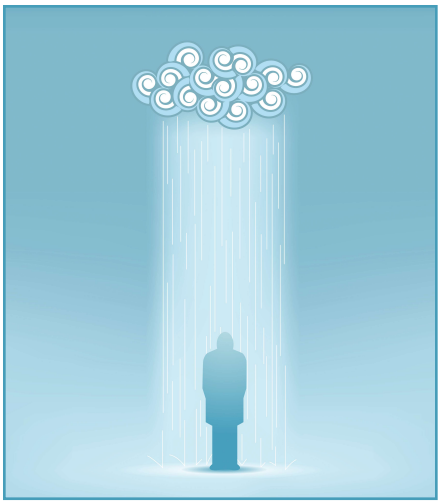

[REVIEW]

Status Update on the Sheehan-Suicidality Tracking Scale (S-STS) 2014

by DAVID V. SHEEHAN, MD, MBA; JENNIFER M. GIDDENS; and IVAN SASCHA SHEEHAN, PhD

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FINANCIAL DISCLOSURES:
Dr. D. Sheehan is the author and copyright holder of the Sheehan-Suicidality Tracking Scale (S-STS), the Sheehan-Suicidality Tracking Scale Clinically Meaningful Change Measure Version (S-STS CMCM), the Pediatric versions of the S-STS, the Sheehan Disability Scale (SDS), and the Suicidality Modifiers Scale; is a co-author of the Suicide Plan Tracking Scale (SPTS), Sheehan-Homicidality Tracking Scale, and the Mini International Neuropsychiatric Interview (MINI); and owns stock in Medical Outcomes Systems, which has computerized the S-STS and the MINI. J. Giddens is the author and copyright holder of the SPTS and is a named consultant on the S-STS, the S-STS CMCM, the Pediatric versions of the S-STS, and the Suicidality Modifiers Scale. Dr. I. S. Sheehan is the co-author of the Sheehan-Homicidality Tracking Scale. He is also the son of Dr. D. Sheehan, who is the author and copyright holder of the S-STS, the S-STS CMCM, the Pediatric versions of the S-STS, the SDS, and the Suicidality Modifiers Scale; a co-author of the SPTS, the Sheehan-Homicidality Tracking Scale, and the MINI; and owns stock in Medical Outcomes Systems, which has computerized the S-STS and the MINI.

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KEY WORDS: Suicide scale, suicide assessment, suicide risk, suicide, suicidality, suicidality scale, patient-rated suicide assessment, pediatric suicide, suicide in children, pediatric suicide scale, adolescent suicide scale, S-STS, homicide assessment, homicidality, homicide, S-HTS

ABSTRACT

There is a need for a choice of scales to evaluate the full range of suicidal phenomena. Such scales must be capable of use as both safety and efficacy outcome measures in research and in clinical settings. Central to the success in finding and developing effective anti-suicidal medications is having a sensitive suicidality scale that can detect an efficacy signal in conventional sample sizes used in clinical trials. The Sheehan-Suicidality Tracking Scale was developed for these purposes. This article provides a 2014 status update on the scale's progress, its use, and its properties. The authors review why and how the scale was developed; the scale structure, versions, and properties; the trials in which it was used; the time frames accommodated; its validation and reliability studies; its utility in screening and assessment; its utility in assessing treatment-emergent suicidal adverse events; its use as an efficacy outcome measure; its availability in self-rated and clinician-rated forms; the availability and linguistic validation of pediatric versions; linguistic validation in other languages; how it compares with global ratings of suicidality; and its possible utility and applications.

INTRODUCTION

There is a need for a choice of scales to evaluate the full range of suicidal phenomena. Such scales must be capable of use as both safety and efficacy outcome measures in research and in clinical settings. Sensitivity to anti-suicidal effects in modest sample sizes is particularly important in the context of efforts to find and develop anti-suicidal medications. The Sheehan-Suicidality Tracking Scale (S-STS) was developed to provide a brief but efficient assessment instrument for use in assessing change in suicidal ideation and behavior while providing a comprehensive description of suicidal ideation and behavior. The primary goals in the design of the S-STS were for the scale to be as follows:

1. Short and inexpensive
2. Simple, clear, and easy to administer or self-rate
3. Highly sensitive (i.e., able to detect a high proportion of patients who are suicidal)
4. Specific (i.e., able to screen out those who are not suicidal)

5. Sensitive to change in suicidal ideation and behavior
6. Compatible with the United States Food and Drug Administration (FDA) categories for prospective assessment of suicidal ideation and behavior[1,2]
7. Useful in clinical as well as research settings
8. Useful in detecting an efficacy signal for anti-suicidal medications
9. Capable of use in pediatric and geriatric settings.

Because of the risks associated with suicidality and in the interest of safety, the expectations and hurdles for a suicide assessment 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 article aims to provide a 2014 status update on the scale, its properties, and its potential uses.

WHY AND HOW WAS THE S-STS DEVELOPED?

Suicide is a leading cause of premature death among psychiatric patients and a leading source of malpractice suits against psychiatrists and mental health professionals.[3-5] A suicidality module was included in the Mini International Neuropsychiatric Interview (MINI)[6] (a structured diagnostic interview coauthored by author D.S.) as early as 1992, because other structured diagnostic interviews did not provide this. The suicidality module, like the other modules in the MINI, is in a yes/no response format. Subsequently, the first author of this article (D.S.), who developed the scales in the MINI Tracking Scales, changed the MINI modules, including the suicidality module, into a set of Likert scales for treatment-outcome tracking. With the FDA expectations of more thorough suicide assessments in clinical trials, several sponsors asked the first author of this article (D.S.) to accommodate all the FDA suicide assessment expectations into the suicidality module of the MINI Tracking. In this process, the S-STS was developed as a separate scale. As it was modified, we modified the MINI suicidality module to keep pace with changes in the S-STS. The MINI 7 structured diagnostic interview for the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (*DSM-5*) is now fully compatible item by item with the S-STS. The S-STS scale evolved further with considerable and thoughtful feedback from regulatory agencies, patients, sponsors, and researchers to its current state. The scale author's consistent primary goal was to develop a scale that could sensitively discriminate anti-suicidal properties between drug and placebo in standard clinical trial sample sizes. In addition, the scale should serve as a sensitive, adverse-event, suicidality detector in modest samples.

CURRENT SCALE VARIANTS

Standard S-STS. The standard version of the S-STS (Appendix A) is a 16-item scale that assesses the seriousness of suicidality phenomena on a Likert-type scale (0–4) ranging from "not at all" (0) to "extremely" (4). It also assesses the frequency of key phenomena and the overall time spent in suicidality. The standard version is available in clinician- and patient-rated formats. These formats are identical, except that the clinician rates the former and the patient rates the latter. There is also a "reconciled" version, which can be used to reconcile discrepancies, if they exist, between the patient and clinician on specific items. The standard S-STS can be used for screening and other purposes (e.g., tracking suicidