greater efficiency and accuracy. Before action is taken on any data collected and processed by this program, it should be reviewed and interpreted by a licensed clinician.

This program is not designed or intended to be used in the place of a full medical and psychiatric evaluation by a qualified licensed physician – psychiatrist. It is intended only as a tool to facilitate accurate data collection and processing of symptoms elicited by trained personnel. It is not a diagnostic test.

Patient Name:	Patient Number:	
Date of Birth:	Time Interview Began:	
Interviewer's Name:	Time Interview Ended:	
Date of Interview:	Total Time:	

Date of Interview:		Total Time:					
	MODULES	TIME FRAME	MEETS CRITERIA	DSM-5	ICD-10	PRIMARY DIAGNOSIS	
Α	MAJOR DEPRESSIVE EPISODE	Current (2 weeks)					
		Past					
		Recurrent	□			_	
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks) Past		296.20-296.26 Single	F32.x F32.x	_	
		Recurrent	ō	296.20-296.26 Single 296.30-296.36 Recurrent	F33.x	ī	
				Estist Estist Netairent	. 55	_	
В	SUICIDALITY	Current (Past Month)		G. G			
	SUICIDE BEHAVIOR DISORDER	Lifetime attempt Current		☐ Low ☐ Moderate ☐ H (In Past Year)	ign		
	SOCIDE BEHAVIOR DISORDER	In early remission	ō	(1 - 2 Years Ago)		ō	
			_				
С	MANIC EPISODE	Current Past					
	HYPOMANIC EPISODE	Current	Ğ				
		Past		☐ Not Explored			
	BIPOLAR I DISORDER	Current		296.41-296.56	F31.0F31.76		
	BIPOLAR II DISORDER	Past Current		296.41-296.56 296.89	F31.0- F31.76 F31.81		
	BIFOLAN II DISONDEN	Past	Ğ	296.89	F31.81	Ī	
	BIPOLAR DISORDER UNSPECIFIED	Current		296.40/296.50	F31.9		
		Past	₫	296.40/296.50	F31.9		
	BIPOLAR I DISORDER WITH PSYCHOTIC FEATURES	Current Past		296.44/296.54 296.44/296.54	F31.2/31.5 F31.2/31.5		
		rasi	•	290.44/290.34	F31.2/31.3	L.*	
D	PANIC DISORDER	Current (Past Month)	₽	300.01	F41.0	□	
Е	AGORAPHOBIA	Lifetime Current		300.01 300.22	F40.0 F40.00		
_	AGORAFIIOBIA	Current	•	300.22	F40.00	L.*	
F	SOCIAL ANXIETY DISORDER (Social Phobia)	Current (Past Month)		300.23	F40.10		
G	OBSESSIVE-COMPULSIVE DISORDER	Current (Past Month)		300.3	F42		
Н	POSTTRAUMATIC STRESS DISORDER	Current (Past Month)		309.81	F43.10		
I	ALCOHOL USE DISORDER	Past 12 Months		303.9	F10.10-20		
J	SUBSTANCE USE DISORDER (Non-alcohol)	Past 12 Months		304.0090/305.2090	F11.1x-F19.288		
Κ	PSYCHOTIC DISORDERS	Lifetime		295.10-295.90/297.1/	F20.xx-F29		
		Current		297.3/293.81/293.82/ 293.89/298.8/298.9	F20.xx-F29		
	SCHIZOPHRENIA	Current	□	295.90	F20.9		
		Lifetime		295.90	F20.9		
	SCHIZOAFFECTIVE DISORDER	Current	□	295.70	F25.0/F25.1	□	
	SCHIZOAFFECTIVE DISORDER	Lifetime	Ğ	295.70	F25.0/F25.1 F25.0/F25.1	Ġ	
			_			_	
	SCHIZOPHRENIFORM DISORDER	Current		295.40	F20.81		
		Lifetime	U	295.40	F20.81		
	BRIEF PSYCHOTIC DISORDER	Current		298.8	F23		
		Lifetime		298.8	F23		
	DELUSIONAL DISORDER	Current	□	297.1	F22.0		
		Lifetime		297.1	F22.0		
	PSYCHOTIC DISORDER DUE TO A GENERAL MEDICAL CONDITION	Current	□	293.81/293.82	F06.0/F06.2	□	
	1. STORIO TIO DISCRIBER DUE TO A GENERAL MIEDICAL CONDITION	Lifetime	j	293.81/293.82	F06.0/F06.2		

	SUBSTANCE INDUCED PSYCHOTIC DISORDER	Current Lifetime	0	291.9-292.9 291.9-292.9	F10.159-F19.959 F10.159-F19.959	
	OTHER SPECIFIED SCHIZOPHRENIA SPECTRUM AND OTHER PSYCHOTIC DISORDER	Current Lifetime	0	298.8 298.8	F28 F28	0
	UNSPECIFIED SCHIZOPHRENIA SPECTRUM AND OTHER PSYCHOTIC DISORDER	Current Lifetime	0	298.9 298.9	F29 F29	0
	MAJOR DEPRESSIVE DISORDER WITH PSYCHOTIC FEATURES	Current Past	_ _	296.24/296.34 296.24/296.34	F32.3/F33.3 F32.3/F33.3	0
	BIPOLAR I DISORDER WITH PSYCHOTIC FEATURES	Current Past		296.44/296.54 296.44/296.54	F31.2/F31.5/ F31.2/F31.5/	0
	OTHER SPECIFIED BIPOLAR & RELATED DISORDER	Current Lifetime	0	296.89 296.89	F31.89 F31.89	<u> </u>
	UNSPECIFIED BIPOLAR & RELATED DISORDER	Current Lifetime	0	296.80 296.80	F31.9 F31.9	0
	OTHER SPECIFIED DEPRESSIVE DISORDER	Current Lifetime	<u> </u>	311 311	F32.8 F32.8	0
	UNSPECIFIED DEPRESSIVE DISORDER	Current Lifetime	0	311 311	F32.9 F32.9	0
L	ANOREXIA NERVOSA	Current (Past 3 Months)	□	307.1	F50.01-02	
М	BULIMIA NERVOSA	Current (Past 3 Months)	□	307.51	F50.2	
МВ	BINGE-EATING DISORDER	Current (Past 3 Months)		307.51	F50.8	
N	GENERALIZED ANXIETY DISORDER	Current (Past 6 Months)		300.02	F41.1	
0	MEDICAL, ORGANIC, DRUG CAUSE RULED OUT		□ No	☐ Yes ☐ Uncertain	1	
Р	ANTISOCIAL PERSONALITY DISORDER	Lifetime		301.7	F60.2	Image: Control of the
	MEDICAL, ORGANIC, DRUG CAUSE RULED OUT					

### **GENERAL INSTRUCTIONS**

The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-5 and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization). The results of these studies show that the M.I.N.I. has similar reliability and validity properties, but can be administered in a much shorter period of time (mean  $18.7 \pm 11.6$  minutes, median 15 minutes) than the above referenced instruments. Clinicians can use it, after a brief training session. Lay interviewers require more extensive training.

### **INTERVIEW:**

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

### **GENERAL FORMAT:**

The M.I.N.I. is divided into modules identified by letters, each corresponding to a diagnostic category.

- •At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.
- •At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

### **CONVENTIONS:**

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « **bold** » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them ( $\Rightarrow$ ) indicate that one of the criteria necessary for the diagnosis or diagnoses is not met. In this case, the interviewer should go to the end of the module, circle « **NO** » in all the diagnostic boxes and move to the next module.

When terms are separated by a slash (/) the interviewer should read only those symptoms known to be present in the patient (for example, questions J2b or K6b).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

### **RATING INSTRUCTIONS:**

All questions must be rated. The rating is done at the right of each question by circling either YES or NO. Clinical judgment by the rater should be used in coding the responses. Interviewers need to be sensitive to the diversity of cultural beliefs in their administration of questions and rating of responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.

The clinician should be sure that each dimension of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives).

Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. has questions that investigate these issues.

For any questions, suggestions, need for a training session or information about updates of the M.I.N.I., please contact: David V Sheehan, M.D., M.B.A.

University of South Florida College of Medicine

tel: +1 813-956-8437

e-mail: dsheehan@health.usf.edu

### A. MAJOR DEPRESSIVE EPISODE

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO IN THE DIAGNOSTIC BOX, AND MOVE TO THE NEXT MODULE)

A1	а	Were you <u>ever</u> depressed or down, or felt sad, empty or hopeless most of the day, nearly every day, for two weeks?  IF NO, CODE NO TO <b>A1b</b> : IF <b>YES</b> ASK:	NO	YES
	b	For the past two weeks, were you depressed or down, or felt sad, empty or hopeless most of the day, nearly every day?	NO	YES
A2	а	Were you <u>ever</u> much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks?	NO	YES
		IF NO, CODE NO TO <b>A2b</b> : IF <b>YES</b> ASK:		
	b	In the <u>past two weeks</u> , were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time?	NO	YES
		IS <b>A1a</b> OR <b>A2a</b> CODED <b>YES</b> ?	<b>→</b> NO	YES

A3 IF **A1b** OR **A2b** = **YES**: EXPLORE THE **CURRENT** AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE IF **A1b** AND **A2b** = **NO**: EXPLORE **ONLY** THE MOST SYMPTOMATIC **PAST** EPISODE

Over that two week period, when you felt depressed or uninterested:

		Over that two week period, when you felt depressed or uninterested:		ı			
			Past 2	<u>Weeks</u>	Past E	<u>pisode</u>	
	а	Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by $\pm 5\%$ of body weight or $\pm 8$ lb or $\pm 3.5$ kg, for a 160 lb/70 kg person in a month)? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES	
	b	Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES	NO	YES	
	С	Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day? Did anyone notice this?	NO	YES	NO	YES	
	d	Did you feel tired or without energy almost every day?	NO	YES	NO	YES	
	e	Did you feel worthless or guilty almost every day?	NO	YES	NO	YES	
		IF YES, ASK FOR EXAMPLES. LOOK FOR DELUSIONS OF FAILURE, OF INADEQUACY, OF RUIN OR OF GUILT, OR OF NEEDING PUNISHMENT OR DELUSIONS OF DISEASE OR DEATH OR NIHILISTIC OR SOMATIC DELUSIONS.  THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. Current Episode					
	f	Did you have difficulty concentrating, thinking or making decisions almost every day?	NO	YES	NO	YES	
	g	Did you repeatedly think about death (FEAR OF DYING DOES NOT COUNT HERE), or have any thoughts of killing yourself, or have any intent or plan to kill yourself? Did you attempt suicide? IF YES TO EITHER, CODE YES.	NO	YES	NO	YES	
4		Did these symptoms cause significant distress or problems at home, at work, at school, socially, in your relationships, or in some other important way, and are they a change from your previous functioning?	NO	YES	NO	O YES	

A4

A5	months, without any significant depression or any significant loss of interes		YES
	ARE <b>5</b> OR MORE ANSWERS <b>(A1-A3)</b> CODED <b>YES</b> AND IS <b>A4</b> CODED YES FOR THAT TIME FRAME?	NO	YES
	AND	MAJOR DEI EPISC	
	IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?		
	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	CURRENT PAST	
	IF <b>A5</b> IS CODED <b>YES,</b> CODE <b>YES</b> FOR RECURRENT.	RECURRENT	
A6	a How many episodes of depression did you have in your lifetime?		

Between each episode there must be at least 2 months without any significant depression.

# **B. SUICIDALITY**

	In the past month did you:			
B1	Have any accident? This includes taking too much of your medication accidentally. IF NO TO B1, SKIP TO B2; IF YES, ASK B1a:	NO	YES	0
B1a	Plan or intend to hurt yourself in any accident, either by not avoiding a risk or by causing the accident on purpose?	NO	YES	0
	IF NO TO B1a, SKIP TO B2: IF YES, ASK B1b:			
B1b	Intend to die as a result of any accident?	NO	YES	0
B2	Think (even momentarily) that you would be better off dead or wish you were dead or needed to be dead?	NO	YES	1
В3	Think (even momentarily) about harming or of hurting or of injuring yourself - with at least some intent or awareness that you might die as a result - or think about suicide (i.e. about killing yourself)?	NO	YES	6
	IF NO TO B2 + B3, SKIP TO B4. OTHERWISE ASK:			
	Frequency Intensity			
	Occasionally			
B4	Hear a voice or voices telling you to kill yourself or have dreams with any suicidal content?  If YES, mark either or both: □ was it a voice or voices? □ was it a dream?	NO	YES	4
B5	Have a suicide method in mind (i.e. how)?	NO	YES	8
В6	Have a suicide means in mind (i.e. with what)?	NO	YES	8
В7	Have any place in mind to attempt suicide (i.e. where)?	NO	YES	8
В8	Have any date/timeframe in mind to attempt suicide (i.e. when)?	NO	YES	8
B9	Think about any task you would like to complete before trying to kill yourself? (e.g. writing a suicide note)	NO	YES	8
B10	Intend to act on thoughts of killing yourself?  If YES, mark either or both:   did you intend to act at the time?  did you intend to act at some time in the future?	NO	YES	8
B11	Intend to die as a result of a suicidal act?  If YES, mark either or both:   did you intend to die by suicide at the time?  did you intend to die by suicide at some time in the future?	NO	YES	8
B12	Feel the need or impulse to kill yourself or to plan to kill yourself sooner rather than later?  If YES, mark either or both:  was this to kill yourself?  was this to plan to kill yourself?  If YES, mark either or both:  was this largely unprovoked?  was this provoked?  IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED ASK: "5 minutes before	NO	YES	8
	this Impulse, could you have predicted it would occur at that time?"			

Points

B13	Have difficulty resisting these impulses?	NO	YES	8
B14	Take any active steps to prepare for a suicide attempt in which you expected or intended to die (include anything done or purposely not done that put you closer to making a suicide attempt)? This includes times when you were going to kill yourself, but were interrupted or stopped yourself, before harming yourself.  IF NO TO B14, SKIP TO B15.	NO	YES	
B14a	Take active steps to prepare to kill yourself, but you did not start the suicide attempt?	NO	YES	9
B14b	Take active steps to prepare to kill yourself, but then <b>you stopped yourself just before</b> harming yourself ("aborted").	NO	YES	10
B14c	Take active steps to prepare to kill yourself, but then someone or something stopped you just before harming yourself ("interrupted")?	NO	YES	11
B15	Injure yourself on purpose without intending to kill yourself?	NO	YES	0
B16	Attempt suicide (to kill yourself)? IF NO TO B16, SKIP TO B17.	NO	YES	
B16a	Start a suicide attempt (to kill yourself), but then <b>you decided to stop</b> and did not finish the attempt?	NO	YES	12
B16b	Start a suicide attempt (to kill yourself), but then <b>you were interrupted</b> and did not finish the attempt?	NO	YES	13
B16c	Went through with a suicide attempt (to kill yourself), <b>completely</b> as you meant to? A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.  IF NO, SKIP TO B17:	NO	YES	14
	Hope to be rescued / survive   Expected / intended to die			
B17	TIME SPENT PER DAY WITH ANY SUICIDAL IMPULSES, THOUGHTS OR ACTIONS:  Usual time spent per day: hours minutes.  Least amount of time spent per day: hours minutes.  Most amount of time spent per day: hours minutes.			
	In your lifetime:			
B18	Did you ever make a suicide attempt (try to kill yourself)?  If YES, how many times?  If YES, when was the last suicide attempt?  Current: within the past 12 months  In early remission: between 12 and 24 months ago  In remission: more than 24 months ago	NO	YES	4
	"A suicide attempt is any self injurious behavior, with at least some intent (> 0) to die as a result the individual intended to kill him-or herself, at least to some degree, can be explicit or inferred circumstance. For example, it is defined as a suicide attempt if it is clearly not an accident or in the act could be lethal, even though denying intent." (FDA Guidance for Industry Suicidal Idea Document 2012 and C-CASA definition). Posner K et al. Am J Psychiatry 2007; 164 (7): 1035-104 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/	ed from th f the indivi tion and B	e behavior o	or
B19	How likely are you to try to kill yourself within the next 3 months on a scale of 0-100%	_% NO	YFS	13

NO YES IS AT LEAST 1 OF THE ABOVE (EXCEPT B1) CODED YES? SUICIDALITY IF YES, ADD THE TOTAL POINTS FOR THE ANSWERS (B1-B19) CHECKED 'YES' AND SPECIFY THE SUICIDALITY SCORE CATEGORY AS INDICATED IN THE DIAGNOSTIC BOX: 1-8 points Low INDICATE WHETHER THE SUICIDALITY IS CURRENT (PAST MONTH) OR A LIFETIME SUICIDE ATTEMPT OR 9-16 points Moderate BOTH BY MARKING THE APPROPRIATE BOXES OR BY LEAVING EITHER OR BOTH OF THEM UNMARKED. > 17 points High CURRENT = ANY POSITIVE RESPONSE IN B1a THROUGH B16c OR ANY TIME SPENT IN B17. LIFETIME ATTTEMPT = B18 CODED YES. LIKELY IN THE NEAR FUTURE = B19 CODED YES. **CURRENT** MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURRENT LIFETIME ATTEMPT AND NEAR FUTURE SUICIDALITY IN THE SPACE BELOW: LIKELY IN NEAR FUTURE NO YES IS **B18** CODED YES? SUICIDAL BEHAVIOR AND A YES RESPONSE TO **DISORDER** Was the suicidal act started when the subject not in a state of confusion or delirium? Current AND A YES RESPONSE TO In early remission In remission Was the suicidal act done without a political or religious purpose?

IF YES, SPECIFY WHETHER THE DISORDER IS CURRENT, IN EARLY REMISSION OR IN REMISSION.

# **C. MANIC AND HYPOMANIC EPISODES**

(➡ MEANS: GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN MANIC AND HYPOMANIC DIAGNOSTIC BOXES, AND MOVE TO NEXT MODULE)					ODULE)	
		Do you have any family history of manic-dor any family member who had mood swing sodium valproate (Depakote) or lamotrigith this QUESTION IS NOT A CRITERION FOR BIPOLAR DOTHE CLINICIAN'S VIGILANCE ABOUT THE RISK FOR BIRD IF YES, PLEASE SPECIFY WHO:	ngs treated with a medication like ne (Lamictal)? ISORDER, BUT IS ASKED TO INCREASE POLAR DISORDER.		NO	YES
64		University and a second of the second			NO	VEC
C1	a	Have you <b>ever</b> had a period of time when and so active or full of energy or full of you other people thought you were not your u times when you were intoxicated on drug.	urself that you got into trouble, - ourself that you got into trouble, - ourself? (Do not consider	* *	NO	YES
		IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT Y	OU MEAN			
		BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS				
		I mean: having elated mood; increased en having rapid thoughts; being full of ideas; creativity, or impulsive behavior; phoning	having an increase in productivity	, motivation,		
		IF NO, CODE NO TO <b>C1b</b> : IF <b>YES</b> ASK:				
	b	Are you currently feeling 'up' or 'high' or '	hyper' or full of energy?		NO	YES
C2	a	Have you <b>ever</b> been persistently irritable, had arguments or verbal or physical fights your family? Have you or others noticed to or over reacted, compared to other peopl were justified?	, or shouted at people outside hat you have been more irritable		NO	YES
		IF NO, CODE NO TO <b>C2b</b> : IF <b>YES</b> ASK:				
	b	Are you currently feeling persistently irrita	able?		NO	YES
		IS C1a OR C2a CODED YES?			NO	YES
C3		IF <b>C1b</b> OR <b>C2b</b> = <b>YES</b> : EXPLORE THE <b>CURRENT</b> EPIS IF <b>C1b</b> AND <b>C2b</b> = <b>NO</b> : EXPLORE ONLY THE MOST		MATIC <b>PAST</b> EPISODE, OT	THERWISE	
		HEN EXPLORING THE CURRENT EPISODE, PREFACE EAR		or irritable, did you	:	
		HEN EXPLORING THE PAST EPISODE, PREFACE EACH Q		of energy or most	irritable,	did you:
				Current Episode	<u>e Pa</u>	ast Episode
	а	Feel that you could do things others could		NO YES	N	O YES
		especially important person? If YES, ASK FOR E THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA.	Current Episode  No Yes  Past Episode  No Yes			
	b	Need less sleep (for example, feel rested a	ifter only a few hours sleep)?	NO YES	N	O YES

		Current	Episode	Past Ep	<u>isode</u>
С	Talk too much without stopping, or felt a pressure to keep talking?	NO	YES	NO	YES
d	Notice your thoughts going very fast or running together or racing or moving very quickly from one subject to another?	NO	YES	NO	YES
e	Become easily distracted so that any little interruption could distract you?	NO	YES	NO	YES
f	Have a significant increase in your activity or drive, at work, at school, socially or sexually or did you become physically or mentally restless? This increase in activity may be with or without a purpose.	NO	YES	NO	YES
g	Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)?	NO	YES	NO	YES
C3 SUMI	WARY: WHEN RATING CURRENT EPISODE:  IF C1b IS NO, ARE 4 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?  IF C1b IS YES, ARE 3 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?	NO	YES	NO	YES
	WHEN RATING PAST EPISODE:  IF C1a IS NO, ARE 4 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?  IF C1a IS YES, ARE 3 OR MORE C3 ANSWERS INCLUDING C3f CODED YES?				
	code YES only if the above $3\ \text{or}\ 4\ \text{symptoms}$ occurred during the same time period.				
	RULE: ELATION/EXPANSIVENESS REQUIRES ONLY THREE C3 SYMPTOMS, WHILE IRRITABLE MOOD ALONE REQUIRES 4 OF THE C3 SYMPTOMS.				
C4	What is the longest time these symptoms lasted (most of the day nearly every ASSESS THIS DURATION FROM THE VERY START TO THE VERY END OF SYMPTOMS, NOT JUST THE				
	a) 3 consecutive days or less				
	b) 4, 5 or 6 consecutive days or more				
	c) 7 consecutive days or more				
C5	Were you hospitalized for these problems?	NO	YES	NO	YES
	IF YES, CIRCLE YES IN MANIC EPISODE FOR THAT TIME FRAME AND GO TO C7.				
C6	Did these symptoms cause significant problems at home, at work, socially, in your relationships, at school or in some other important way?	NO	YES	NO	YES
C7	Were these symptoms associated with a clear change in the way that you previously functioned and that was different from the way that you usually are	NO ?	YES	NO	YES
	Are <b>C3</b> summary and <b>C7</b> and <b>(C4c</b> or <b>C5</b> or <b>C6</b> or any psychotic feature in <b>K1</b> through coded <b>yes</b>	Gн <b>К8</b> )	NO		YES
	AND		MA	NIC EPIS	SODE
	IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?		CURREN PAST	NT	
	SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.				

Is <b>C3</b> SUMMARY CODED <b>YES</b> AND ARE <b>C5</b> AND <b>C6</b> CODED <b>NO</b> AND <b>C7</b> CODED <b>YES</b> , AND IS EITHER <b>C4b</b> OR <b>C4c</b> CODED <b>YES</b> ?	НҮРО	MANIC EPISODE
AND IS "RULE OUT ORGANIC CAUSE ( <b>O2</b> SUMMARY)" CODED <b>YES</b> ?  AND  ARE ALL PSYCHOTIC FEATURES IN <b>K1</b> THROUGH <b>K8</b> CODED <b>NO</b> ?	CURRENT	□ NO □ YES
SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	PAST	□ NO
IF YES TO CURRENT MANIC EPISODE, THEN CODE CURRENT HYPOMANIC EPISODE AS NO.		☐ YES
IF YES TO PAST MANIC EPISODE, THEN CODE PAST HYPOMANIC EPISODE AS NOT EXPLORED.		□ NOT EXPLORED
ARE <b>C3</b> SUMMARY AND <b>C4a</b> CODED <b>YES</b> AND IS <b>C5</b> CODED <b>NO</b> ?	НҮРОЛ	MANIC SYMPTOMS
SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.	CURRENT	□ NO
IF <b>YES</b> TO CURRENT MANIC EPISODE OR HYPOMANIC EPISODE, THEN CODE CURRENT HYPOMANIC SYMPTOMS AS <b>NO.</b>		☐ YES
IF <b>YES</b> TO PAST MANIC EPISODE OR YES TO PAST HYPOMANIC EPISODE, THEN CODE PAST HYPOMANIC SYMPTOMS AS <b>NOT EXPLORED.</b>	PAST	<ul><li>□ NO</li><li>□ YES</li><li>□ NOT EXPLORED</li></ul>
<ul> <li>a) IF MANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK: Did you have 2 or more of these (manic) episodes lasting 7 days or more (C4c) in you lifetime (including the current episode if present)?</li> <li>b) IF MANIC OR HYPOMANIC EPISODE IS POSITIVE FOR EITHER CURRENT OR PAST ASK Did you have 2 or more of these (hypomanic) episodes lasting 4 days or more (C4b)</li> </ul>	:	NO YES
in your lifetime (including the current episode)?	J	NO YES
c) IF THE PAST "HYPOMANIC SYMPTOMS" CATEGORY IS CODED POSITIVE ASK: Did you have these hypomanic <u>symptoms</u> lasting only 1 to 3 days (C4a) 2 or more to in your lifetime, (including the current episode if present)?	imes	NO YES

C8

# **D. PANIC DISORDER**

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

D1	а	Have you, on more than one occasion, had spells or attacks when you <b>suddenly</b> felt anxious, very frightened, uncomfortable or uneasy, even in situations where most people would not feel that way?	<b>→</b> NO	YES
	b	Did the spells surge to a peak within 10 minutes of starting?	<b>→</b> NO	YES
			<b>→</b>	
D2		At any time in the past, did any of those spells or attacks come on unexpectedly or occur in an unpredictable or unprovoked manner?	NO	YES
D3		Have you ever had one such attack followed by a month or more of persistent concern about having another attack, or worries about the consequences of the attack - or did you make any significant change in your behavior because of the attacks (e.g., avoiding unfamiliar situations, or avoiding leaving your house or shopping alone, or doing things to avoid having a panic attack or visiting your doctor or the emergency room more frequently)?	NO	YES
D4		During the worst attack that you can remember:		
	а	Did you have skipping, racing or pounding of your heart?	NO	YES
	b	Did you have sweating or clammy hands?	NO	YES
	С	Were you trembling or shaking?	NO	YES
	d	Did you have shortness of breath or difficulty breathing or a smothering sensation?	NO	YES
	e	Did you have a choking sensation or a lump in your throat?	NO	YES
	f	Did you have chest pain, pressure or discomfort?	NO	YES
	g	Did you have nausea, stomach problems or sudden diarrhea?	NO	YES
	h	Did you feel dizzy, unsteady, lightheaded or feel faint?	NO	YES
	i	Did you have hot flushes or chills?	NO	YES
	j	Did you have tingling or numbness in parts of your body?	NO	YES
	k	Did things around you feel strange, unreal, detached or unfamiliar, or did you feel outside of or detached from part or all of your body?	NO	YES
	I	Did you fear that you were losing control or going crazy?	NO	YES
	m	Did you fear that you were dying?	NO <b>→</b>	YES
D5		ARE BOTH <b>D3</b> , AND <b>4</b> OR MORE <b>D4</b> ANSWERS, CODED <b>YES</b> ?	NO	YES PANIC DISORDER LIFETIME
D6		In the past month did you have persistent concern about having another attack, or worry about the consequences of the attacks, or did you change your behavior in any way because of the attacks?	NO	YES PANIC DISORDER CURRENT

546

IS EITHER <b>D5</b> OR <b>D6</b> CODED <b>YES</b> ,	NO	YES
AND	PANIC DI	SORDER
IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?	LIFETIME	
SPECIFY IF THE EPISODE IS CURRENT AND / OR LIFETIME.	CURRENT	

# E. AGORAPHOBIA

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

E1	Do you feel anxious or uneasy in places or situations where help might not be available or escape might be difficult if you had a panic attack or panic-like or embarrassing symptobeing in a crowd, or standing in a line (queue), being in an open space or when crossing a bridge, being in an enclosed space,	oms, like:		
	when you are alone away from home, or alone at home,	<b>→</b>		
	or traveling in a bus, train or car or using public transportation?	NO	YES	
		<b>→</b>		
	ARE 2 OR MORE OF THE ABOVE SITUATIONS CODED YES?	NO	YES	
		•		
E2	Do these situations almost always bring on fear or anxiety?	NO	YES	
		•		
E3	Do you fear these situations so much that you avoid them, or suffer through them, or need a companion to face them?	NO	YES	
	through them, or need a companion to face them?	<b>→</b>		
E4	Is this fear or anxiety excessive or out of proportion to the real danger in the situation?	NO	YES	
		<b>→</b>		
E5	Did this avoidance, fear or anxiety persist for at least 6 months?	NO	YES	
		<b>→</b>		
E6	Did these symptoms cause significant distress or problems at home, at work, socially, at school or in some other important way?	NO	YES	
	IS <b>E6</b> CODED <b>YES?</b>	NO.	VEC	
	IS LO CODED TES:	NO	YES	
			APHOBIA RRENT	

# F. SOCIAL ANXIETY DISORDER (Social Phobia)

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

F1	In the past month, did you have persistent fear and significant anxiety at being watched, being the focus of attention, or of being humiliated or embarrassed or rejected?  This includes things like speaking in public, eating in public or with others, writing while someone watches, performing in front of others or being in social situations.	, NO	YES
F2	EXAMPLES OF SUCH SOCIAL SITUATIONS TYPICALLY INCLUDE  INITIATING OR MAINTAINING A CONVERSATION,  PARTICIPATING IN SMALL GROUPS,  DATING,  SPEAKING TO AUTHORITY FIGURES,  ATTENDING PARTIES,  PUBLIC SPEAKING,  EATING IN FRONT OF OTHERS,  PERFORMING IN FRONT OF OTHERS,  URINATING IN A PUBLIC WASHROOM, ETC.  Do these social situations almost always bring on fear or anxiety?	<b>→</b> NO	YES
F3	Do you fear these social situations so much that you avoid them, or suffer through them, or need a companion to face them?	→ NO	YES
F4	Is this social fear or anxiety excessive or unreasonable in these social situations?	→ NO	YES
F5	Did this social avoidance, fear or anxiety persist for at least 6 months?	<b>→</b> NO	YES
F6	Did these social fears cause significant distress or interfere with your ability to function at work, at school or socially or in your relationships or in some other important way?	<b>→</b> NO	YES
	IS <b>F6</b> CODED <b>YES</b>	NO	YES
	and		L ANXIETY ORDER
	IS "RULE OUT ORGANIC CAUSE ( <b>O2</b> SUMMARY)" CODED <b>YES</b> ?	(Socia	al Phobia) RRENT
	NOTE TO INTERVIEWER: PLEASE SPECIFY IF THE SUBJECT'S FEARS ARE RESTRICTED TO SPEAKING OR PERFORMING IN PUBLIC.	RESTRICTED TO SAD ON	O PERFORMANCE

# **G. OBSESSIVE-COMPULSIVE DISORDER**

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

G1a	In the past month, have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? - (For example, the idea that you were dirty, contaminated or had germs, <b>or</b> fear of contaminating others, <b>or</b> fear of harming someone even though it disturbs or distresses you, or fear you would act on some impulse, <b>or</b> fear or superstitions that you would be responsible for things going wrong, <b>or</b> obsessions with sexual thoughts, images or impulses, <b>or</b> religious obsessions.)	NO ↓ SKIP TO	YES <b>G3</b> a
G1b	In the past month, did you try to suppress these thoughts, impulses, or images or to neutralize or to reduce them with some other thought or action? -	NO ↓ SKIP TO	YES <b>G3</b> a
	(DO NOT INCLUDE SIMPLY EXCESSIVE WORRIES ABOUT REAL LIFE PROBLEMS. DO NOT INCLUDE OBSESSIONS DIRECTLY RELATED TO HOARDING, HAIR PULLING, SKIN PICKING, BODY DYSMORPHIC DISORDER, EATING DISORDERS, SEXUAL DEVIATIONS, PATHOLOGICAL GAMBLING, OR ALCOHOL OR DRUG ABUSE BECAUSE THE PATIENT MAY DERIVE PLEASURE FROM THE ACTIVITY AND MAY WANT TO RESIST IT ONLY BECAUSE OF ITS NEGATIVE CONSEQUENCES.)		
G2	Did they keep coming back into your mind even when you tried to ignore or get rid of them?	NO	YES
G3a	In the past month, did you feel driven to do something repeatedly in response to an obsession or in response to a rigid rule, like washing or cleaning excessively, counting or checking things over and over, or repeating or arranging things, or other superstitious rituals?	NO	YES
G3b	Are these rituals done to prevent or reduce anxiety or distress or to prevent something bad from happening and are they excessive or unreasonable?	NO	YES
	ARE ( <b>G1</b> a AND <b>G1</b> b AND <b>G2</b> ) OR ( <b>G3</b> a AND <b>G3</b> b) CODED <b>YES</b> ?	<b>→</b> NO	YES

36	In the past month, did these obsessive thoughts and/or compulsive behaviors cause significant distress, or interfere with your ability to function at home, at work, at	NO	YES
	school or socially or in your relationships or in some other important way or did they take more than one hour a day?	O.C.D. CURRENT	Τ
	and	INSIGHT:	
	IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?	GOOD OR FAIR	
	(CHECK FOR ANY OC SYMPTOMS STARTING WITHIN 3 WEEKS OF AN INFECTION)	POOR	
		ABSENT	
	SPECIFY THE LEVEL OF INSIGHT AND IF THE EPISODE IS TIC-RELATED.	DELUSIONAL	
		TIC-RELATED	

# H. POSTTRAUMATIC STRESS DISORDER

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

Н1		Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury or sexual violence	<b>→</b> NO	YES
		EXAMPLES OF TRAUMATIC EVENTS INCLUDE: SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, WAR, OR NATURAL DISASTER, WITNESSING THE VIOLENT OR SUDDEN DEATH OF SOMEONE CLOSE TO YOU, OR A LIFE THREATENING ILLNESS.		
H2		Starting after the traumatic event, did you repeatedly re-experience the event in an unwanted mentally distressing way, (such as in recurrent dreams related to the event, intense recollections or memories, or flashbacks or as if the event was recurring) or did you have intense physical or psychological reactions when you were reminded about the event or exposed to a similar event?	<b>→</b> NO	YES
Н3	_	In the past month:		
	а	Did you persistently try to avoid thinking about or remembering distressing details or feelings related to the event ?	NO	YES
	b	Did you persistently try to avoid people, conversations, places, situations, activities or things that bring back distressing recollections of the event?	NO <b>→</b>	YES
		ARE <b>1</b> OR MORE <b>H3</b> ANSWERS CODED <b>YES</b> ?	NO	YES
H4		In the past month:		
	а	Did you have trouble recalling some important part of the trauma?		
	_	(but not because of or related to head trauma, alcohol or drugs).	NO	YES
	b		NO NO	YES
		(but not because of or related to head trauma, alcohol or drugs).		
	b	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?	NO	YES
	b c	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?	NO NO	YES YES
	b c d	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that	NO NO	YES YES YES
	b c d	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that were meaningful to you before?	NO NO NO	YES YES YES YES
	b c d e	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that were meaningful to you before?  Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction	NO NO NO NO	YES YES YES YES YES
Н5	b c d e	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that were meaningful to you before?  Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?	NO NO NO NO NO NO	YES YES YES YES YES YES
Н5	b c d e	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that were meaningful to you before?  Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?  ARE 2 OR MORE H4 ANSWERS CODED YES?	NO NO NO NO NO NO	YES YES YES YES YES YES
Н5	b c d e f g	(but not because of or related to head trauma, alcohol or drugs).  Were you constantly and unreasonably negative about yourself or others or the world?  Did you constantly blame yourself or others in unreasonable ways for the trauma?  Were your feelings always negative (such as fear, horror, anger, guilt or shame)?  Have you become much less interested in participating in activities that were meaningful to you before?  Did you feel detached or estranged from others?  Were you unable to experience any good feelings (such as happiness, satisfaction or loving feelings)?  ARE 2 OR MORE H4 ANSWERS CODED YES?  In the past month:	NO NO NO NO NO NO	YES YES YES YES YES YES YES

	d	Were you more easily startled?	NO	YES
	e	Did you have more difficulty concentrating?	NO	YES
	f	Did you have more difficulty sleeping?	NO	YES
		ARE <b>2</b> OR MORE <b>H5</b> ANSWERS CODED <b>YES</b> ?	<b>→</b> NO	YES
Н6		Did all these problems start after the traumatic event and last for more than one month	<b>→</b> ? NO	YES
H7		During the past month, did these problems cause significant distress, or interfere with your ability to function at home, at work, at school or socially or in your relationships or in some other important way? and	STRESS	YES AUMATIC DISORDER RRENT
		IS "RULE OUT ORGANIC CAUSE ( <b>O2</b> SUMMARY)" CODED <b>YES</b> ?  SPECIFY IF THE CONDITION IS ASSOCIATED WITH DEPERSONALIZATION, DEREALIZATION OR	W DEPERSONAL DEREALIZATI DELAYED EXF	on $\square$
		WITH DELAYED EXPRESSION.		

# I. ALCOHOL USE DISORDER

(➡ MEANS: GO TO DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

I1		In the past 12 months, have you had 3 or more alcoholic drinks, - w 3 hour period, - on 3 or more occasions?	vithin a	<b>→</b> NO	YES
I2		In the past 12 months:			
	а	During the times when you drank alcohol, did you end up drinking you planned when you started?	more than	NO	YES
	b	Did you repeatedly want to reduce or control your alcohol use? Did you try to cut down or control your alcohol use, but failed? IF YES TO EITHER, CODE YES.		NO	YES
	С	On the days that you drank, did you spend substantial time obtaining alcohol, drinking, or recovering from the effects of alcohol?	ng	NO	YES
	d	Did you crave or have a strong desire or urge to use alcohol?		NO	YES
	e	Did you spend less time meeting your responsibilities at work, at so or at home, because of your repeated drinking?	chool,	NO	YES
	f	If your drinking caused problems with your family or other people, did you still keep on drinking?		NO	YES
	g	Were you intoxicated more than once in any situation where you o at risk, for example, driving a car, riding a motorbike, using machine		NO	YES
	h	Did you continue to use alcohol, even though it was clear that the a had caused or worsened psychological or physical problems?	alcohol	NO	YES
	i	Did you reduce or give up important work, social or recreational ac because of your drinking?	tivities	NO	YES
	j	Did you need to drink a lot more in order to get the same effect that started drinking or did you get much less effect with continued use		NO	YES
	k1	When you cut down on heavy or prolonged drinking did you have a	nny of the following:	NO	YES
		<ol> <li>increased sweating or increased heart rate,</li> <li>hand tremor or "the shakes"</li> <li>trouble sleeping</li> <li>nausea or vomiting</li> <li>hearing or seeing things other people could not see or hear or having sensations in your skin for no apparent reason</li> <li>agitation</li> <li>anxiety</li> <li>seizures</li> </ol>			
		IF YES TO 2 OR MORE OF THE ABOVE 8, CODE k1 AS YES.			
	k2	Did you drink alcohol to reduce or avoid withdrawal symptoms or t	o avoid being hung-over?	NO	YES

ARE  $\bf 2$  OR MORE  $\bf I\bf 2$  ANSWERS FROM  $\bf I\bf 2a$  THROUGH  $\bf 1\bf 2J$  AND  $\bf 1\bf 2k$  SUMMARY CODED YES? ( $\bf I\bf 2k1$  AND  $\bf I\bf 2k2$  TOGETHER COUNT AS ONE AMONG THESE CHOICES)

NO YES

ALCOHOL USE DISORDER

PAST 12 MONTHS

SPECIFIERS FOR ALCOHOL USE DISORDER:

MILD = 2-3 OF THE I2 SYMPTOMS MODERATE = 4-5 OF THE I2 SYMPTOMS SEVERE = 6 OR MORE OF THE I2 SYMPTOMS

IN EARLY REMISSION = CRITERIA NOT MET FOR BETWEEN 3 & 12 MONTHS IN SUSTAINED REMISSION = CRITERIA NOT MET FOR 12 MONTHS OR MORE (BOTH WITH THE EXCEPTION OF CRITERION d. – (CRAVING) ABOVE).

IN A CONTROLLED ENVIRONMENT = WHERE ALCOHOL ACCESS IS RESTRICTED

SPECIFY IF:	
MILD	
MODERATE $\square$	
SEVERE $\square$	
IN EARLY REMISSION	
IN SUSTAINED REMISSION $\ \square$	
IN A CONTROLLED ENVIRONMENT	

# J. SUBSTANCE USE DISORDER (NON-ALCOHOL)

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO AND MOVE TO THE NEXT MODULE)

		Now I am going to show you / read to you a list of street drugs or medicines.	•	
J1	a	In the past 12 months, did you take any of these drugs more than once, to get high, to feel elated, to get "a buzz" or to change your mood?	NO	YES
		CIRCLE EACH DRUG TAKEN:		
		Stimulants: amphetamines, "speed", crystal meth, "crank", Dexedrine, Ritalin, diet pills.		
		Cocaine: snorting, IV, freebase, crack, "speedball".		
		Opiates: heroin, morphine, Dilaudid, opium, Demerol, methadone, Darvon, codeine, Percodan,	Vicodin,	OxyContin.
		Hallucinogens: LSD ("acid"), mescaline, peyote, psilocybin, STP, "mushrooms", "ecstasy", MDA,	MDMA.	
		Dissociative Drugs: PCP (Phencyclidine, "Angel Dust", "Peace Pill", "Hog"), or ketamine ("Special	ıl K").	
		Inhalants: "glue", ethyl chloride, "rush", nitrous oxide ("laughing gas"), amyl or butyl nitrate ("p	oppers")	
		Cannabis: marijuana, hashish ("hash"), THC, "pot", "grass", "weed", "reefer".		
		Sedatives, Hypnotics or Anxiolytics: Quaalude, Seconal ("reds"), Valium, Xanax, Librium, Ativan	, Dalman	e, Halcion,
		barbiturates, Miltown, GHB, Roofinol, "Roofies".		
		Miscellaneous: steroids, nonprescription sleep or diet pills. Cough Medicine? Any others?		
		SPECIFY THE MOST USED DRUG(S):		
		WHICH DRUG(S) CAUSE THE BIGGEST PROBLEMS?		
		FIRST EXPLORE THE CRITERIA BELOW FOR THE DRUG CLASS CAUSING THE BIGGEST PROBLEMS AND THE ONE MOST LIKELY TO MEET CRIT	ΓERIA	
		FOR SUBSTANCE USE DISORDER. IF SEVERAL DRUG CLASSES HAVE BEEN MISUSED, EXPLORE AS MANY OR AS FEW AS REQUIRED BY THE F	PROTOCOL.	
J2		Considering your use of (NAME OF DRUG / DRUG CLASS SELECTED), in the past 12 months:		
	а	During the times when you drank alcohol, did you end up drinking more (NAME OF DRUG / DRUG CLASS SELECTED) than you planned when you started?	NO	YES
	b	Did you repeatedly want to reduce or control your (NAME OF DRUG / DRUG CLASS SELECTED) use? Did you try to cut down or control your (NAME OF DRUG / DRUG CLASS SELECTED) use, but failed? IF YES TO EITHER, CODE YES.	NO	YES
	С	On the days that you used more (NAME OF DRUG / DRUG CLASS SELECTED), did you spend substantial time obtaining (NAME OF DRUG / DRUG CLASS SELECTED), using it, or recovering from the its effects?	NO	YES
	d	Did you crave or have a strong desire or urge to use (NAME OF DRUG / DRUG CLASS SELECTED)?	NO	YES
	е	Did you spend less time meeting your responsibilities at work, at school, or at home, because of your repeated (NAME OF DRUG / DRUG CLASS SELECTED) use?	NO	YES
	f	If your (NAME OF DRUG / DRUG CLASS SELECTED) use caused problems with your family or other people, did you still keep on using it?	NO	YES
	g	Did you use the drug more than once in any situation where you or others were physically at risk, for example, driving a car, riding a motorbike, using machinery, boating, etc.?	NO	YES
	h	Did you continue to use (NAME OF DRUG / DRUG CLASS SELECTED), even though it was clear that the (NAME OF DRUG / DRUG CLASS SELECTED) had caused or worsened psychological or physical problems?	NO	YES

i	Did you reduce or give up important work, social or recreational ac because of your (NAME OF DRUG / DRUG CLASS SELECTED) use?	NO	YES	
j	Did you need to use (NAME OF DRUG / DRUG CLASS SELECTED) a lot more in or same effect that you got when you first started using it or did you gwith continued use of the same amount?		NO	YES
	THIS CRITERION IS CODED NO IF THE MEDICATION IS PRESCRIBED AND USED UNDER	R APPROPRIATE MEDICAL SUPER	VISION.	
k1	When you cut down on heavy or prolonged use of the drug did you any of the following withdrawal symptoms:	have	NO	YES
	IF YES TO THE REQUIRED NUMBER OF WITHDRAWAL SYMPTOMS FOR EACH CLASS, THIS CRITERION IS CODED NO IF THE MEDICATION IS PRESCRIBED AND USED UNDER		VISION.	
	Sedatives, Hypnotics or Anxiolytics (2 or more withdrawal sympton	ms)		
	1. increased sweating or increased heart rate			
	2. hand tremor or "the shakes"			
	3. trouble sleeping			
	4. nausea or vomiting			
	5. hearing or seeing things other people could not see or hear			
	or having sensations in your skin for no apparent reason			
	6. agitation			
	7. anxiety			
	8. seizures			
	Opiates (3 or more withdrawal symptoms)			
	1. feeling depressed			
	2. nausea or vomiting			
	3. muscle aches			
	4. runny nose or teary eyes			
	5. dilated pupils, goose bumps or hair standing on end			
	or sweating			
	6. diarrhea			
	7. yawning			
	8. hot flashes			
	9. trouble sleeping			
	5. trouble sleeping			
	Stimulants and Cocaine (2 or more withdrawal symptoms)			
	1. fatigue			
	2. vivid or unpleasant dreams			
	3. difficulty sleeping or sleeping too much			
	4. increased appetite			
	5. feeling or looking physically or mentally slowed down			
	Cannabis (3 or more withdrawal symptoms)			
	1. irritability, anger or aggression			
	2. nervousness or anxiety			
	3. trouble sleeping			
	4. appetite or weight loss			
	5. restlessness			
	6. feeling depressed			
	7. significant discomfort from one of the following:			
	"stomach pain", tremors or "shakes", sweating, hot flashes,			
	chills, headaches.			

chills, headaches.

k2	Did you use (NAME OF DRUG / DRUG CLASS SELECTED) to reduce or avoid withdrawal symptoms?	NO	YES
J2l	k summary: if yes to J2k1 <u>or</u> J2k2, code yes	NO	YES

ARE **2** OR MORE **J2** ANSWERS FROM **J2a** THROUGH **J2k SUMMARY** CODED **YES**? (**J2**k1 AND **J2**k2 TOGETHER COUNT AS ONE AMONG THESE CHOICES)

NO YES

SUBSTANCE (Drug or Drug Class Name) USE DISORDER

**PAST 12 MONTHS** 

SPECIFIERS FOR SUBSTANCE USE DISORDER:

MILD = 2-3 OF THE J2 SYMPTOMS MODERATE = 4-5 OF THE J2 SYMPTOMS SEVERE = 6 OR MORE OF THE J2 SYMPTOMS

IN EARLY REMISSION = CRITERIA NOT MET FOR BETWEEN 3 & 12 MONTHS IN SUSTAINED REMISSION = CRITERIA NOT MET FOR 12 MONTHS OR MORE (BOTH WITH THE EXCEPTION OF CRITERION d. – (CRAVING) ABOVE).

IN A CONTROLLED ENVIRONMENT = WHERE SUBSTANCE / DRUG ACCESS IS RESTRICTED

### K. PSYCHOTIC DISORDERS AND MOOD DISORDER WITH PSYCHOTIC FEATURES

ASK FOR AN EXAMPLE OF EACH QUESTION ANSWERED POSITIVELY. CODE **YES** ONLY IF THE EXAMPLES CLEARLY SHOW A DISTORTION OF THOUGHT OR OF PERCEPTION OR IF THEY ARE NOT CULTURALLY APPROPRIATE. THE PURPOSE OF THIS MODULE IS TO EXCLUDE PATIENTS WITH PSYCHOTIC DISORDERS. THIS MODULE NEEDS EXPERIENCE.

Now I am going to ask you about unusual experiences that some people have.

K1	a	Have you ever believed that people were spying on you, or that someone was plotting against you, or trying to hurt you?  NOTE: ASK FOR EXAMPLES TO RULE OUT ACTUAL STALKING.	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K2	а	Have you ever believed that someone was reading your mind or could hear your thoughts, or that you could actually read someone's mind or hear what another person was thinking?	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K3	а	Have you ever believed that someone or some force outside of yourself put thoughts in your mind that were not your own, or made you act in a way that was not your usual self? Have you ever felt that you were possessed?  CLINICIAN: ASK FOR EXAMPLES AND DISCOUNT ANY THAT ARE NOT PSYCHOTIC.	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
К4	а	Have you ever believed that you were being sent special messages through the TV, radio, internet, newspapers, books, or magazines or that a person you did not personally know was particularly interested in you?	NO	YES
	b	IF YES: do you currently believe these things?	NO	YES
K5	а	Have your relatives or friends ever considered any of your beliefs odd or unusual? INTERVIEWER: ASK FOR EXAMPLES. ONLY CODE YES IF THE EXAMPLES ARE CLEARLY DELUSIONAL IDEAS NOT EXPLORED IN QUESTIONS K1 TO K4, FOR EXAMPLE, RELIGIOUS, DEATH, DISEASE OR SOMATIC DELUSIONS, DELUSIONS OF GRANDIOSITY, JEALOUSY OR GUILT, OR OF FAILURE, INADEQUACY, RUIN, OR DESTITUTION, OR NIHILISTIC DELUSIONS.	NO	YES
	b	IF YES: do they currently consider your beliefs strange or unusual?	NO	YES
К6	а	Have you ever heard things other people couldn't hear, such as voices?	NO	YES
		<b>IF YES TO VOICE HALLUCINATION:</b> Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO	YES
	b	IF YES TO K6a: have you heard sounds / voices in the past month?	NO	YES
		<b>IF YES TO VOICE HALLUCINATION:</b> Was the voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other?	NO	YES
K7	а	Have you ever had visions when you were awake or have you ever seen things		NO

YES

### other people couldn't see?

CLINICIAN: CHECK TO SEE IF THESE ARE CULTURALLY INAPPROPRIATE.

	b	IF YES: have you seen these things in the past month?	N	O YES
		CLINICIAN'S JUDGMENT		
К8	а	DID THE PATIENT EVER IN THE PAST EXHIBIT DISORGANIZED, INCOHERENT OR DERAILED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS?	N	O YES
К8	b	IS THE PATIENT CURRENTLY EXHIBITING INCOHERENCE, DISORGANIZED OR DERAILED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS?	N	O YES
К9	а	DID THE PATIENT EVER IN THE PAST EXHIBIT DISORGANIZED OR CATATONIC BEHAVIOR?	N	O YES
К9	b	IS THE PATIENT CURRENTLY EXHIBITING DISORGANIZED OR CATATONIC BEHAVIOR?	N	O YES
K10	а	DID THE PATIENT EVER IN THE PAST HAVE NEGATIVE SYMPTOMS, E.G. SIGNIFICANT REDUCTION OF EMOTIONAL EXPRESSION OR AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION)?	N	O YES
K10	b	ARE NEGATIVE SYMPTOMS OF SCHIZOPHRENIA, E.G. SIGNIFICANT REDUCTION OF EMOTIONAL EXPRESSION OR AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION), PROMINENT DURING THE INTERVIEW?	N	O YES
K11	а	ARE 1 OR MORE « a » QUESTIONS FROM K1a TO K7a, CODED YES?		
		AND IS EITHER:		
		MAJOR DEPRESSIVE EPISODE, (CURRENT, RECURRENT OR PAST)  OR  MANIC OR HYPOMANIC EPISODE, (CURRENT OR PAST) CODED YES?		
		AND		
		HOW LONG HAS THE MOOD EPISODE LASTED?		
		HOW LONG HAS THE PSYCHOTIC EPISODE LASTED?		
		IF SUCH A MOOD EPISODE IS PRESENT, CODE YES TO K11a ONLY IF THE MOOD DISTURBANCE IS PRESENT		
		FOR THE MAJORITY OF THE TOTAL DURATION OF THE ACTIVE AND RESIDUAL PERIODS OF THE PSYCHOTIC SYMPTOMS. OTHERWISE CODE NO.	NO	YES
		I DI CITO TIC DITITITI I DITIDI DI II ENVIDE CODE NOI		

ARE THE ONLY SYMPTOMS PRESENT THOSE IDENTIFIED BY THE CLINICIAN FROM  ${\bf K10}$  and not fully endorsed by the patient?

IF YES, SPECIFY IF THE LAST EPISODE IS CURRENT (AT LEAST ONE "b" QUESTION IS CODED "YES" FROM K1b TO K10b) AND/OR LIFETIME (ANY "a" OR "b" QUESTION CODED YES FROM K1a TO K10b) AND PASS TO THE NEXT DIAGNOSTIC MODULE.

IF NO, CONTINUE.

WARNING: IF AT LEAST ONE "b" QUESTION IS CODED YES, CODE K11c AND K11d.

IF ALL "b" QUESTIONS ARE CODED NO, CODE ONLY K11d.

NO YES

UNSPECIFIED\*

SCHIZOPHRENIA SPECTRUM

AND

OTHER PSYCHOTIC DISORDER

Current 

Lifetime

\*Provisional diagnosis due to insufficient information available at this time..

K11c ARE ONE OR MORE "b" QUESTIONS FROM K1b TO K8b CODED YES?

AND

ARE TWO OR MORE "b" ITEMS FROM K1b TO K10b CODED YES?

AND

DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME  $\bf 1$  MONTH PERIOD OR LESS IF SUCCESSFULLY TREATED?

Then Criterion "A" of Schizophrenia

- ☐ Is currently met
- ☐ Is not currently met
- ☐ Uncertain, code later

K11d ARE ONE OR MORE "a" QUESTIONS FROM K1a TO K8a CODED YES?

AND

ARE TWO OR MORE "a" ITEMS FROM **K1**a **TO K10**a CODED **YES**?

AND

DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME  $\bf 1$  MONTH PERIOD OR LESS IF SUCCESSFULLY TREATED?

OR IS K11c CODED YES?

Then Criterion "A" of Schizophrenia

- ☐ Is met Lifetime
- ☐ Is not met Lifetime
- Uncertain, code later

### **DISABILITY**

K12 Did your ability to function at work, at school, with your family and in taking care of yourself and socially with others, return completely to how you were before these experiences (CLINICIAN: PROVIDE EXAMPLES OF EXISTING HALLUCINATIONS, DELUSIONS OR DISORGANIZED SPEECH OR BEHAVIOR)?

NO

YES

YES

K13 a During or after a period when you had these beliefs or experiences, did you have difficulty working, or difficulty in your relationships with others, or in taking care of yourself?

\_\_\_\_

NO

b IF YES, how long did these difficulties last? IF ≥6 MONTHS, GO TO K16.

NO YES

c Have you been treated with medications or were you hospitalized because of these beliefs or experiences, or the difficulties caused by these problems?

d	IF <b>YES</b> , what was the lor hospitalized for these p	-	ere treated	d with m	edication or were				_		
K14 a	THE PATIENT REPORTED DISA HOSPITALIZED FOR PSYCHOS		D YES) OR V	WAS TREA	TED OR			NO	YES		
b	CLINICIAN'S JUDGMENT: CC										
		absent		1							
		mild		2							
		moderate		3							
		severe		4							
K15	How long was the long	est period during	which you	u had th	ose beliefs or experien	ces?					
	WHAT WAS THE TOTAL DURAPHASE ( <b>K15</b> ) AND THE ASSO TREATMENT ( <b>K13d</b> ) IN CHO	CIATED DIFFICULTIES	s <b>(K13b)</b> AN			1 2 3 4		nonths	month <6 months		
RULE C	OUT "ORGANIC CAUSE" (I	DUE TO A MEDIC	AL ILLNES	S OR TO	EXPOSURE OR WITHD	RAWA	L FROM	A MEDIC	INE/DRUG)		
	Just before these symp	otoms began:									
K16 a	Were you taking any di	rugs or medicines	s or in with	ndrawal	from any of these?		□ No	□ Yes	□ Uncertain		
b	Did you have any medi	cal illness?					□ No	□ Yes	□ Uncertain		
c	IF K16a OR K16b IF CODED										
	IS EITHER LIKELY TO BE A DIR IF NECESSARY, ASK ADDITION			SORDER!			□ No	□ Yes	□ Uncertain		
<b>K16d</b> : ⊦	HAS AN "ORGANIC" / MEDICAL	/ DRUG RELATED CA	USE BEEN RU	ULED OUT	?		□ No	□ Yes	□ Uncertain		
	IF K16d = NO: IF K16d = YES: IF K16d = UNCERTAIN:	CODE <b>NO</b> IN <b>K</b>	17 (a and I	<b>b)</b> AND GO	THE NEXT MODULE O TO <b>K14</b> ) AND GO TO <b>K18</b>						
K17a	IS <b>K16d</b> CODED <b>NO</b> BECAUSE	OF A GENERAL MED	ICAL CONDIT	TION (INCL	UDING DELIRIUM)?		NO		YES		
If response to K13a is coded <b>yes</b> , specify if the last episode is <b>current</b> or <b>lifetime</b> or both: <b>current</b> : (at least one "b" question is coded <b>yes</b> either from ( <b>K1b</b> to <b>K5b</b> = delusion) or from ( <b>K6b</b> or <b>K7b</b> = hallucination).  And/or <b>lifetime</b> : at least one "a" question is coded <b>yes</b> from <b>K1a</b> through <b>K7b</b> , with at least one of these from ( <b>K1a</b> to <b>K5a</b> = delusion) or from ( <b>K6b</b> or <b>K7b</b> = hallucination) or at least one "b" question is coded <b>yes</b> from ( <b>K1b</b> to <b>K5b</b> = delusion) or from ( <b>K6b</b> or <b>K7b</b> = hallucination).  AND IS <b>K13a</b> coded <b>yes</b> ?								PSYCHOTIC DISORDER  Due to a General Medica  Condition  Current  Lifetime  Uncertain, code later			

K17	'b	IS <b>K12d</b> CODED <b>NO</b> BECAUSE OF A DRUG/MEDICINE OR WITHDRAWAL FROM A DRUG /MEDICINE OR FROM	NO	YES
		DELIRIUM?  If RESPONSE TO K13b is CODED YES, SPECIFY IF THE LAST EPISODE IS CURRENT OR LIFETIME OR BOTH:  CURRENT: (AT LEAST ONE "b" QUESTION IS CODED YES EITHER FROM (K1b TO K5b = DELUSION)  OR FROM (K6b OR K7b = HALLUCINATION).  AND/OR LIFETIME: AT LEAST ONE "a" QUESTION IS CODED YES FROM K1a THROUGH K7b, WITH AT LEAST  ONE OF THESE FROM (K1a TO K5a = DELUSION) OR FROM (K6b OR K7b = HALLUCINATION) OR AT LEAST  ONE "b" QUESTION IS CODED YES FROM (K1b TO K5b = DELUSION) OR FROM (K6b OR K7b = HALLUCINATION),  AND IS K13a CODED YES?  IF YES TO K17b CURRENT, GO TO MODULE L AND SKIP REMAINING K QUESTIONS	Substance In PSYCHOTIC DI  Current Lifetime Uncertain, code	SORDER
CHR	ON	OLOGY		
K18		How old were you when you first began having these unusual beliefs or experiences?	age	
CODE	: TH	PART 2 - DIFFERENTIAL DIAGNOSIS BETW PSYCHOTIC DISORDER AND A MOOD DISORDER WITH P  E QUESTIONS K19 TO K23 ONLY IF THE PATIENT DESCRIBED AT LEAST 1 PSYCHOTIC SYMPTOM (K11a = YES A CAUSE (K12d = YES OR UNCERTAIN).	SYCHOTIC FE	
K19	а	DOES THE PATIENT CODE POSITIVE FOR CURRENT AND/OR PAST MAJOR DEPRESSIVE EPISODE (QUESTIONS A3 SUMMARY OR A4b CODED YES)?	NO	YES
	b	YES: IS A1a OR A1b (DEPRESSED MOOD) CODED YES?	NO	YES
	С	DOES THE PATIENT CODE POSITIVE FOR CURRENT AND/OR PAST MANIC EPISODE (MODULE C)?	NO	YES
	d	Is <b>K19a</b> or <b>K19c</b> coded <b>yes</b> ?	NO ↓ STOP. Skip to K24	YES
		NOTE: VERIFY THAT THE RESPONSES TO THE QUESTIONS <b>K20</b> TO <b>K23</b> REFER TO THE PSYCHOTIC, DEPRESSIVE ( <b>A3 SUMMARY OR A4b</b> ) AND MANIC EPISODES ( <b>MODULE C</b> ), ALREADY IDENTIFIED IN <b>K1</b> : <b>A3 SUMMARY OR A4b AND MODULE C</b> . IN CASE OF DISCREPANCIES, RE-EXPLORE THE SEQUENCE OF EINTO ACCOUNT IMPORTANT LIFE ANCHOR POINTS/MILESTONES AND CODE <b>K20</b> TO <b>K23</b> ACCORDINGLY.		
K20		When you were having the beliefs and experiences you just described (GIVE EXAMPLES TO PATIENT), were you also feeling depressed/high/irritable at the same time?	NO ↓ STOP. Skip to K24	YES
K21		Were the beliefs or experiences you just described (GIVE EXAMPLES TO PATIENT) restricted exclusively to times you were feeling depressed/high/irritable?	NO	YES
K22		Have you ever had a period of two weeks or more of having these beliefs or experiences when you were not feeling depressed/high/irritable?	NO ↓ STOP.	YES

Skip to K24

K23	a) Which lasted longer: these beliefs or experiences or the periods of feeling depressed/high/irritable?	1 2 3	0	mood belief same	s, experiences
	IF THE RESPONSE TO K23a) was 2, ask K23b) and K23c):				
	b) Did the beliefs or experiences you just described (GIVE EXAMPLES OF DELUSIONS OR HALLUCINATIONS TO PATIENT) occur for at least 2 weeks without your also feeling depressed/high/irritable?		N	10	YES
	c) Did the depressed/high/irritable feelings last more than 50% of the total time that you had these beliefs and experiences? (GIVE EXAMPLES TO PATIENT)  THIS CALCULATION SHOULD EMBRACE THE TOTAL DURATION OF THE ACTIVE AND RESIDUAL PHASES OF THE JULIESTS.		N	10	YES

K24 AT THE END OF THE INTERVIEW, GO TO THE DIAGNOSTIC ALGORITHMS FOR PSYCHOTIC DISORDERS.

CONSULT ITEMS **K11a** AND **K11b**:

### **CURRENT:**

IF THE CRITERION "A" OF SCHIZOPHRENIA IS MET (**K11c** = **YES**) GO TO DIAGNOSTIC ALGORITHM I

IF THE CRITERION "A" OF SCHIZOPHRENIA IS NOT MET (**K11c** = **NO**) GO TO DIAGNOSTIC ALGORITHM II

FOR MOOD DISORDERS GO TO THE DIAGNOSTIC ALGORITHM III.

### LIFETIME:

IF THE CRITERION "A" OF SCHIZOPHRENIA IS MET (**K11d** = **YES**) GO TO DIAGNOSTIC ALGORITHM I

IF THE CRITERION "A" OF SCHIZOPHRENIA IS NOT MET (**K11d** = **NO**) GO TO DIAGNOSTIC ALGORITHM II

FOR MOOD DISORDERS GO TO THE DIAGNOSTIC ALGORITHM III.

### L. ANOREXIA NERVOSA

( $\Rightarrow$  Means: go to the diagnostic box, circle NO, and move to the next module)

		IS <b>L5</b> CODED <b>YES</b> ?	NO AN		YES A <i>NERVOSA</i> RENT	
L5		ARE 1 OR MORE ITEMS FROM <b>L4</b> CODED <b>YES</b> ?		NO	YES	
	С	Have you thought that your current low body weight was normal or excessive?		NO <b>→</b>	YES	
	b	Has your body weight or shape greatly influenced how you felt about yourself?		NO	YES	
L4	а	Have you considered yourself too big / fat or that part of your body was too big / fat?		NO	YES	
L3		Have you intensely feared gaining weight or becoming fat, even though you were under	weight?	<b>→</b> NO	YES	
L2		In spite of this low weight, have you tried not to gain weight or to restrict your food inta	ke?	<b>→</b> NO	YES	
		In the past 3 months:				
	С	IS PATIENT'S WEIGHT EQUAL TO OR BELOW THE THRESHOLD CORRESPONDING TO HIS / HER HEIGHT? (SEE TABLE BELOW)		<b>→</b> NO	YES	
	b	What was your lowest weight in the past 3 months?			☐ ☐ Ib	
L1	а	How tall are you?		☐ ft	☐ ☐ cm	

### HEIGHT / WEIGHT TABLE corresponding to a BMI THRESHOLD of 17.0 kg/m $^2$

Height/Weight														
ft/in	4'9	4'10	4'11	5'0	5'1	5'2	5'3	5'4	5'5	5'6	5'7	5'8	5'9	5'10
lb	79	82	84	87	90	93	96	99	102	106	109	112	115	119
cm	145	147	150	152	155	158	160	163	165	168	170	173	175	178
kg	36	37	38.5	39.5	41	42.5	43.5	45.5	46.5	48	49	51	52	54
Height/Weight														
ft/in	5'11	6'0	6'1	6'2	6'3									
lb	122	125	129	133	136									
cm	180	183	185	188	191									
kg	55	57	58.5	60	62									

The weight thresholds above are calculated using a body mass index (BMI) equal to or below 17.0 kg/m<sup>2</sup> for the patient's height using the Center of Disease Control & Prevention BMI Calculator. This is the threshold guideline below which a person is deemed underweight by the DSM-5 for Anorexia Nervosa.

# M. BULIMIA NERVOSA

(▶ MEANS: GO TO THE DIAGNOSTIC BOXES, CIRCLE NO IN THE 4 BULIMIA SECTION DIAGNOSTIC BOXES, AND MOVE TO BINGE EATING DISORDER)

M1 M2	In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period?  During these binges, did you feel that your eating was out of control?	<b>-</b>	0	YES
M3	In the last 3 months, did you have eating binges as often as once a week?	<b>→</b> N	0	YES
M4	Did you do anything to compensate for, or to prevent a weight gain, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications? Did you do this as often as once a week?	N	0	YES
	CODE YES TO M3 ONLY IF THE ANSWER TO BOTH THESE M3 QUESTIONS IS YES.			
M4a	Number of Episodes of Inappropriate Compensatory Behaviors per Week?			
	Number of Days of Inappropriate Compensatory Behaviors per Week?			
M5	Does your body weight or shape greatly influence how you feel about yourself?	<b>→</b> N	0	YES
M6	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	↓	0	YES
		Si	kip to N	/18
M7	Do these binges occur only when you are under (lb/kg)? INTERVIEWER: WRITE IN THE ABOVE PARENTHESIS THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.	N	0	YES
M8	IS <b>M5</b> CODED <b>YES</b> AND IS EITHER <b>M6</b> OR <b>M7</b> CODED <b>NO</b> ?	NO		YES
			<i>IMIA I</i> CURR	NERVOSA BENT
	IS M7 CODED YES?	NO		YES
				NERVOSA Purging Type EENT

DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?		
AND	NO	YES
ARE M2 AND M4 CODED NO?	ANOREXIA NERVOSA Restricting Type CURRENT	
SPECIFIERS OF EATING DISORDER:	SPECIFY IF:	
MILD = 1-3 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS  MODERATE = 4-7 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS  SEVERE = 8-13 EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS  EXTREME = 14 OR MORE EPISODES OF INAPPROPRIATE COMPENSATORY BEHAVIORS	MILD MODEF SEVER	E 🗆

# **MB. BINGE EATING DISORDER**

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO IN THE DIAGNOSTIC BOX, AND MOVE TO THE NEXT MODULE)

MB1	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA?	NO	→ YES
MB2	DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR BULIMIA NERVOSA?	NO	<b>→</b> YES
MB3	M2 IS CODED YES	<b>→</b> NO	YES
MB4	M3 IS CODED YES	<b>→</b> NO	YES
MB5	M4 IS CODED YES	NO	<b>→</b> YES
	In the last 3 months during the binging did you:		
MB6a	Eat more rapidly than normal?	NO	YES
MB6b	Eat until you felt uncomfortably full?	NO	YES
MB6c	Eat large amounts of food when you were not hungry?	NO	YES
MB6d	Eat alone because you felt embarrassed about how much you were eating?	NO	YES
MB6e	Feel guilty, depressed or disgusted with yourself after binging?	NO	YES
	ARE 3 OR MORE <b>MB6</b> QUESTIONS CODED YES?	<b>→</b> NO	YES

∕IB7	Does your binging distress you a lot?	<b>→</b> NO	YES
MB8	Number of Binge Eating Episodes per Week?		
	Number of Binge Eating Days per Week?		
	IS MB7 CODED YES?		YES NG DISORDER RENT
	SPECIFIERS OF EATING DISORDER:	SPECIFY IF:	
	MILD = 1-3 EPISODES OF BINGE EATING PER WEEK MODERATE = 4-7 EPISODES OF BINGE EATING PER WEEK SEVERE = 8-13 EPISODES OF BINGE EATING PER WEEK EXTREME = 14 OR MORE EPISODES OF BINGE EATING PER WEEK	MILD MODER/ SEVERE EXTREN	ATE   E

#### N. GENERALIZED ANXIETY DISORDER

(→ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT MODULE)

		Out the Of Cause you significant distress:  ND IS "RULE OUT ORGANIC CAUSE (O2 SUMMARY)" CODED YES?  O. RULE OUT MEDICAL, ORGANIC OR DRUG CAUSES FOR ALL	<i>DIS</i>	ORDER RRENT
N4	to	o these anxieties and worries significantly disrupt your ability to work, of function socially or in your relationships or in other important areas of our life or cause you significant distress?	NO GENERALI	YES  ZED ANXIETY
		ARE <b>3</b> OR MORE <b>N3</b> ANSWERS CODED <b>YES?</b>	NO	YES
	f	Have difficulty sleeping (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO	YES
	e	Feel irritable?	NO	YES
	d	Have difficulty concentrating or find your mind going blank?	NO	YES
	С	Feel tired, weak or exhausted easily?	NO	YES
	b	Have muscle tension?	NO	YES
	а	Feel restless, keyed up or on edge?	NO	YES
		When you were anxious over the past 6 months, did you, most of the time:		
N3		FOR THE FOLLOWING, CODE <b>NO</b> IF THE SYMPTOMS ARE CONFINED TO FEATURES OF ANY DISORDER EXPLORED PRIOR TO THIS POINT.		
N2		Do you find it difficult to control the worries?	<b>→</b> NO	YES
		ARE THE PATIENT'S ANXIETY AND WORRIES RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT?	NO	<b>→</b> YES
	b	Are these anxieties and worries present most days?	<b>→</b> NO	YES
N1	а	Were you excessively anxious or worried about several routine things, over the past 6 months?  IN ENGLISH, IF THE PATIENT IS UNCLEAR ABOUT WHAT YOU MEAN, PROBE BY ASKIN (Do others think that you are a worrier or a "worry wart"?) AND GET EXAMPLES.	NO G	YES
			<b>→</b>	

IF THE PATIENT CODES POSITIVE FOR ANY CURRENT DISORDER OR A MAJOR DEPRESSIVE EPISODE OR A MANIC OR A HYPOMANIC EPISODE ASK:

	Just before these symptoms began:				
O1a	Were you taking any drugs or medicines or in withdrawal from any of these?	□ No	☐ Yes	☐ Uncertain	
O1b	Did you have any medical illness?	□ No	□ Yes	□ Uncertain	
О2	If $O1a$ or $O1b$ is coded yes, in the clinician's judgment, is either likely to be a direct cause of the patient's disorder? If necessary, ask additional open-ended questions.	□ No	□ Yes	☐ Uncertain	
	2 SUMMARY: HAS AN "ORGANIC" / MEDICAL / DRUG RELATED CAUSE BEEN RULED OUT?				

#### P. ANTISOCIAL PERSONALITY DISORDER

(→ MEANS: GO TO THE DIAGNOSTIC BOX AND CIRCLE NO)

#### P1 Before you were 15 years old, did you:

Р2

a	repeatedly skip school or run away from home overnight or stayed out at night against your parent's rules?	NO	YES
b	repeatedly lie, cheat, "con" others, or steal or break into someone's house or car?	NO	YES
С	start fights or bully, threaten, or intimidate others?	NO	YES
d	deliberately destroy things or start fires?	NO	YES
е	deliberately hurt animals or people?	NO	YES
f	force someone into sexual activity?	NO	YES
	ARE <b>2</b> OR MORE <b>P1</b> ANSWERS CODED <b>YES</b> ?	NO	YES
	DO NOT CODE <b>YES</b> TO THE BEHAVIORS BELOW IF THEY ARE EXCLUSIVELY POLITICALLY OR RELIGIOUSLY MOTIV	ATED.	
	Since you were 15 years old, have you:		
а	done things that are illegal or would be grounds to get arrested, even if you didn't get caught (for example destroying property, shoplifting, stealing, selling drugs, or committing a felony)?	NO	YES
b	often lied or "conned" other people to get money or pleasure, or lied just for fun?	NO	YES
С	been impulsive and didn't care about planning ahead?	NO	YES
d	been in physical fights repeatedly or assaulted others (including physical fights with your spouse or children)?	NO	YES
е	exposed others or yourself to danger without caring?	NO	YES
f	repeatedly behaved in a way that others would consider irresponsible, like failing to pay for things you owed, deliberately being impulsive or deliberately not working to support yourself?	NO	YES
g	felt no guilt after hurting, mistreating, lying to, or stealing from others, or after damaging property?	NO	YES

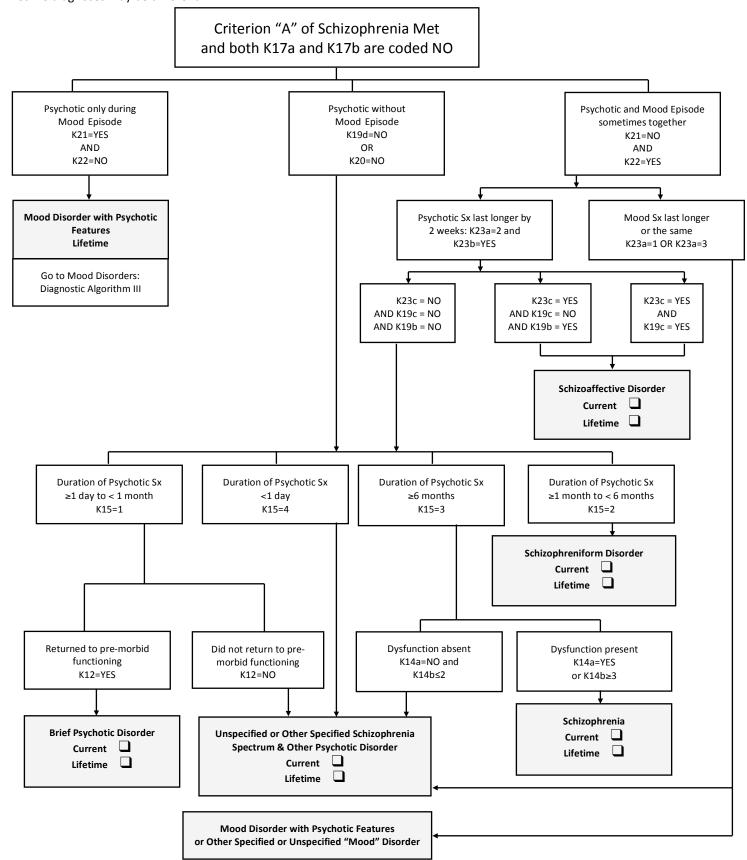
NO YES

ANTISOCIAL PERSONALITY
DISORDER
LIFETIME

ARE **3** OR MORE **P2** QUESTIONS CODED **YES?** 

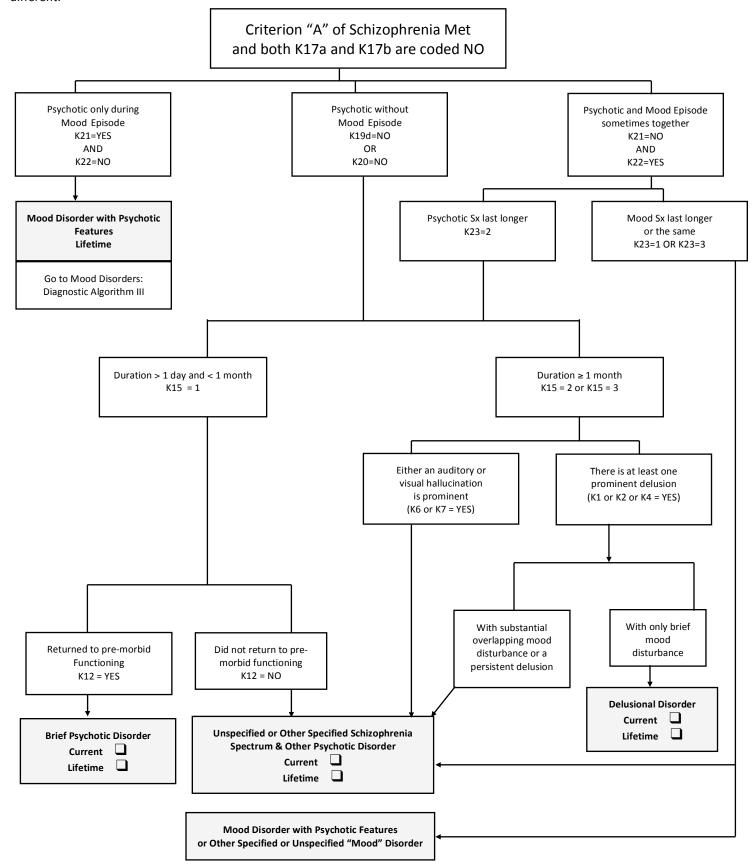
#### PSYCHOTIC DISORDERS: DIAGNOSTIC ALGORITHM I

For both current and lifetime diagnoses, circle the appropriate diagnostic box (separately if necessary). One positive diagnosis excludes the others for that time frame. If criterion A of schizophrenia is not currently met, but is present lifetime, current and lifetime diagnoses may be different.



#### PSYCHOTIC DISORDERS: DIAGNOSTIC ALGORITHM II

For both current and lifetime diagnoses, circle the appropriate diagnostic box (separately if necessary). One positive diagnosis excludes the others for that time frame. If criterion A of schizophrenia is present lifetime, current and lifetime diagnoses may be different.



#### MOOD DISORDERS: DIAGNOSTIC ALGORITHM

Coi	nsult	t Modules:	A C K	Major Depressive Episodo (Hypo)manic Episode Psychotic Disorders	e			
МС	DU	LE K:						
	í	1a IS <b>K21</b> CODED YES an	d <b>K22</b>	CODED NO?	NO	YES		
МС	DU	LES A and C:			Current	Past		
2	а	CIRCLE YES IF A DELUSION OR ANY PSYCHOTIC FEATURE			YES	YES		
	b	CIRCLE YES IF A DELUSIO OR ANY PSYCHOTIC FEATURE			YES	YES		
	С	and is Manic Episode coded N and is Hypomanic Episode co	NO (cu				_	or DEPRESSIVE DISORDER  current past
		and is "Rule out Organic Caus  Specify:  If the depressive e		Summary)" coded YES? is <b>current</b> or <b>past</b> or both			With Ps Current Past	ychotic Features
		-		If 1a alone or (1a and 2a) = eatures are current or past c				

d	Is a Manic Episode coded YES (current or past)? and	BIPOLA: DISORD		
	Is "Rule out Organic Cause (O2 Summary)" coded YES?			
	Specify:	<b>Bipolar I Disorder</b> Single Manic Episod	current 	past
	If the Bipolar I Disorder is current or past or both			
		With Psychotic	Feature	25
	<ul> <li>With Single Manic Episode: If Manic episode (current or past) = YES</li> </ul>	Current		
	and MDE (current and past) = NO	Past		
	• With Psychotic Features Current: If 1a and (2a (current) or 2b (current)) = YES	Most Recent	Episode	
	With Psychotic Features Past: If 1a and (2a (past) or 2b (past)) = YES	Manic		
	With 1 Sycholic Federics Fasti II Id and (Ed (past) of Es (past))	Depressed		
	If the most recent episode is manic, depressed,	Hypomanic		
	or hypomanic or unspecified (all mutually exclusive)	Unspecified		
		Most Bosont	Enicodo	
	<ul> <li>Most Recent Episode Unspecified if the Past Manic Episode is coded YES</li> </ul>	<b>Most Recent</b> Mild	<i>Episoae</i> □	
		Moderate		
	AND	Severe	_	
	(If any current C3 symptoms are coded YES and current C3 Summary is coded NO)			
	OR			
	(If current C3 Summary is coded YES			
	AND If current Manic Episode diagnostic box is coded NO current)			
e	Is Major Depressive Episode coded YES (current or past)			
	and	BIPOLAI		
	Is Hypomanic Episode coded YES (current or past)	DISORD	ER	
	and			
	Is Manic Episode coded NO (current and past)?		current	past
	and Is "Rule out Organic Cause (O2 Summary)" coded YES?	Bipolar II Disorder		4
	is Rule out Organic Cause (O2 Summary) Coded 123:	Most Recent	Episode	
	Specify:			
		Hypomanic		
	<ul> <li>If the Bipolar Disorder is current or past or both</li> </ul>	Depressed		
		Hypomanic Unspecified		
	• If the most recent mood episode is <b>hypomanic</b> or <b>depressed</b> (mutually exclusive)	Olispecified	_	
	Most Recent Episode Unspecified if the Past Manic / Hypomanic Episode is	Most Recent	Episode	
	coded YES	Mild		
	AND	Moderate		
		Severe		
	(If any current C3 symptoms are coded YES and current C3 Summary is coded NO)			
	OR			
	(If current C3 Summary is coded YES AND			
	If current Hypomanic Episode diagnostic box is coded NO current)			

f	Is MDE coded NO (current and past)  and	BIPOLA DISORDER UNS			
	Is Manic Episode coded NO (current and past)  and		cur	rent	past
	Is C4b coded YES for the appropriate time frame  and	Bipolar Disc	order NOS		
	Is C7b coded YES?				
	or				
	Is Manic Episode coded NO (current and past) and				
	Is Hypomanic Episode coded NO (current and past)  and				
	Is C4a coded YES for the appropriate time frame  and Is C7c coded YES?				
	is C/C coueu 1E3:				

Specify if the Bipolar Disorder NOS is **current** or **past** or both.

#### **Z. SUICIDALITY DISORDERS CLASSSIFICATION INTERVIEW**

#### In your lifetime did you:

Z1	Have any accident? This includes taking too much of your med IF NO TO Z1, SKIP TO Z2; IF YES, ASK Z1a:	ication accidentally.	NO	YES
Z1a	Plan or intend to hurt yourself in any accident, either by not as by causing the accident on purpose?	voiding a risk or	NO	YES
	IF NO TO Z1a, SKIP TO Z2: IF YES, ASK Z1b:			
Z1b	Intend to die as a result of any accident?		NO	YES
Z2	Think (even momentarily) that you would be better off dead o needed to be dead?	r wish you were dead or	NO	YES
Z3	Think (even momentarily) about harming or of hurting or of in - with at least some intent or awareness that you might die as - or think about suicide (i.e. about killing yourself)?	= -	NO	YES
Z4	Hear a voice or voices telling you to kill yourself or have dream If YES, was it either or both:   was it a voice or voices?	ns with any suicidal content?	NO	YES
<b>Z</b> 5	Have a suicide method in mind (i.e. how)?		NO	YES
<b>Z</b> 6	Have a suicide means in mind (i.e. with what)?		NO	YES
<b>Z</b> 7	Have any place in mind to attempt suicide (i.e. where)?		NO	YES
Z8	Have any date/timeframe in mind to attempt suicide (i.e. whe	n)?	NO	YES
<b>Z</b> 9	Think about any task you would like to complete before trying (e.g. writing a suicide note)	to kill yourself?	NO	YES
Z10	Intend to act on thoughts of killing yourself?		NO	YES
Z11	Intend to die as a result of a suicidal act?		NO	YES
Z12	Feel the need or impulse to kill yourself or to plan to kill yourself yes, mark either or both:   was this largely unprovoked?		NO	YES
	IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED AS this Impulse, could you have predicted it would occur at that t			
Z13	Take any active steps to prepare for a suicide attempt in which or intended to die (include anything done or purposely not do to making a suicide attempt)? This includes times when you w but were interrupted or stopped yourself, before harming you IF NO TO Z13, SKIP TO Z14.	ne that put you closer ere going to kill yourself,	NO	YES
Z13a	Take active steps to prepare to kill yourself, but you did not st	art the suicide attempt?	NO	YES
Z13b	Take active steps to prepare to kill yourself, but then <b>you stop</b> harming yourself ("aborted").	ped yourself just before	NO	YES
Z13c	Take active steps to prepare to kill yourself, but then <b>someone stopped you just before</b> harming yourself ("interrupted")?	e or something	NO	YES
Z14	Injure yourself on purpose without intending to kill yourself?		NO	YES
M.I.N.I.	. 7.0.1 (January 6, 2016) (1/6/16) 575			

Z15	Attempt suicide (to kill yourself)? IF NO TO Z15, SKIP TO Z16.	NO	YES
Z15a	Start a suicide attempt (to kill yourself), but then <b>you decided to stop</b> and did not finish the attempt?	NO	YES
Z15b	Start a suicide attempt (to kill yourself), but then <b>you were interrupted</b> and did not finish the attempt?	NO	YES
Z15c	Went through with a suicide attempt (to kill yourself), <b>completely</b> as you meant to? A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.	NO	YES
	A suicide attempt is any (set of) behavior(s), whether incomplete or completed, perceive lethal connected with any level of intent* to die that does not result in a fatality. The beharm to the patient and the (set of) behavior(s) may be incomplete due to an interruption body or existence or may be incomplete due to the patient aborting the already started it (they) are fully executed. The intent to die can be inferred by a reasonable group of eassumed unless the evidence is compelling. Not all self-injury is suicidal. This intent to of initiation of the suicide attempt. * Intent is defined as the state of a person's mind the action.	ehavior <i>may no</i> on by events ou , perceived leth xperts, but shoud die refers to the	t result in any actual itside the patient's al behavior(s) before ald not always be intent at the time
Z16	ARE ALL THE LIFETIME SUICIDALITY MODULE QUESTIONS (Z1a THROUGH Z13c) AND (Z15 THROUGH Z15c) CODED ${f No}$ ?	NO	YES
	is Z16 coded no?	NO	YES
		LIFETIME	SUICIDALITY
	IF LIFETIME SUICIDALITY IS CODED NO, END THIS MODULE HERE.		
	IF LIFETIME SUICIDALITY IS CODED YES, CONTINUE BY ASKING THE QUESTIONS BELOW.		
Z17	DOES THE PATIENT HAVE:  a. A PSYCHOTIC DISORDER OR A MOOD DISORDER WITH PSYCHOTIC FEATURES?	Yes	
	b. OBSESSIVE COMPULSIVE DISORDER?		
	<ul><li>b. OBSESSIVE COMPULSIVE DISORDER?</li><li>c. POSTTRAUMATIC STRESS DISORDER?</li></ul>		
	C. POSTTRAUMATIC STRESS DISORDER?  d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS?  THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES.  USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION,		
	C. POSTTRAUMATIC STRESS DISORDER?  d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS?  THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES.  USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION, AND LABORATORY RESULTS (E.G. DRUG SCREENS, GGT, MCV).		
	<ul> <li>C. POSTTRAUMATIC STRESS DISORDER?</li> <li>d. SUBSTANCE USE WITHIN 6 WEEKS OF THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS? THIS INCLUDES BOTH DRUGS OF ABUSE AND PRESCRIPTION AND NON-PRESCRIPTION SUBSTANCES. USE ALL THE INFORMATION AVAILABLE IN ADDRESSING THIS QUESTION, INCLUDING INFORMATION FROM THE HISTORY, COLLATORAL INFORMATION FROM SIGNIFICANT OTHERS, PHYSICAL EXAMINATION, AND LABORATORY RESULTS (E.G. DRUG SCREENS, GGT, MCV).</li> <li>e. A MEDICAL ILLNESS OR NEUROLOGICAL CONDITION?</li> </ul>		

#### Z. IMPULSE ATTACK SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS IASD MODULE, CODE THE IMPULSE ATTACK SUICIDALITY EPISODE AS NO. THEN FOLLOW THE CODING INSTRUCTIONS FOR THE NON SUICIDAL PHYSICAL SYMPTOM ATTACKS BEFORE CODING IT.)

Z18	Have you ever had a sudden urge or impulse or urgent need to make a suicide attempt, or to plan a suicide attempt?	<b>→</b> NO	YES	
Z19	Did these attacks or impulses usually surge to a peak with in 10 minutes of starting?	NO	YES	
Z20	At any time in the past, did any of those attacks or impulses, come on unexpectedly, or occur in an unpredictable or unprovoked manner?  IN ASSESSING WHETHER THIS WAS LARGELY UNPROVOKED ASK: "5 minutes before this Impulse, could you have predicted it would occur at that time?"	<b>→</b> NO	YES	

	During the worst suicidal impulse attack that you can remember:		
Z21	Prodromal Aura  a. At first, did everything around you suddenly appear different from the way it normally does?	NO	YES
	b. At first, did you feel as if you were loosing control?	NO	YES
	c. At first, did the loss of control feeling and the awareness of things appearing different, last between 30 seconds and 5 minutes?	NO	YES
	Z21 SUMMARY: ARE Z21a AND Z21b AND Z21c ALL CODED YES?	NO	YES
Z22	Physical Symptoms  a. Did you have a sensation of external pressure on your upper central forehead?	NO	YES
	b. Did you feel outside of, or detached from, part or all of your body, <b>o</b> r did you feel that things around you were strange, detached or unfamiliar, <b>or</b> did you have difficulty recalling what happened for a block of time, even though there was no loss of consciousness?	NO	YES
	c. Did you have a sudden onset of pain, in the middle of your back, surrounding your spine?	NO	YES
	d. Did you have skipping or racing of your heart, or feel these sensations in your neck arteries?	NO	YES
	e. Did you have difficulty or more effort, in breathing or interrupted breathing, or slow, shallow breathing?	NO	YES
	f. Did you have an interruption in swallowing or an increased frequency of swallowing, or a sensation of prolonged swallowing, or repetitive swallowing?	NO	YES
	g. Did you have chest pain, pressure, or discomfort?	NO	YES
	h. Did you have a headache at the front of your head?	NO	YES
	Z22 SUMMARY: DID 2 OR MORE OF THE Z22a THROUGH Z22h SYMPTOMS OCCUR WITHIN THE SAME 10 MINUTES?	NO	YES

#### 723 Pro Awareness Need to Be Dead Sensation

Z23	Pre Awareness Need to Be Dead Sensation  a. Did you have an unusual sensation, that you have learned from experience, to associate with a need to be dead? This sensation may or may not be followed,		
	by an awareness of a need to be dead, or a suicidal impulse.	NO	YES
Z24	Sensory a. Were all sensations muffled or muted?	NO	YES
	b. Did you suddenly become aware of things close to you that could be used to attempt suicide?	NO	YES
	c. Did time become distorted or slowed down?	NO	YES
	Z24 SUMMARY: IS EITHER Z24a OR Z24b OR Z24c CODED YES?	NO	YES
Z25	Gambit		
	a. Did resting the urge to plan a suicide attempt lead into an urge to act on the suicidal impulse?	NO	YES
	b. Did resisting the urge to plan or the urge to act, result in an increase in the suicidal and (associated) physical symptoms?	NO	YES
	c. Did giving into the urge to plan a suicide attempt or to act on suicidal impulses result in a reduction of suicidal and (associated) physical symptoms?	NO	YES
	Z25 SUMMARY: ARE (Z25a OR Z25b) AND Z25c CODED YES?	NO	YES
Z26	Hours After the Suicidal Impulse		
	a. Did you feel exhausted hours after the suicidal impulse attack?	NO	YES
	b. Were you very sleepy hours after the suicidal impulse attack?	NO	YES
	c. Did you have aches in parts of your body, that earlier in the impulse attack, felt detached from you?	NO	YES
		110	123
	d. Did you have diarrhea hours after the suicidal impulse attack?	NO	YES
	Z26 SUMMARY: IS EITHER Z26a OR Z26 b OR Z26c OR Z26c CODED YES?	NO	YES
Z27	Days After		
	a. Did you have more depression in the days after the suicidal impulse attack?	NO	YES
	b. Did you deliberately think about, plan, prepare, or take action to make a suicide attempt in the days after the suicidal impulse attack?	NO	YES
	c. Did you have a craving for fatty or calcium-rich foods, about a week after the suicidal impulse attack?	NO	YES
	Z27 SUMMARY: IS EITHER Z27a OR Z27b OR Z27c CODED YES?	NO	YES
Z28	Minimization		
	a. Did you feel a need at multiple points during and after the suicidal impulse attack,	NO	VEC

Minimization a. Did you feel a need at multiple points during and after the suicidal impulse attack, to minimize the symptoms to yourself, in an attempt to cope with them?	NO	YES
b. Did you feel a need at multiple points during and after the suicidal impulse attack, to minimize the symptoms to others, because they might overreact or not understand?	NO	YES

Z28 SUMMARY: IS EITHER Z28a OR Z28b CODED YES? NO YES

Z29 ARE THE SUMMARIES OF Z22 AND Z24 AND Z25 AND Z26 ALL CODED YES?

NO YES

ARE THE SUMMARIES OF EITHER Z22 OR Z24 OR Z26 CODED NO?

NO YES

YES

NO

IS EITHER Z29 OR Z30 CODED YES?

Z30

IF Z20 IS CODED YES, CODE EPISODE AS USIA PHYSICAL & IDEATION SUBTYPE.

IF Z30 IS CODED YES, CODE EPISODE AS USIA IDEATION ONLY SUBTYPE.

CLARIFICATIONS FOR CODING DIRECTIONS IN Z29 AND Z30:

Z21 SUMMARY IS USUALLY PRESENT, BUT MAY BE DIFFICULT FOR SOME PATIENTS TO ACCURATELY PERCEIVE IN THE EARLY YEARS OF THE DISORDER. HENCE IT IS NOT MANDATORY IN THE CALCULATIONS FOR THE IIMPULSE ATTACK SUICIDALITY EPISODE.

THE Z23 CRITERION IS NOT MANDATORY, BECAUSE IT IS SO BRIEF, AND SINCE IT OCCURS IN THE CONTEXT OF OTHER MORE INTENSE SYMPTOMS, IT MAY BE DIFFICULT FOR SOME PATIENTS TO IDENTIFY AND TO RECALL.

THE Z27 CRITERION IS NOT MANDATORY, BECAUSE PATIENTS MAY NOT MAKE THE CONNECTION BETWEEN THE IMPULSE ATTACK AND THE SYMPTOMS THEY EXPERIENCE IN THE DAYS FOLLOWING THE ATTACK.

THE Z28 CRITERION IS NOT MANDATORY, BECAUSE SOME PATIENTS DO NOT MINIMIZE THEIR SYMPTOMS.

USIA Physical & Ideation subtype 📮

**IMPULSE ATTACK** 

**SUICIDALITY** 

**EPISODE** 

USIA Ideation Only subtype

WHEN IMPULSE ATTACK SUICIDALITY DISORDER GOES INTO PARTIAL REMISSION, SOME PATIENTS HAVE ATTACKS LIMITED TO THE CHARACTERISTIC PHYSICAL SYMPTOMS (CRITERIA Z22 AND Z24 AND Z26), BUT WITHOUT ANY OVERY SUICIDAL IDEATION, IMPULSES, OR BEHAVIORS. THEY DESCRIBE THESE ATTACKS AS BEING ALMOST IDENTICAL TO THE USIA ATTACKS, BUT THESE PHYSICAL SYMPTOMS OCCUR IN THE ABSENCE OF ANY SUICIDALITY.

TO CAPTURE THE PRESENCE OF SUCH ATTACKS, CODE NON SUICIDAL PHYSICAL SYMPTOM ATTACK EPISODE AS YES, IF THE PATIENT DESCRIBES SUCH ATTACKS.

OTHERWISE CODE NO.

NO

YES

NON SUICIDAL
PHYSICAL SYMPTOM
ATTACK EPISODE

IS IMPULSE ATTACK SUICIDALITY EPISODE CODED YES?

NO

YES

IMPULSE ATTACK
SUICIDALITY DISORDER

#### Specifiers for Impulse Attack Suicidality Disorder

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SPECIFIER)

#### Z31 Most Recent Episode

During the most recent attack:	
a. Did you have the suicidal impulse?	NO YES
b. Did you have the typical associated physical symptoms?	NO YES
c. Was the most recent attack?	
☐ unexpected (i.e. came on for no apparent reason)	
☐ expected (i.e. occurred as a direct and immediate response to a stressor)	
IF Z31a AND Z31b ARE CODED YES AND Z31c IS CODED AS UNEXPECTED, THEN CODE THE MOST RECENT EPSISODE AS USIA PHYSICAL & IDEATION SUBTYPE.  IF Z31a IS CODED YES AND Z31b IS CODED NO AND Z31c IS CODED AS UNEXPECTED, THEN CODE THE MOST RECENT EPSISODE AS USIA IDEATION ONLY SUBTYPE.  IF Z31a AND Z31b ARE CODED YES AND Z31c IS CODED AS UXPECTED, THEN CODE THE MOST RECENT EPSISODE AS EXPECTED SUICIDAL IMPULSE ATTACK EPISODE.	MOST RECENT IMPULSE ATTACK SUICIDALITY EPISODE  USIA Physical & Ideation subtype
	USIA Ideation Only subtype
	Expected Suicidal Impulse Attack

If Z31a is coded no and Z31b is coded yes, then code the most recent epsisode as non suicidal physical symptom attack.

NON SUICIDAL
PHYSICAL SYMPTOM
ATTACK EPISODE

YES

NO

#### Z32 **Symptom Pattern**

a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	NO	YES
b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	NO	YES
d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES
f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	<b>→</b> NO	YES
g. How long have the times without any suicidal impulses, thoughts, or acts lasted?		
☐ it is always less than 3 months		
☐ it is always more than 3 months		
☐ it varies (sometimes less than 3 months, sometimes more than 3 months)		

#### IF Z32b AND Z32f ARE CODED YES THEN CODE THE SYMPTOM PATTERN AS PERSISTENT. IF Z32d IS CODED YES AND Z32e AND Z32f ARE CODED NO, AND Z32g IS CODED LESS THAN 3 MONTHS, THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING. IF Z32d IS CODED YES AND Z32e AND Z32f ARE CODED NO, AND Z32g IS CODED MORE THAN 3 MONTHS, THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING. IF Z32d IS CODED YES AND Z32e AND Z32f ARE CODED NO, AND Z32g IS CODED AS "IT VARIES", THEN CODE THE SYMPTOM PATTERN AS RECURRENT, NO APPARENT CYCLING. IF Z32e IS CODED YES AND Z32c IS CODED NO, OR IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW CYCLING OR RECURRENT, NO APPARENT CYCLING

#### **IMPULSE ATTACK SUICIDALITY DISORDER SYMPTOM PATTERN** Persistent Recurrent, Rapid Cycling Recurrent, Slow Cycling Recurrent, No Apparent Cycling Fresh Onset

THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

	Did the su	icidal impulse attack occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z34	Age of On	set		
	a. How old	d were you when you had the first suicidal impulse attack? years of age		
	Did the	MEN WITH CHILDREN ONLY: suicidal impulse attack first occur within 3 months following the birth of our children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z34b IS YES, CHECK THIS CATEGORY		
Z35	Current Le	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

Z33

**Timeframes** 

#### **Z. PSYCHOTIC SUICIDALITY DISORDERS**

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS PSYCHOTIC SUICIDALITY DISORDERS MODULE, CODE THE PSYCHOTIC SUICIDALITY EPISODE AS NO.)

Z36	IS Z17a CODED YES?	<b>→</b> NO	YES
Z37	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of a voice or voices telling you to kill yourself?	NO <b>→ z38</b>	YES
	b. Tell me about <b>these</b> voices and what they said.  CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ONLY CODE  THE RESPONSE TO <b>Z37</b> b AS YES, IF THE EXAMPLES PROVIDED ARE HALLUCINATIONS. OTHERWISE CODE NO.	. NO → z38	YES
	c. Did you have <b>these</b> suicidal impulses, thoughts, or acts on 3 or more separate occasion CLINICIAN: BY "THESE SUICIDAL IMPLULSES, THOUGHTS, OR ACTS" WE MEAN HERE THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS THAT A DIRECT RESULT OF A HALLUCINATION.	s? NO	YES
Z38	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of believing, that for some reason, you needed to kill yourself?	<b>→</b> NO	YES
	b. Tell me about <b>these</b> reasons.  CLINICIAN: REVIEW ALL THE REASONS WITH THE PATIENT, AND ONLY CODE THE RESPONSE TO Z38b AS YES, IF THE EXAMPLES ARE CLEARLY DELUSIONAL. OTHERWISE CODE NO.	, → NO	YES
	c. Did you have <b>these</b> suicidal impulses, thoughts, or acts on 3 or more separate occasion CLINICIAN: BY "THESE SUICIDAL IMPLULSES, THOUGHTS, OR ACTS" WE MEAN HERE THE SUICIDAL IMPULSES, THOUGHTS, OR ACTS THAT A DIRECT RESULT OF A DELUSION.	s? NO	YES
	IF (Z37a AND Z37b) OR (Z38a AND Z38b) ARE CODED YES, THEN CODE PSYCHOTIC SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.		YES SUICIDALITY SODE

IF (Z37a AND Z37b AND Z37c) OR (Z38a AND Z38b AND Z38c) ARE CODED YES, THEN CODE PSYCHOTIC SUICIDALITY DISORDER AS YES. OTHERWISE CODE NO.

NO YES

PSYCHOTIC SUICIDALITY

DISORDER

#### **Specifiers for Psychotic Suicidality Disorder**

# Z39 Timeframes Did the psychotic suicidality occur: Current: within the past 2 weeks Recent Past: between 2 weeks ago and 1.5 years ago Past: more than 1.5 years ago

#### Z40 Disorder Involved

SPECIFY PRECISELY WHICH DISORDER IS ASSOCIATED WITH THE PSYCHOTIC SUICIDALITY FEATURES IDENTIFIED IN THIS MODULE.

#### **DISORDER ASSOCIATED WITH THIS PSYCHOTIC SUICIDALITY DISORDER** Which Mood Disorder with **Psychotic Features?** Major Depressive Disorder Bipolar ! Disorder Bipolar !I Disorder Which Psychotic Disorder? Schizophrenia Schizoaffective Disorder Schizophreniform Disorder

Other (specify):

Z41	Age of Or	nset		
	a. How ol	d were you when you had the first psychotic suicidality? years of age		
	Did the	MEN WITH CHILDREN ONLY: psychotic suicidality first occur within 3 months following the birth of your children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		late adult onset: 65 years and above		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z41b IS YES, CHECK THIS CATEGORY		
Z42	Current L	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

Z41

#### Z. OBSESSIVE COMPULSIVE SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS OBSESSIVE COMPULSIVE SUICIDALITY DISORDER MODULE, CODE THE OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AS NO.)

Z44	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of one of the obsessive thoughts or compulsive rituals you described to me earlier?		
	CLINICIAN: REFRESH THE PATIENT'S MEMORY WITH INFORMATION ABOUT THEIR OBSESSIONS AND / OR COMPULSIONS IDENTIFIED EARLIER IN MODULE ${\sf G}.$	<b>→</b> NO	YES
	b. Tell me how <b>these</b> suicidal impulses, thoughts, or acts are connected to your obsessions or compulsions.		
	CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE ATTACKS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.		
	CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF AN IMPULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM A <b>TRUE</b> OBSESSION OR COMPULSION.	<b>→</b> NO	YES
Z45	a. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
	b. Did you have <b>these</b> suicidal impulses, thoughts, or acts connected to obsessions or compulsions, on 3 or more separate occasions?	NO	YES
	IF Z44a AND Z44b ARE CODED YES, THEN CODE OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.		YES E COMPULSIVE LITY EPISODE
		OBSESSIV	

IF OBSESSIVE COMPULSIVE SUICIDALITY EPISODE AND IF Z45b are both coded yes, then code obsessive compulsive suicidality disorder as yes. Otherwise code no.

NO YES

OBSESSIVE COMPULSIVE
SUICIDALITY DISORDER

#### **Specifiers for Obsessive Compulsive Suicidality Disorder**

Z46	Timeframes
	Did the obsessive compulsive suicidality occur:
	☐ Current: within the past 2 weeks
	☐ Recent Past: between 2 weeks ago and 1.5 years ago
	☐ Past: more than 1.5 years ago
Z47	Age of Onset
	a. How old were you when you had the first obsessive compulsive suicidality? years of age
	b. FOR WOMEN WITH CHILDREN ONLY: Did the obsessive compulsive suicidality first occur within 3 months following the birth of one of your children?  NO YES
	$\square$ Early Childhood onset: $0$ through the age of $5$
	$\square$ Latency Childhood onset: 6 through the age of 11
	$\square$ Adolescent onset: 12 through the age of 17
	$\square$ Early adult onset: 18 through the age of 24
	$\square$ MID ADULT ONSET: 25 THROUGH THE AGE OF 64
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE
	□ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION <b>Z47</b> b is yes, check this category
Z48	Current Level of Symptoms
	☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE)
	☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)
	$\Box$ STILL SYMPTOMATIC − REMISSION, BUT NOT YET RECOVERED ( $\leq$ 100% RESPONSE, FOR $<$ 3 MONTHS)
	☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

#### Z. POSTTRAUMATIC STRESS DISORDER INDUCED SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS POSTTRAUMATUC STRESS DISORDER INDUCED SUICIDALITY DISORDER MODULE, CODE THE POSTTRAUMATUC STRESS DISORDER INDUCED SUICIDALITY EPISODE AS NO.)

<b>Z</b> 49	IS Z17c CODED YES?	<b>→</b> NO	YES
Z50	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of the PTSD symptoms that you described to me earlier?		
	CLINICIAN: REFRESH THE PATIENT'S MEMORY WITH INFORMATION ABOUT THEIR PTSD SYMPTOMS IDENTIFIED EARLIER IN MODULE G.	<b>→</b> NO	YES
	b. Tell me how <b>these</b> suicidal impulses, thoughts, or acts are connected to your PTSD symptoms.		
	CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE ATTACKS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.		
	CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF AN IMPULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM PTSD.	<b>→</b> NO	YES
Z51	a. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	<b>→</b> NO	YES
	b. Did you have <b>these</b> suicidal impulses, thoughts, or acts connected to PTSD, on 3 or more separate occasions?	NO	YES
	IF Z50a AND Z50b ARE CODED YES, THEN CODE PTSD INDUCED SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.	DISORDI	YES MATIC STRESS ER INDUCED ITY EPISODE
	IF PTSD INDUCED SUICIDALITY EPISODE AND IF Z51b ARE BOTH CODED YES, THEN CODE PTSD INDUCED SUICIDALITY DISORDER AS YES. OTHERWISE CODE NO.	NO	YES  MATIC STRESS

DISORDER INDUCED
SUICIDALITY DISORDER

#### Specifiers for Posttraumatic Stress Disorder Induced Suicidality Disorder

#### Z52 **Timeframes** Did the PTSD induced suicidality occur: ☐ Current: within the past 2 weeks ☐ Recent Past: between 2 weeks ago and 1.5 years ago ☐ Past: more than 1.5 years ago Z53 Age of Onset a. How old were you when you had the first PTSD induced suicidality? \_\_\_\_\_ years of age b. FOR WOMEN WITH CHILDREN ONLY: Did the PTSD induced suicidality first occur within 3 months following the birth of one of your children? NO YES ☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5 ☐ LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11 ☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17 ☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24 ☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64 ☐ LATE ADULT ONSET: 65 YEARS AND ABOVE □ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z53b IS YES, CHECK THIS CATEGORY Z54 **Current Level of Symptoms** ☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE) ☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE) STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS) ☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

#### **Z. SUBSTANCE INDUCED SUICIDALITY DISORDERS**

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS SUBSTANCE INDUCED SUICIDALITY DISORDERS MODULE, CODE THE SUBSTANCE INDUCED SUICIDALITY EPISODE AS NO.)

<b>Z</b> 55	ıs <b>Z1</b>	L <b>7d</b> co	DED YES?	<b>→</b> NO	YES
Z56	a. W	/hich	drugs or medications or substances did you use?	_	
			of these drugs or medications or substances are most likely lated to your suicidal impulses, thoughts, or acts?		
			ng was the interval between the drug use and the onset of the impulses, thoughts, or acts.		
	A S ("V	UBSTAI WITHDF	I: PATIENTS MAY HAVE SUICIDALITY WITHIN MINUTES OF AN INGESTION OF NCE ("INTOXICATION") OR WITHIN 5 HALF LIVES OF STOPPING A SUBSTANCE (AWAL"). USING YOUR KNOWLEDGE OF PHARMACOLOGY AND DRUG HALF LIVES, BASED ON THE SUBSTANCES USED BY EACH PATIENT WHETHER THE SUICIDALITY OCCURRED:		
	c.		DURING THE INGESTION PHASE OF THE SUBSTANCE / MEDICATION		
	d.		AS PART OF THE WITHDRAWAL PHASE FROM THE SUBSTANCE / MEDICATION (WITHIN 5 HALF LIVES)		
	e.		NEITHER DURING THE INGESTION OR WITHDRAWAL PHASES		
	f.		AS A RESULT OF STOPPING AN ANTISUICIDAL MEDICATION TREATMENT		
	СН	ECK AL	L THAT APPLY.		_
	Z5(	6 SUM	MARY: ARE (Z56e AND Z56f) CHECKED AND ARE (Z56c AND Z56d) UNCHECKED?	NO	YES
Z57	in	an ep	nese suicidal impulses, thoughts, or acts come and gone isodic pattern? By episodic I mean, that you have had periods lasting 1 day without any suicidality.	<b>→</b> NO	YES
		•	have <b>these</b> suicidal impulses, thoughts, or acts connected to ingestion drawal of a substance, on 3 or more separate occasions?	NO	YES

IF Z56c or Z56d are checked, then code substance induced suicidality episode as yes. Otherwise code no.

NO YES

SUBSTANCE INDUCED SUICIDALITY EPISODE

IF (Z56c OR Z56d) ARE CHECKED, AND Z57b IS CODED YES,
THEN CODE SUBSTANCE INDUCED SUICIDALITY DISORDER AS YES. OTHERWISE CODE NO.

NO YES

SUBSTANCE INDUCED SUICIDALITY DISORDER

#### **Specifiers for Substance Induced Suicidality Disorder**

Z58

**Timeframes** 

	Did the su	bstance induced suicidality occur:		
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z59	Substance	e(s)		
	Which sub	ostance(s) are most likely to be related to the Substance Induced Suicidality Disorder in	this cas	se:
Z60	Time of O	nset		
	IF <b>Z</b> 56c IS C	HECKED, CODE TIME OF ONSET AS "ONSET DURING INGESTION PHASE".		
	IF <b>Z</b> 56d is c	HECKED, CODE TIME OF ONSET AS "ONSET DURING WITHDRAWAL PHASE".		
Z61	Age of On	set		
	a. How old	d were you when you had the first substance induced suicidality? years of age		
	Did the	MEN WITH CHILDREN ONLY: Substance induced suicidality first occur within 3 months following the birth of our children?	NO	YES
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z61b IS YES, CHECK THIS CATEGORY		
Z62	Current Le	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
	П	PECOVEDED LINDED COMPLETE CONTROL (CLISTAINED 100% DESDONSE > 3 MONTHS)		

#### Z. MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDER

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDER MODULE, CODE THE MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AS NO.)

			_	
Z63	IS Z17e CODED YES?		NO	YES
Z64	a. Did you ever have any suicidal impulse, thought, or act, as a direct result of having a medical illness or a neurological condition?		<b>→</b> NO	YES
	b. Which medical illness / neurological condition caused this?			
	c. Tell me how <b>these</b> suicidal impulses, thoughts, or acts are connected to your medical illness / neurological condition.			
	CLINICIAN: REVIEW ALL THE EXAMPLES PROVIDED BY THE PATIENT, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, OR ACTS) ARE DIFFERENT FROM ANY IMPULSE ATTACKS THAT MAY HAVE BEEN IDENTIFIED EARLIER IN IMPULSE ATTACK SUICIDALITY DISORDER.			
	CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE IS CLEARLY NOT PART OF AN IMPULSE ATTACK SUICIDALITY DISORDER AND RESULTS FROM A MEDICAL ILLNESS / NEUROLOGICAL CON	IDITION.	<b>→</b> NO	YES
	d. Did you have the suicidal impulses, thoughts, or acts persist even after the medical illness / neurological condition resolved?		<b>→</b> NO	YES
Z65	a. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.		<b>→</b> NO	YES
	b. Did you have <b>these</b> suicidal impulses, thoughts, or acts connected to your medical illness / neurological condition, on 3 or more separate occasions?		NO	YES
	IF (Z64a AND Z64c) ARE BOTH CODED YES, AND Z64d IS NO, THEN CODE MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AS YES. OTHERWISE CODE NO.	NO		YES
		MEDICAL ILLI NEUROLOG CONDITION IN SUICIDALITY E		DLOGICAL ON INDUCED

IF MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY EPISODE AND IF Z65b are both coded yes, then code medical illness / neurological condition induced suicidality disorder as yes. Otherwise code no.

NO YES

MEDICAL ILLNESS /
NEUROLOGICAL
CONDITION INDUCED
SUICIDALITY DISORDER

#### Specifiers for Medical Illness / Neurological Condition Induced Suicidality Disorder

Z66	Timeframes  Did the medical illness / neurological condition induced suicidality occur:			
		Current: within the past 2 weeks		
		Recent Past: between 2 weeks ago and 1.5 years ago		
		Past: more than 1.5 years ago		
Z67	Medical	Illness / Neurological Condition		
		edical illness / neurological condition(s) is most likely to be related to the Medical Illness / Neurological Condition uced Suicidality Disorder in this case:		
Z68	Age of On	set		
		d were you when you had the first medical illness / neurological condition suicidality? years of age		
	Did the i	MEN WITH CHILDREN ONLY: medical illness / neurological condition induced suicidality first occur within as following the birth of one of your children?  NO YES		
		EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
		LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
		ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
		EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
		MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
		LATE ADULT ONSET: 65 YEARS AND ABOVE		
		POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z68b IS YES, CHECK THIS CATEGORY		
Z69	Current Le	evel of Symptoms		
		STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)		
		STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)		
		STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)		
		RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)		

#### Z. MOOD DISORDER INDUCED SUICIDALITY DISORDER

( MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS MOOD DISORDER INDUCED SUICIDALITY DISORDER MODULE, CODE THE MOOD DISORDER INDUCED SUICIDALITY EPISODE AS NO.)

Z70	IS Z17f CODED YES?	<b>→</b> NO	YES	
Z71	a. Did it ever cross your mind that you get depressed because your suicidal impulses, thoughts, or acts interfere with your life, rather than the other way around?	NO <b>→ z72</b>	YES	
	b. Tell me why you think the suicidal impulses, thoughts, or acts causes your depression			
Z72	Did you ever have any depressed mood as a direct result of your suicidal impulses, thoughts, or acts?			
	CLINICIAN: IF Z71a IS CODED YES AND Z72 IS CODED NO, ASK THE PATIENT TO EXPLAIN THIS APPARENT DISCREPANCY. RECODE THE RESPONSE TO Z72 IF NECESSARY.	NO	YES	
Z73	Did you ever have any suicidal impulses, thoughts, or acts as a direct result of your depression or Bipolar Disorder?	NO	YES	
	CLINICIAN: IF EITHER Z72 OR Z73 ARE CODED NO, SKIP TO THE INSTRUCTIONS ON DIAGNOSTIC BOXES AT THE END OF THIS MOOD DISORDER INDUCED DISORDER MODULE.  IF Z72 AND Z73 ARE BOTH CODED YES, THEN ASK:			
Z74	What % of the suicidal impulses, thoughts, or acts are a direct result of you depression or Bipolar Disorder?			
	CLINICIAN: GET THE PATIENT'S PERSPECTIVE ON THIS, NOT YOUR INTERPRETATION OF WHAT YOU THINK IT SHOULD BE%			
	IF (Z71a AND Z72) ARE BOTH CODED YES, AND Z74 IS $\leq$ 50%, THEN CODE AS PRIMARY SUICIDALITY DISORDER WITH SECONDARY MOOD DISTURBANCE. OTHERWISE CODE NO.	NO	YES	
	IF (Z71a AND Z72) ARE BOTH CODED YES, AND Z74 IS > 50%, THEN CODE AS PRIMARY MOOD DISORDER WITH SECONDARY MOOD DISORDER INDUCED SUICIDALITY	MOOD DISORDER INDUCED SUICIDALITY DISORDER  Is the Mood Disorder Induced Suicidality Disorder:		,
	DISORDER. OTHERWISE CODE NO.  IF Z73 IS CODED NO,			
	THEN CODE NO TO MOOD DISORDER INDUCED SUICIDALITY DISORDER.	Primary	٠	
		Seconda	ry 🗀	
				1

#### **Specifiers for Mood Disorder Induced Suicidality Disorder**

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SPECIFIER)

#### Z75 **Symptom Pattern**

a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	N	O YES	i
b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifeting	me? No	O YES	;
c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	No	O YES	į
d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.	→ N0	O YES	į
e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetim	ne? No	O YES	;
f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	→ No	O YES	;
g. How long have the times without any suicidal impulses, thoughts, or acts lasted?			
☐ it is always less than 3 months			
☐ it is always more than 3 months			
☐ it varies (sometimes less than 3 months, sometimes more than 3 months)			
IF Z75b AND Z75f ARE CODED YES THEN CODE THE SYMPTOM PATTERN AS PERSISTENT.  IF Z75d IS CODED YES AND Z75e AND Z75f ARE CODED NO, AND Z75g IS CODED LESS THAN 3 MONTHS,	MOOD DISORDER INDUCED SUICIDALITY DISORDER SYMPTOM PATTERN		
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING.	Persistent		
IF Z75d IS CODED YES			
AND Z75e AND Z75f ARE CODED NO,		Rapid Cycling	g
AND Z75g IS CODED MORE THAN 3 MONTHS, THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING.	,	· , ,	-
332 3 3	D	ela coale	

IF Z75d IS CODED YES

and  ${\sf Z75e}$  and  ${\sf Z75f}$  are coded no,

AND Z75g IS CODED AS "IT VARIES",

THEN CODE THE SYMPTOM PATTERN AS RECURRENT, NO APPARENT CYCLING.

IF Z75e IS CODED YES

AND Z75c IS CODED NO,

IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW CYCLING OR RECURRENT, NO APPARENT CYCLING

THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

### Recurrent, Slow Cycling

Recurrent, No Apparent Cycling

Fresh Onset

	Did the mood disorder induced suicidal impulses, thoughts, or acts occur:		
	☐ Current: within the past 2 weeks		
	☐ Recent Past: between 2 weeks ago and 1.5 years ago		
	☐ Past: more than 1.5 years ago		
Z77	Disorder Involved		
	SPECIFY WHICH MOOD DISORDER IS ASSOCIATED WITH THE MOOD DISORDER INDUCED SUICIDALITY FEATURES IDENTIFIED IN THIS MODULE.	MOOD DISORDER ASSOCIATED WITH TH MOOD DISORDER INDUCED SUICIDALIT DISORDER	
		Major Depressive Disorder	۵
		Bipolar I Disorder	۵
		Bipolar II Disorder	٥
		Other (specify):	_ 0
Z78	Age of Onset		
	a. How old were you when you had the first mood disorder induced suicidal impulses, thoughts, or acts? years of age		
	b. FOR WOMEN WITH CHILDREN ONLY: Did the mood disorder induced suicidal impulses, thoughts, or acts first occur within 3 months following the birth of one of your children?	NO YES	
	☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5		
	☐ LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11		
	☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17		
	☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24		
	☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64		
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE		
	□ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION <b>Z78</b> b is yes, check this category		
<b>Z</b> 79	Current Level of Symptoms		

Z76

**Timeframes** 

STILL SYMPTOMATIC – NO RESPONSE (< 50% RESPONSE)
STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)
STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)
RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

#### Z. LIFE EVENT INDUCED SUICIDALITY DISORDER

( MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS LIFE EVENT INDUCED SUICIDALITY DISORDER MODULE, CODE THE LIFE EVENT INDUCED SUICIDALITY EPISODE AS NO.)

Z80 IS Z17g CODED YES? NO YES

Tell me about the significant life stressor(s), to which you attribute your suicidal impulses, thoughts, or acts.

CLINICIAN: REVIEW ALL THE EXAMPLES GIVEN, AND ENSURE THAT THE SUICIDALITY (IMPULSES, THOUGHTS, ACTIONS) ARE CLEARLY A DIRECT RESULT OF THESE STRESSORS, AND NOT AUTONOMOUS EVENTS OF SUICIDAL IMPULSES, THOUGHTS, OR ACTS, FOR WHICH THE PATIENT IS TRYING TO FIND AN EXPLANATION. REACTION TO STRESSORS THAT ARE CLEARLY OUT OF PROPORTION TO THE REALITY AND GRAVITY OF THE STRESSOR, MAY INDICATE THE NEED TO CONSIDER ANOTHER SUICIDALITY DISORDER. THE REASONABLE PERSON'S JUDGEMENT TEST, SHOULD APPLY WHEN DETERMINING, IF THE STRESSOR IS SUFFICIENTLY GRAVE TO JUSTIFY THE OBSERVED SUICIDALITY.

CODE YES, ONLY IF THE SUICIDALITY IDENTIFIED HERE, IS CLEARLY DIRECTLY ATTRIBUTIBLE TO THE STRESSOR(S) IDENTIFIED.

IF Z81 IS CODED YES,
THEN CODE AS LIFE EVENT INDUCED SUICIDALITY DISORDER AS YES.
OTHERWISE CODE NO.

NO YES

NO YES

LIFE EVENT INDUCED
SUICIDALITY DISORDER

#### **Specifiers for Life Event Induced Suicidality Disorder**

(➡ MEANS: GO TO THE DIAGNOSTIC BOX, CIRCLE NO, AND MOVE TO THE NEXT SPECIFIER)

#### Z82 Symptom Pattern

a. Have you had any suicidal impulses, thoughts, or acts in the past 3 months?	NO	YES	
b. Did you have more than 12 events of suicidal impulses, thoughts, or acts in your lifetime?		YES	
c. Have you had any suicidal impulses, thoughts, or acts on a daily basis for more than 3 months?	NO	YES	
d. Have <b>these</b> suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.			
e. Did you have <b>only</b> 1 or 2 episodes of suicidal impulses, thoughts, or acts in your lifetime?	NO	YES	
f. Have the times without suicidal impulses, thoughts, or acts only occurred when you had obvious distracting life events that intruded to prevent suicidality (e.g. an immediate serious illness or death of a loved one or being seriously ill yourself)?	<b>→</b> NO	YES	
g. How long have the times without any suicidal impulses, thoughts, or acts lasted?			
☐ it is always less than 3 months			
☐ it is always more than 3 months			
☐ it varies (sometimes less than 3 months, sometimes more than 3 months)			

IF Z82b and Z82f are coded yes then code the symptom pattern as persistent.

IF Z82d IS CODED YES

AND Z82e AND Z82f ARE CODED NO,

AND Z82g IS CODED LESS THAN 3 MONTHS,

THEN CODE THE SYMPTOM PATTERN AS RECURRENT, RAPID CYCLING.

AND Z82e AND Z82f ARE CODED NO,
AND Z82g IS CODED MORE THAN 3 MONTHS,
THEN CODE THE SYMPTOM PATTERN AS RECURRENT, SLOW CYCLING.

IF Z82d is coded yes and Z82e and Z82f are coded no, and Z82g is coded as "it varies", then code the symptom pattern as recurrent, no apparent cycling.

AND Z82c IS CODED NO,
OR
IF THE SYMPTOM PATTERN IS NOT PERSISTENT OR RECURRENT, RAPID CYCLING, OR RECURRENT SLOW
CYCLING OR RECURRENT, NO APPARENT CYCLING
THEN CODE THE SYMPTOM PATTERN AS FRESH ONSET.

## LIFE EVENT INDUCED SUICIDALITY DISORDER SYMPTOM PATTERN

Recurrent, Rapid Cycling	

Persistent

Recurrent, Slow Cycling	

Recurrent No Annarent Cycling	

Fresh Onset

IF Z82e IS CODED YES

IF Z82d IS CODED YES

#### **Specifiers for Life Event Induced Suicidality Disorder**

Z83	Timeframes			
	Did the suicidal impulses, thoughts, or acts caused by a stressful life event occur:			
	☐ Current: within the past 2 weeks			
	☐ Recent Past: between 2 weeks ago and 1.5 years ago			
	☐ Past: more than 1.5 years ago			
Z84	Age of Onset			
	a. How old were you when you had the first suicidal impulses, thoughts, or acts caused by a stressful life event? years of age			
	b. FOR WOMEN WITH CHILDREN ONLY: Did the suicidal impulses, thoughts, or acts caused by a stressful life event first occur within 3 months following the birth of one of your children? If you consider the birth of your child as a stressful life event which caused you to feel suicidal then answer this question as yes.  NO YES			
	☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5			
	☐ LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11			
	☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17			
	☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24			
	$\square$ mid adult onset: 25 through the age of 64			
	☐ LATE ADULT ONSET: 65 YEARS AND ABOVE			
	□ POSTPARTUM ONSET: IF THE ANSWER TO QUESTION <b>Z84b</b> IS YES, CHECK THIS CATEGORY			
Z85	Current Level of Symptoms			
	☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE)			
	☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE)			
	☐ STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS)			
	□ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)			

#### Z. SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED

(➡ MEANS: SKIP OVER ALL THE REAMAINING QUESTIONS, GO TO THE DIAGNOSTIC BOXES AT THE END OF THIS SECTION. THEN CODE **BOTH** THE SUICIDALITY **EPISODE**, NOT ELSEWHERE CLASSIFIED AND SUICIDALITY **DISORDER**, NOT ELSEWHERE CLASSIFIED MODULE AS NO.)

Z86 IS ANY OTHER SUICIDALITY DISORDER ENDORSED UP TO THIS POINT?

**>** 

NO YES

CLINICIAN: IF NO OTHER SUICIDALITY DISORDER IS CODED YES UP TO THIS POINT, THEN REEVALUATE WHETHER THE EXISTING SUICIDALITY IDENTIFIED IN THE LIFETIME SUICIDALITY MODULE QUESTIONS (Z1A THROUGH Z13C) AND (Z15 THROUGH Z15C) MIGHT BELONG IN ONE OF THE PRIOR SUICIDALITY DISORDERS. OTHERWISE CODE YES TO SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED. THEN ASK:

a. Have your suicidal impulses, thoughts, or acts come and gone in an episodic pattern? By episodic I mean, that you have had periods lasting 1 day or more, without any suicidality.

**→** 

YES

b. Did you have **these** suicidal impulses, thoughts, or acts, on 3 or more separate occasions?

NO

YES

IF Z86 IS CODED NO,

OTHERWISE CODE NO.

THEN CODE SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED AS YES. OTHERWISE CODE NO.

NO

YES

SUICIDALITY EPISODE, NOT ELSEWHERE CLASSIFIED

IF SUICIDALITY EPISODE, NOT OTHERWISE CLASSIFIED IS CODED YES AND IF Z87a AND Z87b ARE CODED YES, THEN CODE SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED AS YES.

NO

YES

SUICIDALITY DISORDER, NOT ELSEWHERE CLASSIFIED

#### Specifiers for Suicidality Disorder, Not Elsewhere Classified

# **Z88 Timeframes** Did the suicidal impulses, thoughts, or acts occur: ☐ Current: within the past 2 weeks ☐ Recent Past: between 2 weeks ago and 1.5 years ago ☐ Past: more than 1.5 years ago Age of Onset Z89 a. How old were you when you had the first suicidal impulses, thoughts, or acts? \_\_\_\_\_ years of age b. FOR WOMEN WITH CHILDREN ONLY: Did the suicidal impulses, thoughts, or acts first occur within 3 months following the birth of one of your children? NO YES ☐ EARLY CHILDHOOD ONSET: 0 THROUGH THE AGE OF 5 ☐ LATENCY CHILDHOOD ONSET: 6 THROUGH THE AGE OF 11 ☐ ADOLESCENT ONSET: 12 THROUGH THE AGE OF 17 ☐ EARLY ADULT ONSET: 18 THROUGH THE AGE OF 24 ☐ MID ADULT ONSET: 25 THROUGH THE AGE OF 64 ☐ LATE ADULT ONSET: 65 YEARS AND ABOVE POSTPARTUM ONSET: IF THE ANSWER TO QUESTION Z89b IS YES, CHECK THIS CATEGORY Z90 **Current Level of Symptoms** ☐ STILL SYMPTOMATIC — NO RESPONSE (< 50% RESPONSE) ☐ STILL SYMPTOMATIC — RESPONSE, BUT NOT YET REMISSION (≥ 50% RESPONSE, BUT < 70% RESPONSE) ☐ STILL SYMPTOMATIC — REMISSION, BUT NOT YET RECOVERED (≤ 100% RESPONSE, FOR < 3 MONTHS) ☐ RECOVERED, UNDER COMPLETE CONTROL (SUSTAINED 100% RESPONSE ≥ 3 MONTHS)

Patient Name:	Patient Number:	
Date of Birth:	Time Interview Began:	
Interviewer's Name:	Time Interview Ended:	
Date of Interview:	Total Time:	

	MODULES	TIME FRAME	MEETS CRITERIA	MOST RECENT EPISODE	MEETS CRITERIA	* PRIMARY DIAGNOSIS
Z	SUICIDALITY	Lifetime				
	IMPULSE ATTACK SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _	USIA Physical & Ideation Subtype Only USIA Ideation Only Subtype Expected Suicidal Impulse Attack Non-Suicidal Physical Symptom Attack		0
	PSYCHOTIC SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0
	OBSESSIVE COMPULSIVE SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			_ _ _
	PTSD INDUCED SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0
	SUBSTANCE INDUCED SUICIDALITY DISORDERS	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0
	MEDICAL ILLNESS / NEUROLOGICAL CONDITION INDUCED SUICIDALITY DISORDERS	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _ _			0
	MOOD DISORDER INDUCED SUICIDALITY DISORDERS Major Depressive Disorder Bipolar I Disorder Bipolar II Disorder	Current (2 weeks) Recent Past Past (> 1.5 years ago)	0			0
	LIFE EVENT INDUCED SUICIDALITY DISORDER	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _			<u> </u>
	SUICIDALITY DISORDERS, NOT ELSEWHERE CLASSIFIED	Current (2 weeks) Recent Past Past (> 1.5 years ago)	_ _			_ _

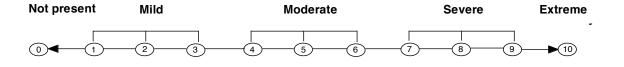
<sup>\*</sup> PRIMACY IS USUALLY DETERMINED BY WHICH DISORDER IS THE DOMINANT CLUSTER IN THE PATEINT'S PRESENTATION OF SYMPTOMS AND / OR WHICH CAME FIRST IN THE PATIENT'S NATURAL HISTORY.

### **OPTIONAL ASSESSMENT MEASURES TO TRACK CHANGES OVER TIME**

#### **A: CROSS CUTTING MEASURES**

#### **SEVERITY OF SYMPTOM**

Use this scale to rate the severity of your symptom in the score column in the table below:



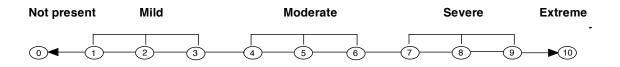
## **Assessment of Symptoms That Cut Across Disorders**

	Symptom Name	Score		
1	Depression			
2	Anger			
3	Mania (feeling up or high or hyper or full of energy with racing thoughts)			
4	Anxiety			
5	Physical (somatic) symptoms			
6	Suicidal thoughts (having ANY thoughts of killing yourself)			
	Hearing sounds or voices others can't hear or fearing someone can hear or read			
	your thoughts or believing things others don't accept as true e.g. that people			
7	are spying on you or plotting against you or talking about you (Psychosis)			
8	Sleep problems			
9	Memory problems			
10	Repetitive thoughts or behaviors			
	Feeling things around you are strange, unreal, detached or unfamiliar, or			
11	feeling outside or detached from part or all of your body (Dissociation)			
	Ability to function at work, at home, in your life, or in your relationships			
12	(Personality functioning)			
13	Overusing alcohol or drugs			

### **B: DISABILITY / FUNCTIONAL IMPAIRMENT**

#### **SEVERITY OF DISABILITY / IMPAIRMENT**

Use this scale to rate in the score column of the table below, how much your symptoms have disrupted your ability to function in the following areas of your life:



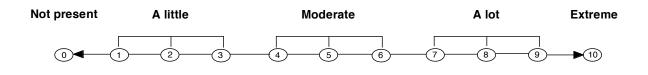
## Assessment of Impairment of Functioning /Disability

	Domain Name	Score
1	Work or school work	
2	Social life or leisure activities (like hobbies or things you do for enjoyment)	
3	Family life and / or home responsibilities	
4	Ability to get along with people	
5	Personal and social relationships	
6	Ability to understand and to communicate with others	
	Ability to take care of yourself (washing, showering, bathing, dressing properly,	
7	brushing teeth, laundry, combing / brushing hair, eating regularly)	
8	Made you disruptive or aggressive towards others	
9	Financially (ability to manage your money)	
10	Ability to get around physically	
11	Spiritual or religious life	
12	How much did your condition have an impact on other people in your family?	

#### C: CROSS CUTTING DOMAINS FOR SUICIDLITY DISORDERS ONLY

#### **ASSOCIATION OF DOMAIN WITH SUICIDALITY**

Use this scale to rate in the score column of the table below, how much your suicidality Is associated with each of the following domains:



## **Assessment of Suicidality Cross Cutting Domains**

	Domain Name	Score		
1	with hopelessness			
2	motivated by a wish to avoid a future loss that the subject feels is essential to their wish to live (e.g. love, good health)			
3	3 with bereavement / reunification intent			
4	4 with obsessive compulsive features			
5	with "overwhelmed state" features			
6	with psychotic features			
7	with anhedonia / depressive / melancholic features			
8	8 with anger / aggressive features			
9 with serious / terminal illness				
10 with anxiety / tension				
11	with sleep disturbance			
12	with seasonal pattern			
13	with depersonalization / derealization / dissociative features			
14	with non-suicidal self-injury			
15	with social / political motivation or sanction			
16	with religious motivation or sanction			
17	with martyrdom motivation or sanction			
18	with motivation to control another or others			
19	with motivation to use suicidality to communicate a message			
20	with homicidal features			
21	with impairment in work, school, social life, leisure activities, family life or home responsibilities			

#### **REFERENCES**

- 1. Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar G: The Mini International Neuropsychiatric Interview (M.I.N.I.): The Development and Validation of a Structured Diagnostic Psychiatric Interview. J. Clin Psychiatry, 1998;59(suppl 20): 22-33.
- 2. Sheehan DV, Lecrubier Y, Harnett-Sheehan K, Janavs J, Weiller E, Bonara LI, Keskiner A, Schinka J, Knapp E, Sheehan MF, Dunbar GC. Reliability and Validity of the MINI International Neuropsychiatric Interview (M.I.N.I.): According to the SCID-P. European Psychiatry. 1997; 12:232-241.
- 3. Lecrubier Y, Sheehan D, Weiller E, Amorim P, Bonora I, Sheehan K, Janavs J, Dunbar G. The MINI International Neuropsychiatric Interview (M.I.N.I.) A Short Diagnostic Structured Interview: Reliability and Validity According to the CIDI. European Psychiatry. 1997; 12: 224-231.
- 4. Amorim P, Lecrubier Y, Weiller E, Hergueta T, Sheehan D: DSM-III-R Psychotic Disorders: procedural validity of the Mini International Neuropsychiatric Interview (M.I.N.I.). Concordance and causes for discordance with the CIDI. European Psychiatry. 1998; 13:26-34.

#### **ACKNOWLEDGEMENTS**

The author wishes to acknowledge the valuable contributions made to the earlier versions of the MINI for DSM III-R and DSM IV by:

- 1. Yves Lecrubier, my close collaborator (now deceased) on the initial development of the MINI for III-R, the DSM IV and ICD-10.
- 2. Juris Janavs, Emanuelle Weiller, Christer Allgulander, Kathy Harnett-Sheehan, Roxy Baker, Michael Sheehan, Chris Gray. Thietrry Hergueta, N. Kadri, David Baldwin, Christian Even, Rosario Hidalgo, Marelli Soto-Colon, Ossama Osman.
- 3. Patricia Amorim for her extensive work on the development of the expanded version of the Psychotic Disorders Module and algorithms for DSM III-R. We have evolved her model further evolved further in the MINI for Psychotic Disorders 7 and in the MINI Plus 7 for DSM-5.
- 4. Executive Scientific committee for the MINI 6.0.0:

Christer Allgulander, Stockholm, Sweden

A. Carlo Altamura, Milano, Italy

Cyril Hoschl, Praha, Czech Republic

George Papadimitriou, Athens, Greece

Hans Ågren, Göteborg, Sweden

Hans-Jürgen Möller, München, Germany

Hans-Ulrich Wittchen, Dresden, Germany

István Bitter, Budapest, Hungary

Jean-Pierre Lépine, Paris, France

Jules Angst, Zurich, Switzerland

Julio Bobes, Oviedo, Spain

Luciano Conti, Pisa, Italy

Marelli Colon-Soto MD, Puerto Rico, United States

Michael Van Ameringen MD, Toronto, Canada

Rosario Hidalgo MD, Tampa, United States

Siegfried Kasper, Vienna, Austria

Thomas Schlaepfer, Bonn, Germany

- 5. Mapi and the many academic translation teams internationally who collaborated in ensuring that quality translations became available in over 70 languages or language variants. Mapi (<a href="http://www.mapigroup.com">http://www.mapigroup.com</a>) is now the official transaltion and linguistic validation service for all variants of the MINI.
- 6. Individual clinicians who over the years made countless suggestions to help improve the accuracy and clinical value to the MINI.
  JM Giddens for her advice on the MINI 7 version of the Suicidality Module, Dr. Michael Van Ameringen for assistance with the ADHD module, and Dr P Powers for her advice on the modules on Anorexia Nervosa and Bulimia.
- 7. A validation study of this instrument was made possible, in part, by grants from SmithKlineBeecham and the European Commission.

#### M.I.N.I. PLUS

The shaded modules below are additional modules available in the MINI PLUS beyond what is available in the standard MINI. The un-shaded modules below are in the standard MINI.

These MINI PLUS modules can be inserted into or used in place of the standard MINI modules, as dictated by the specific needs of any study.

	MODULES	TIME FRAME			
Α	MAJOR DEPRESSIVE EPISODE	Current (2 weeks) Past Recurrent			
	MAJOR DEPRESSIVE DISORDER	Current (2 weeks) Past Recurrent			
	MDE WITH MELANCHOLIC FEATURES MDE WITH CATATONIC FEATURES MDE WITH ATYPICAL FEATURES	Current (2 weeks) Current (2 weeks) Current (2 weeks)			
	MAJOR DEPRESSIVE DISORDER WITH PSYCHOTIC FEATURES	Current Past			
	MINOR DEPRESSIVE DISORDER (DEPRESSIVE DISORDER UNSPECIFIED)	Current (2 weeks) Past Recurrent			
	MOOD DISORDER DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	SUBSTANCE INDUCED MOOD DISORDER	Current (2 weeks) Past			
A۱	PERISITENT DEPRESSIVE DISORDER	Current			
В	SUICIDALITY	Current (Past Month) ☐ Low ☐ Moderate ☐ High	,		
	SUICIDE BEHAVIOR DISORDER	Current In early remission In remission		(In Past Year) (1 - 2 Years Ago)	
С	MANIC EPISODE	Current Past	L.	(> 2 Years Ago)	
	HYPOMANIC EPISODE	Current Past			
	BIPOLAR I DISORDER	Current Past			
	BIPOLAR II DISORDER	Current Past			
	BIPOLAR DISORDER UNSPECIFIED	Current Past			
	BIPOLAR I DISORDER WITH PSYCHOTIC FEATURES	Current Past			
	MANIC EPISODE DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	HYPOMANIC EPISODE DUE TO A GENERAL MEDICAL CONDITION	Current (2 weeks) Past			
	SUBSTANCE INDUCED MANIC EPISODE	Current (2 weeks) Past			

	SUBSTANCE INDUCED HYPOMANIC EPISODE	Current (2 weeks) Past
	MOOD DISORDER UNSPECIFIED	Lifetime
D	PANIC DISORDER	Current (Past Month) Lifetime
	ANXIETY DISORDER WITH PANIC ATTACKS DUE TO A GENERAL MEDICAL CONDITION	Current
	SUBSTANCE INDUCED ANXIETY DISORDER WITH PANIC ATTACKS	Current
E	AGORAPHOBIA	Current
F	SOCIAL ANXIETY DISORDER (Social Phobia)	Current (Past Month) Generalized Non-Generalized
FA	SPECIFIC PHOBIA	Current
G	OBSESSIVE-COMPULSIVE DISORDER (OCD)	Current (Past Month)
	OCD DUE TO A GENERAL MEDICAL CONDITION	Current
	SUBSTANCE INDUCED OCD	Current
H	POSTTRAUMATIC STRESS DISORDER POSTTRAUMATIC STRESS DISORDER	Current (Past Month) Lifetime
I	ALCOHOL USE DISORDER	Past 12 Months
IL	ALCOHOL USE DISORDER	Lifetime
J	SUBSTANCE DEPENDENCE (Non-alcohol) SUBSTANCE ABUSE (Non-alcohol)	Past 12 Months Past 12 Months
JL	SUBSTANCE USE DISORDER (Non-alcohol)	Lifetime
K	PSYCHOTIC DISORDERS	Lifetime Current
	MOOD DISORDER WITH PSYCHOTIC FEATURES MOOD DISORDER WITH PSYCHOTIC FEATURES	Lifetime Current
	SCHIZOPHRENIA	Current Lifetime
	SCHIZOAFFECTIVE DISORDER	Current Lifetime
	SCHIZOPHRENIFORM DISORDER	Current Lifetime
	BRIEF PSYCHOTIC DISORDER	Current Lifetime
	DELUSIONAL DISORDER	Current Lifetime
	PSYCHOTIC DISORDER DUE TO A GENERAL MEDICAL CONDITION	Current Lifetime

	SUBSTANCE INDUCED PSYCHOTIC DISORDER	Current Lifetime
	PSYCHOTIC DISORDER UNSPECIFIED	Current Lifetime
L	ANOREXIA NERVOSA	Current (Past 3 Months)
	ANOREXIA NERVOSA, BINGE EATING/PURGING TYPE	Current
	ANOREXIA NERVOSA, RESTRICTING TYPE	Current
М	BULIMIA NERVOSA	Current (Past 3 Months)
	BULMIA NERVOSA, PURGING TYPE	Current
	BULMIA NERVOSA, NON-PURGING TYPE	Current
МВ	BINGE-EATING DISORDER	Current (Past 3 Months)
N	GENERALIZED ANXIETY DISORDER (GAD)	Current (Past 6 Months)
	GAD DUE TO A GENERAL MEDICAL CONDITION	Current
	SUBSTANCE INDUCED GAD	Current
0	SOMATIZATION DISORDER	Current Lifetime
Р	HYPOCHONDRIASIS	Current
Q	BODY DYSMORPHIC DISORDER	Current
R	PAIN DISORDER	Current
S	CONDUCT DISORDER	Current (past 12 months)
Т	ATTENTION DEFICIT/ HYPERACTIVITY DISORDER	Current (Past 6 months) (Children /Adolescents)
	ADHD COMBINED	
	ADHD INATTENTIVE	
	ADHD HYPERACTIVE / IMPULSIVE	
TA	ATTENTION DEFICIT/ HYPERACTIVITY DISORDER	Current (Past 6 months) (Adults)
	ADHD COMBINED	
	ADHD INATTENTIVE	
	ADHD HYPERACTIVE / IMPULSIVE	
U	PREMENSTRUAL DYSPHORIC DISORDER	Current
V	MIXED ANXIETY DEPRESSIVE DISORDER	Current
W	ADJUSTMENT DISORDERS	Current
Χ	MEDICAL, ORGANIC, DRUG CAUSE RULED OUT	

For Schizophrenia and psychotic disorder studies and for psychotic disorder subtyping in clinical settings, use the MINI for Psychotic Disorders instead of the standard MINI. For many clinical settings this level of psychotic disorder subtyping detail is not necessary.

Lifetime

For children and adolescents, use the MINI Kid or the MINI Kid Parent of the MIN Kid for Psychotic Disorders. A computerized version of the MINI is available from Medical Outcomes Systems <a href="https://www.medical-outcomes.com">https://www.medical-outcomes.com</a>

ANTISOCIAL PERSONALITY DISORDER

# 15

# Appendices of Other Topics

- 15.1 Safety / No Harm / No Suicide / (Insert Phrase Here) Contracts: A patient's perspective
- 15.2 Response to United States Preventive Screening Task Force (USPSTF) Recommendation Against Screening for Suicide Risk in Primary Care

# 15.1

Safety / No Harm / No Suicide / (Insert Phrase Here) Contracts:
A patient's perspective.

#### Introduction

For years there has been controversy over the use of 'safety' contracts. There are countless ways of naming such contracts. They are variously referred to as 'no self-harm', 'no harm', or 'no suicide' contracts. For the purposes of this chapter the phrase *safety contracts* will be used. It should be understood to include all of the previously mentioned types of contracts. Some professionals insist they have no valid use and others insist that they are tremendously helpful. One study reported that the use of these contracts made patients less comfortable in discussing their suicidality with the clinician<sup>1</sup>. Both sides in this controversy make different points to support their position. As a patient with a history of chronic suicidality and self-injury, I will share my perspective of and experience with these safety contracts.

#### What is a Safety Contract?

Safety contracts are a written document signed by a patient, in which the patient promises the clinician, that they will not harm themself or attempt to kill themself. It is common for these documents to contain some type of language stating that the patient will contact the clinician or other emergency number(s), like a crisis hotline, prior to engaging in any self-injury or prior to attempting suicide. Many companies that provide behavioral health care have a standard version of the form that is photocopied and used with any patient that mentions and / or has a history of self-injury and / or suicidality.

Patients are usually presented with this safety contract by a mental health care clinician. In theory, the clinician asks the patient to sign the contract and the patient then makes the decision if they want to sign it or not.

#### Patient's Perspective

Unfortunately, that is not usually how these contracts are used or how the patient interprets the situation. Many patients with a history of mental health concerns, and specifically those with a history of self-injury and / or suicidality, are fairly aware of the laws of involuntary hospitalization in their state. In Florida, where I live, any doctor or counselor can decide you need to be in a hospital and, regardless of your actual need to be there, you are stuck there for up to 72 hours, or until you meet with the psychiatrist on staff and are cleared for discharge. As a result of the clinician's clear power to disrupt a patient's life by involuntary hospitalization, many patients interpret the clinician asking them to sign a safety contract as feeling forced to sign the safety contract or risk involuntary hospitalization. Most clinicians will not directly state that a patient

<sup>&</sup>lt;sup>1</sup>Miller, MC. Contracting for safety. Chapter 40 (pages 372-377) in A Concise Guide to Understanding Suicide: Epidemiology, Pathophysiology and Prevention. Edited by Stephen H. Koslow, Pedro Ruiz, and Charles B. Nemeroff. Cambridge University Press 2014.

must sign said contract in order to be free to go home, but many will clearly imply this to their patients. I have experienced this with the vast majority of clinicians I have interacted with. I have also had clinicians literally tell me that if I did not sign the contract, they would put me in the hospital. In addition, there were times when I was in a hospital and the clinician told me I would not be released from the hospital until I agreed to sign such a contract. I view this as a form of emotional blackmail and I am not alone in this belief.

In my years of interacting with mental health care clinicians, I have heard a spectrum of reasons for the use of safety contracts. On one end of this spectrum lays the clinicians that believe having a patient sign a safety contract actually helps the patient stay safe. Meanwhile, on the other end of the spectrum, are the clinicians that feel they are somehow protected from any legal action if their patient ends up harming or killing themself. (I am amazed clinicians actually believe the latter, but this will be discussed further below.) Thankfully, the beliefs of most clinicians fall somewhere between these two extremes.

#### Arguments For / Against

#### In Support

There are many arguments for and against these safety contracts, but I will limit the discussion to the more common ones I have encountered. Those in support of safety contracts frequently state that in some patient / clinician relationships the use of safety contracts helps to assist in the therapeutic rapport by showing the genuine concern the clinician has for the safety of the patient. If a particular patient and clinician have a good rapport, the use of and / or discussion of a safety contract can further strengthen the bond between them. As a result the patient may be more likely to reach out to the clinician in the event of a future crisis. Supporters of safety contracts point out that this stronger bond can and does save lives. This is true in some patient / clinician relationships. One of my former therapists used to insist that every session I pledge I would not harm myself until after our next scheduled appointment (where she again insisted I repeat this vow to keep myself safe until the following appointment). At that time, it helped assist me in not attempting suicide, because it reminded me that someone cared enough about me to ask that I keep myself safe.

Another argument some give to support the use of safety contracts is that by asking a patient to sign a safety contract, it allows the clinician a better glimpse into the patient's situation. The idea here is that if a patient who is usually truthful is seriously struggling with their ability to commit to keeping themself safe, then the patient likely needs additional support and, possibly, hospitalization. Similarly, if a patient has sometimes not been truthful and is eager to sign the contract, the clinician may interpret this as the patient being untruthful and decide to involuntarily hospitalize them anyway. The pitfall of this use of a safety contract is that it

requires the clinician to play the role of a lie detector and pick up on the subtle clues about the patient's truthfulness. There have been times I have purposely minimized my suicidality and signed safety contracts, fully intending to not follow them, because I knew not signing a safety contract would have resulted in an involuntary hospitalization. Other patients have told me they also have done this.

#### Against

Those who discount the usefulness of safety contracts say that regular use of them gives the clinician a false sense of security about the patient's safety. In my prior example, I used this to my advantage in order to avoid the disruption caused by hospitalization. I did so because I disagreed with the clinician's assessment of my ability to cope with my suicidality. Others who experience suicidality have told me that they have signed such safety contracts simply to be free to make a suicide attempt.

The fact that patients sign safety contracts in order to reduce the likelihood of being involuntarily hospitalized highlights another flaw in the use of safety contracts; they are sometimes improperly used in place of a thorough suicidality assessment. I have witnessed this. One night in my late teens I experienced acute suicidality while I was driving home from a school related function. I drove directly to the local Crisis Stabilization Unit (CSU) and asked for an assessment. While sitting there waiting, I found my suicidality quickly dissipating as I faced the looming prospect and threat of another week long stay in CSU. Prior to any assessment, my suicidality had reduced to an easily manageable level and I explained this to a behavioral tech. They simply asked that I sign their company's standard safety contract form and, since I did, I was allowed to leave and go home without any assessment at all. (I am still amazed this ever happened.) Unfortunately for me, shortly after getting home the suicidality resurfaced and I seriously struggled to keep myself safe that night. As another example, one time I was about to leave a therapist's office when she asked me to sign a safety contract. Throughout the session my suicidality and my self-injury were never discussed. After I refused to sign the contract because I fully expected that I would need to self-injure at some point during that week, she told me that because I would not sign it, I needed to be in the hospital. (I have always hoped she had some other reason for that conclusion, but, if she did, she never shared it with me.)

#### **False Assumptions**

As previously mentioned, some clinicians, though probably not many, believe that a safety contract signed by a patient somehow negates the potential for the family of someone who died by suicide, from being able to prove negligence on the part of the clinician. I encountered this stance with one clinician. In an attempt to help him understand the flaws in his position, I

provided him with the following hypothetical situation, one very similar to examples other patients described to me:

The patient blurts out that they plan to kill themself later that night. The patient has been labeled as 'borderline', so the topic was diverted to the patient's relationship with their spouse and the mention of suicidality was ignored to not feed into the assumed attention seeking of the patient. At the end of the session the patient is asked and agrees to sign a safety contract. Later that night the patient attempted suicide and died as a result of the attempt.

I asked the clinician in question if he thought the clinician in the hypothetical example used good clinical judgment in allowing the patient to walk out of the office without further discussing the suicidality. He agreed that the hypothetical clinician used poor judgment. This example allowed that clinician to understand that a safety contract with a patient does not magically disprove negligence. (In this particular instance, documentation of a safety contract alone would suggest that the clinician was concerned about the patient's safety. However, there would be no details about a proper exploration of the suicidality, since that discussion did not occur.)

#### Personal Perspective

As previously mentioned, I have a history of self-injury and chronic suicidality. I have my own perspective on the use of safety contracts. I have never had a clinician approach the topic of a safety contract with me in what I consider to be the optimum manner.

I do not like the idea of a safety contract being a promise between a patient and their clinician or between a patient and any other person. For me personally, and for my clinicians and others involved in the contract, this was always a source of frustration. There were times when some of my loved ones asked me to promise them I would not kill myself and would not self-injure. In hopes of lessening their stress and trying to make them more at ease about my situation, I made these promises even though it I did not think I could live up to the agreement for the following reason. I soon found myself struggling to keep myself alive simply because the one thing that assisted me in coping with my chronic suicidality, self-injury, was now something I promised I would not do. Instead of being somewhat reasonable and seeing that it would be better for me to self-injure to keep myself alive, I did nothing and all of my emotions intensified, until they very nearly exploded in a suicide attempt. I figured that I was destined to break the contract. I reasoned that if I killed myself, at least I would not be around to deal with the disappointment of the loved one with whom I made this contract. Sometimes I opted for self-injury instead of allowing all of my emotions to build and my loved ones were always very frustrated by what they viewed as my unwillingness to keep myself safe. Other times, I entered in a safety contract with a clinician and similar issues occurred.

#### Recommendations

#### "Safety Promise"

To avoid these issues, I suggest that we stop using traditional "safety contracts". Usually a contract is defined as a written agreement between two or more parties. Instead of engaging in these 'contracts' I suggest having the patient sign a *safety promise*, a written promise to themself, that they will not engage in self-injury and / or not make a suicide attempt. In order to make it more formal, ask that a clinician or another person witness it. Doing this prevents the patient from feeling as though they are disappointing another by breaking the promise and likely decreases the frustration the clinician and / or other person may feel if the promise is broken since the patient is not breaking a promise *to them*. It eases some of the tension the patient may feel if they are considering breaking the promise for a good reason. (An example of a good reason is a patient that feels the need to kill themself opting for self-injury, in order to reduce their suicidality enough, so that they no longer feel they need to engage in a suicide attempt.)

#### Use

Secondly, as previously mentioned, many times patients feel coerced into signing safety contracts. One way to avoid the likelihood of a patient feeling this way, is to present a safety promise to a patient, as an *option* for the patient to consider. Keep in mind that it is only appropriate to present it to a patient in this manner if it *really is optional*. It is important that this be a decision for the patient to make of their own free will, without any pressure from others, including the potential that their decision is somehow factored into some type of risk assessment. In order to do this, clinicians *must stop using the concept of safety promises, or contracts, as a factor in their assessment of a patient's suicidality!* Those clinicians willing to make this change could tell the patient:

I would like you to consider signing a safety promise. This would be a promise you would make to yourself. The decision to do so or not to do so is entirely up to you. Know that your decision will not influence any decision I might make about your treatment. Think about this and I will ask you about your decision a little later.

#### Deciding

Thirdly, safety promises should be presented to the patient in a direct manner and the patient should be allowed time to actually engage in a decision making process. Too many times I have encountered clinicians that suddenly present the safety contract at the end of a session, as they are walking me out the door. It is unreasonable to expect a patient to immediately weigh the pros and cons of signing a safety promise, and to make a decision in the matter of seconds. A safety promise is not something that should be taken lightly! Depending upon the patient's

history with self-injury and / or suicidality, it can take days or weeks for a patient to go through the thought process in order to properly make this decision. Many times it is helpful if a clinician or another person assists the patient in this decision making process, by pointing out pros and cons, that the patient may have overlooked. I have found that allowing the time to actually think about the potential implications of my decision to sign or not to sign a safety promise, forces me to take any promise I do end up making much more seriously. It gives me the added confidence that this is a promise I am capable of fulfilling.

Sometimes, in order to assist the patient in coming to a decision, it is helpful to create a version of the safety promise so that the patient has it to refer to when making their decision. I always ask to see a copy of any safety contract and review it carefully before I agree to sign it, because many times, the standard safety contract forms used by behavioral health care companies have broad statements that the patient "will not engage in any self-injury or make a suicide attempt" and that if the patient feels the need to do so, they will call an emergency number listed on the form. Safety contracts that are worded this way are not sensible to me, as they do not allow for the possibility of unforeseen circumstances, and they have no end date. My experiences with these broad safety contracts have always resulted in my dismissal of the contract, because they are so poorly worded that they are impractical. These poorly crafted contracts also conveyed a lack of understanding about suicidality.

#### Creating a reasonable "safety promise"

If a patient or a clinician want to draft a reasonable safety promise and the patient agrees, the following details should be included. The promise should be reasonable for the patient making the promise. If a patient regularly self-injures in order to decrease the tension that sometimes results in a suicide attempt, it is more practical for the patient to promise not to attempt to kill themselves, and to leave open the option of self-injury, than it is to expect the patient to magically have control over both their suicidality and self-injury at the same time.

#### *Timeframe*

The promise must have a time frame that is appropriate for the individual making the promise. If a patient is in the hospital due to repeated serious self-injury, it might be appropriate for the promise to only last a few hours or a day. Another patient that infrequently self-injures may be able to promise they will not self-injure for a week or month at a time. Seeing that the promise has a time frame that is appropriate for the specific patient signing it increases the likelihood of the patient being able to fulfill their promise. It is important to not allow the end of one safety promise to expire before the patient considers and, possibly, creates and signs another one. Realistically, most patients will find that they want to alter their safety promise over time, and they should be encouraged to do so, as is appropriate for them.

#### **Alternatives**

In order to assist the patient in fulfilling this promise it is important that alternatives to self-injury and / or a suicide attempt are clearly outlined. If a patient frequently self-injures in order to create a positive mood state, have the patient detail other coping mechanisms that they may use to create a positive mood state. If a patient frequently self-injures to ground following depersonalization, assist the patient in finding alternative grounding techniques, and list these on the safety promise. If it is a technique the patient is not familiar with, detail the steps of that technique on the safety promise. If a patient experiences suicidality, detail crisis hotline numbers and / or crisis chat addresses. (For those not aware, there are now crisis chats available online. See the resources at the International Suicide Prevention Wiki [http://suicideprevention.wikia.com/] for more information.)

#### Detailed steps

For some patients, it may be helpful for the alternatives to self-injury and / or suicide attempt part of the safety promise to be written as a step-by-step process. Some patients who are more experienced with suicidality might not need to immediately call a clinician or a crisis hotline. These patients may list some type of distraction or other coping mechanisms towards the top of the steps, with the call to the clinician or to a crisis hotline lower on the list. (If you do this, please emphasize that it is not necessary for the patient to complete all previous steps on the list prior to calling a clinician or crisis hotline, that they can skip steps if they feel they need to, and that these steps are a general guide.) Another patient that has less experience with suicidality may need to list the call to the clinician or to a crisis hotline at the top of the list. Writing this as a step-by-step process allows a patient to read and follow the various agreed upon steps.

#### Safety kit

It may also be helpful for the patient to put together and store a safety kit, with some of the items needed to complete these steps. This precludes a patient struggling to find a particular item during an acute crisis. If I am feeling completely overwhelmed, I tend to have difficulty figuring out where to start when it comes to keeping myself safe. Having the plan detailed in this manner, and having the items close at hand avoids this becoming an issue.

#### Simplistic

It is very important for any safety promise to be clearly legible and to use simple language. Often when a person is in crisis, their mind is not as clear and is not functioning normally. One night, while experiencing acute suicidality, I attempted to complete a self-rated suicidality scale that I had assisted in developing. While doing so, I struggled to even understand the meaning of the questions. (The frustration I felt at not being able to understand something that I had coauthored, increased my hopelessness and suicidality.) If a safety promise is written in complex language, there is a risk that the patient will not be able to follow it, because they cannot easily

understand it. There is also the potential that the patient may become more frustrated by it and as a result, be unable to fulfill their safety promise.

#### Reason for signing

It is important to ensure that the patient making the decision to sign a safety promise is doing it for themself. All too often, I have experienced and heard stories of others being bullied into a safety contract by a clinician or by a loved one. A patient is more likely to keep their promise if the promise is made to themself, rather than to another.

#### Signing

Once all of the above details have been worked out, the safety promise may be handwritten or typed and signed and dated by the patient. Anyone else signing the safety promise should be signing it as a witness. Once everyone signs the promise, copies should be made. At the very least, one copy is for the patient and one is for every witness. There will be some instances where the patient may wish to have multiple copies, possibly one to keep at home, one in their car, and maybe even one at work. They may also want to give a copy to a close and trusted friend who would like to help support them in keeping their promise. As previously stated, some patients will want to edit or change their safety promise. In this event, follow the same steps used in crafting the first safety promise to create the second one.

#### Not signing

Despite following the above steps in crafting a safety promise, some patients will decide not to sign one. If a patient decides not to sign one, remind them that you will impose no negative consequences on them because of their decision. This is a great time to tell them:

If you ever do decide that you would like to sign a safety promise, please let me know. From time to time, I will check in with you about this decision. But please do not feel any pressure to agree to it then.

#### Be supportive

Signing a safety promise does not mean a patient will be successful in fulfilling their promise. If they end up breaking their promise, it is important to look at the reason why the promise was broken, and to explore with them what can be done to prevent it being an issue in the future. Sometimes the promise needs to be changed. If it does, alter it, have the patient and a witness sign and date it, and make copies. If it does not need to be changed, go through the ceremony of having the patient sign and date it again. Have a witness sign and date it, and again make copies. Be as supportive as possible in these circumstances. The patient is trying to make their life better and that is to be commended. Additionally, if a patient is able to fulfill their promise until the end of the time frame, it is important to celebrate it with the patient, in order to acknowledge their accomplishment!

## 15.2

Response to United States Preventive Screening Task Force (USPSTF) Recommendation Against Screening for Suicide Risk in Primary Care

Jennifer M. Giddens<sup>1</sup>, David V. Sheehan MD, MBA<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup>Tampa Center for Research on Suicidality / Harm Research Institute, Tampa, FL 33618, USA

<sup>&</sup>lt;sup>2</sup> University of South Florida College of Medicine, Tampa, FL 33548, USA

The June 20<sup>th</sup>, 2014 edition of Psychiatric News reported, "Task Force Recommends Against Suicide Screening in Primary Care"<sup>1</sup>. The article discussed a recommendation by United States Preventive Screening Task Force (USPSTF)<sup>2</sup> stating that evidence in support of the value of routine screening for *suicide risk* in primary care settings is inconclusive. They conclude that there are too many false positives and too may false negatives using available methods used to predict suicide, to justify routine screening for suicide risk.

The article does not, as the title suggests, discuss recommendations about screening for the presence of suicidal phenomena ("Suicide Screening") in primary care. The review and summary of evidence on the USPSTF website<sup>3 4 5 6</sup>, suggest that the task force focused on the issue of screening for *suicide risk*, and not on screening for *suicidality*. Some assume that screening for the presence of suicidality (suicidality phenomena) and attempting to assess suicide risk are the same. They are not. Suicide risk, although not defined in that article, is commonly referred to as the likelihood, that a patient will die as the result of suicide (death by suicide), or will make a suicide attempt. This is different from *screening for the presence of suicidality*. We define suicidality as all suicidal phenomena including ideation, behaviors, impulses, command hallucinations, dreams, delusions, and / or precognitive experiences related to suicide and / or any suicidal phenomenon related to suicide that arches across a time frame, but did not appear as an ideation or behavior during that time frame.

Although most of the points in the article also apply to the "likelihood a patient will make a suicide *attempt*" definition of suicide risk, for the purposes of this chapter, the focus is on the "likelihood a patient will *die* as a result of suicide" definition.

Because of time constraint limitations, primary care physicians cannot focus on routine suicide *risk* assessments for all patients, unless there is an indication to do so with a specific patient. Predicting suicide at the individual level is very weak, even if it is possible to predict suicide

http://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2014.6b9

<sup>&</sup>lt;sup>1</sup> Moran, M. Task Force Recommends Against Suicide Screening in Primary Care. Psychiatric News. June 2014,49:12 1-1. Online version with revised title available at

<sup>&</sup>lt;sup>2</sup> LeFevre, M. L. (2014). Screening for suicide risk in adolescents, adults, and older adults in primary care: US Preventive Services Task Force recommendation statement. *Annals of internal medicine*, *160*(10), 719-726. Available at http://www.uspreventiveservicestaskforce.org/Home/GetFile/1/1060/suicidefinalrs/pdf

<sup>&</sup>lt;sup>3</sup> Recommendation Summary. U.S. Preventive Services Task Force. September 2014.

http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/suicide-risk-in-adolescents-adults-and-older-adults-screening?ds=1&s=

<sup>&</sup>lt;sup>4</sup> O'Connor, E., Gaynes, B. N., Burda, B. U., Soh, C., & Whitlock, E. P. (2013). Screening for and treatment of suicide risk relevant to primary care: a systematic review for the US Preventive Services Task Force. *Annals of internal medicine*, 158(10), 741-754. Available at

http://www.uspreventiveservicestaskforce.org/Home/GetFile/1/988/suicideart/pdf

<sup>&</sup>lt;sup>5</sup> O'Connor, E., Gaynes, B., Burda, B. U., Williams, C., & Whitlock, E. P. (2013). Screening for Suicide Risk in Primary Care. Available at http://www.uspreventiveservicestaskforce.org/Home/GetFile/1/986/suicidees/pdf

<sup>&</sup>lt;sup>6</sup> LeFevre, M. L. (2014). Screening for suicide risk in adolescents, adults, and older adults in primary care: US Preventive Services Task Force recommendation statement. *Annals of internal medicine*, 160(10), 719-726. Available at http://www.uspreventiveservicestaskforce.org/Home/GetFile/1/1060/suicidefinalrs/pdf

better at a group level in very large samples<sup>7</sup>. However there is no reason why primary care physicians cannot include questions to assess current suicidality into their routine health screening questionnaires.

There is an assumption that everyone thinking about suicide is doing so willingly or chooses suicidality in order to either escape their problems or to manipulate others. There are other reasons people experience suicidality. We need to investigate other reasons for suicidality to capture a more comprehensive, compassionate, and accurate perspective of each patient's suicidality. This involves better communication with patients about their unique experiences.

If the primary care clinician cannot predict suicide risk at the individual level, why bother screening for suicidality? The reason is that suicidality is itself associated with considerable functional impairment and with it's own unique human suffering. Many individuals have functional impairment as a direct consequence of their suicidality<sup>8</sup>. Suicidality impairs educational achievement, work performance, and career advancement. The economic burden of suicidality is enormous 9 10. This is reflected in costly hospitalizations, economic loss from work impairment, economic impact on families, and the cost to the military in caring for suicidal veterans. In the field of mental health it is the leading cause of death directly related to most of the major psychiatric disorders. Suicide is the 10<sup>th</sup> leading cause of death in the US (United States Center for Disease Control and Prevention 2013 data)<sup>11</sup> and the 15<sup>th</sup> leading cause of death internationally (World Health Organization data for 2012)<sup>12</sup>. The failure to address and manage suicidality in a timely and efficient manner in health care systems reflects poorly on any nations health care system, and the humanity and quality of its society. That a healthcare policy advisory group like the United States Preventive Screening Task Force (USPSTF) could dismiss the value of the inclusion of a few questions to assess current suicidality in routine primary care screening questionnaires is a rather serious healthcare oversight. It reflects a misunderstanding of the nature of the problem, a focus on the wrong target (trying to predict suicide risk instead of assessing current suicidality), a misunderstanding of how to tackle the problem, blindness to how much impairment, economic burden and human suffering results directly from suicidality itself, and how much of this might be alleviated by early detection.

<sup>&</sup>lt;sup>7</sup> Greist, John H., et al. "Predictive Value of Baseline Electronic Columbia–Suicide Severity Rating Scale (eC–SSRS) Assessments for Identifying Risk of Prospective Reports of Suicidal Behavior During Research Participation." *Innovations in clinical neuroscience* 11.9-10 (2014): 23.

<sup>&</sup>lt;sup>8</sup> Giddens JM, Sheehan DV. Is there any value in asking the question "Do you think you would be better off dead?" in assessing suicide? Innov Clin Neurosci. 2014;11(9–10):182–190.

<sup>&</sup>lt;sup>9</sup> Law, Chi-Kin, Paul SF Yip, and Ying-Yeh Chen. "The economic and potential years of life lost from suicide in Taiwan, 1997–2007." *Crisis* (2015).

<sup>&</sup>lt;sup>10</sup> Clayton, Dale, and A. Barcel. "The cost of suicide mortality in New Brunswick, 1996." *Chronic diseases in Canada* 20.2 (1999): 89-95.

<sup>&</sup>lt;sup>11</sup> Suicide: Facts at a Glance. (2015, September 3). Retrieved September 15, 2015, from http://www.cdc.gov/violenceprevention/pub/suicide datasheet.html

<sup>&</sup>lt;sup>12</sup> Suicide data. (n.d.). Retrieved May 15, 2015, from

http://www.who.int/mental\_health/prevention/suicide/suicideprevent/en/

The clinicians quoted in the article "all agreed on the greater utility of screening for major depression" (which we assume to mean major depressive disorder, although this is unclear). In the context of the article, this statement suggests that this is viewed as an alternative to suicide risk screening. Although studies report that a large portion of patients who make suicide attempts and psychological autopsies have shown that a large number of people that kill themself have experienced depression, there is scant data to support the idea that the depression always comes first in the suicidal patient's natural history. While depression precedes suicidality in some patients, it is not true for all patients. Screening for major depressive disorder or even major depressive episode will not detect the patients who are suicidal and are not depressed, and it may not detect the patients who are depressed and suicidal, but have only been depressed and suicidal for less than two weeks. This latter group would be missed because they will not meet the criteria for major depressive disorder. Patients who are impulsively suicidal may also be missed. By screening specifically for suicidality, the patients that fit these three populations will be detected. If the focus is on major depressive disorder screening, the population of patients that is suicidal but not experiencing major depressive disorder will have their suicidality missed because they do not fit the stereotypical assumptions of suicidality. In a 2011 study in Italy, researchers found that at least 29.4% (or 89) of 303 college students surveyed experienced suicidal ideation in the 4 weeks prior to the survey<sup>13</sup>. If 29.4% of college students experienced suicidal ideation, 1.9% engage in preparatory suicidal behaviors, and 2.6% engaged in a suicide attempt in the 4 weeks prior to answering the survey, then it is reasonable to assume that the prevalence of suicidality in the general population is not trivial. The same paper provides evidence supporting the position that if you want to screen for suicidality you should screen for suicidality, and NOT for some proxy, like major depressive disorder.

In addition to the issues with screening for major depressive disorder, by focusing the efforts on major depressive disorder, it reinforces the idea that treating major depressive disorder will properly treat suicidality in all patients (a widely held myth). The treatments for major depressive disorder may actually make suicidality worse in some patients (See chapter 12.2 for a case study on citalopram and impulsive suicidality for more information). This may be why some of the pediatric patients reported an increase in their suicidality as a result of antidepressants, which lead to the boxed warnings. If clinicians focus exclusively on major depressive disorder in their screening, and do not also ask about suicidality, some of these patients may be prescribed an antidepressant that may increase the severity of their suicidality<sup>14</sup> <sup>15</sup>.

<sup>&</sup>lt;sup>13</sup> Preti A, Sheehan DV, Coric V, et al. Sheehan-Suicidality Tracking Scale (S-STS): reliability, convergent and discriminative validity in young Italian adults. Compr Psychiatry. 2013;54(7):842–849.

<sup>&</sup>lt;sup>14</sup> JG personal communication with suicidal subjects in 1995, 1998, 2000, 2004, 2006, 2007, 2009, 2010, 2011, 2012, 2013, 2014, and 2015.

<sup>&</sup>lt;sup>15</sup> Sheehan DV, Giddens JM, Sheehan KH. Current assessment and classification of suicidal phenomena using the FDA 2012 Draft Guidance document on suicide assessment: a critical review Innov Clin Neurosci. 2014;11(9–10):54–65.

Some of the suicidality assessment tools (like the patient-rated Sheehan - Suicidality Tracking Scale) can be completed in less than 10 minutes<sup>16</sup> <sup>17</sup> <sup>18</sup> by the patient sitting in the waiting room and then simply reviewed by the clinician, just as a clinician would review lab results, prior to or while meeting with the patient. Although this may result in a discussion between the patient and the clinician during the first visit the patient reports experiencing suicidality, subsequent visits will take a significant amount of time to discuss *only if* the patient's symptoms of suicidality have changed. There is also an online assessment the patient can take just prior to their primary care appointment<sup>19</sup>. This may be a better fit for the patient's and clinician's time. There are even linguistically validated versions of one suicidality assessment tool for 3 different pediatric age groups<sup>20</sup>. Patient-rated tools are available that can help primary care clinicians conduct suicidality screening without too much of a burden on the primary care clinician's time.

We suggest that those faced with the task of investigating the value of screening for suicidality in primary care re-examine their policy positions on this subject and offer recommendations that are more likely to have an impact on national suicide statistics and in reducing the impairment and human suffering associated with suicidality, than ignoring suicidality itself, where it first presents in primary care.

<sup>&</sup>lt;sup>16</sup> Mundt JC, Greist JH, Gelenberg A, et al. Feasibility and validation of a computer-automated Columbia-Suicide Severity Rating Scale using interactive voice response technology. J Psychiatr Res. 2010;44:1224–1228.

<sup>&</sup>lt;sup>17</sup> Sheehan DV, Alphs L, Mao L. Comparative validation of the S-STS, the ISST-Plus, and the C-SSRS for assessing the suicidal thinking and behavior FDA 2012 Suicidality Categories. Innov Clin Neurosci 2014;11(9–10):32–46.

<sup>&</sup>lt;sup>18</sup> Sheehan DV, Giddens JM, Sheehan IS. Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014. Innov Clin Neurosci. 2014;11(9–10):93–140.

<sup>&</sup>lt;sup>19</sup> Gray, C. (2013, October 1). In Home Screening from Medical Outcome Systems, Inc. Retrieved October 1, 2013, from <a href="http://lnHomeScreening.com">http://lnHomeScreening.com</a>

<sup>&</sup>lt;sup>20</sup> Amado DM, Beamon DA, Sheehan DV. The linguistic validation of the Pediatric versions of the Sheehan-Suicidality Tracking Scale (S-STS). Innov Clin Neurosci 2014;11(9–10):141–163.

## 16

# List of Acronyms

+Mg-Ca High Magnesium / Low Calcium Dietary Intake

2D 2-Dimensional3D 3-DimensionalAD Antidepressant

ALS Amyotrophic Lateral Sclerosis

AMPA α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic Acid

ASCP American Society of Clinical Psychopharmacology

BDNF Brain-Derived Neurotrophic Factor

C-CASA Columbia-Classification Algorithm of Suicide Assessment

C-SSRS Columbia-Suicide Severity Rating Scale

CBT Cognitive Behavior Therapy

CMCM Clinically Meaningful Change Measure of the Sheehan-Suicidality Tracking Scale

CNS Central Nervous System
CSU Crisis Stabilization Unit

DBT Dialectical Behavior Therapy

DISCAN <u>Disc</u>retized Visual <u>An</u>alog

DNA Deoxyribonucleic Acid

DSM-5 Diagnostic and Statistical Manual of Mental Disorders 5<sup>th</sup> Edition

DSM-III-R Diagnostic and Statistical Manual of Mental Disorders 3<sup>rd</sup> Edition (Revised)

DSM-IV-TR Diagnostic and Statistical Manual of Mental Disorders 4<sup>th</sup> Edition (Text Revised)

DSMB Data Safety Monitoring Board(s)

ECT <u>E</u>lectro<u>c</u>onvulsive <u>T</u>herapy

EMA European Medicines Agency

ER Emergency Room

FDA United States Food and Drug Administration

FDA-CASA 2012 US FDA Classification Algorithm for Suicide Assessment from 2012 draft guidance

HPTS Homicide Plan Tracking Scale

IASD Impulse Attack Suicidality Disorder

ICD-10 International Statistical Classification of Diseases & Related Health Problems (10th rev.)

ISCTM International Society for CNS Clinical Trials and Methodology

ISST-Plus InterSePT Scale for Suicide Thinking - Plus

LOCF Last Observation Carried Forward

LGBTQIAA+ Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual persons and Advocates

MDD Major Depressive Disorder

MINI Mini International Neuropsychiatric Interview

MINI Screen Mini International Neuropsychiatric Interview Screen

MIT Massachusetts Institute of Technology

MMRM Mixed Model Repeated Measures

NMDA N-Methyl-D-aspartic Acid or N-Methyl-D-Aspartate

NOS Not Otherwise Specified

NSPSA Non-Suicidal Physical Symptom Attack

NSSI Non-Suicidal Self-Injury

OCD Obsessive Compulsive Disorder

OTC Over-the-Counter

PCP Phencyclidine or 1-(1-Phenyl Cyclohexyl)Piperidine

PDD Pervasive Developmental Disorder

PTSD Posttraumatic Stress Disorder

RGB Roux-en-Y Gastric Bypass

RNA Ribonucleic Acid

S-HTS Sheehan-Homicidality Tracking Scale

S-SNTS Sheehan-Suinocerality Tracking Scale

S-STS Sheehan-Suicidality Tracking Scale

S-STS CMCM Sheehan-Suicidality Tracking Scale Clinically Meaningful Change Measure

SIAS Suicidality Impulse Attack Scale

SIBAT Suicidal Ideation and Behavior Assessment Tool

SMR Standard Mortality Ratio

SMS Suicidality Modifiers Scale

SNRI Serotonin–Norepinephrine Reuptake Inhibitor

SOC Standard of Care

SNP Single Nucleotide Polymorphism

SPTS Suicide Plan Tracking Scale

SSRI Selective Serotonin Re-uptake Inhibitor or Serotonin-Specific Reuptake Inhibitor

T-CASA Tampa-Classification Algorithm for Suicidality Assessment

TAU Treatment As Usual

TCA Tricyclic Antidepressant

TCP <u>Trichlorophenylmethyliodosalicyl</u>

TCCN Turbulent Calcium Channel of the NMDA Receptor

TMS Transcranial Magnetic Stimulation

USFDA United States Food and Drug Administration

USPSTF United States Preventive Services Task Force

USIA Unexpected Suicidal Impulse Attack

VGB Vertical Banded Gastroplasty

VNS Vagus Nerve Stimulation

VSCCs Voltage Sensitive Calcium Channels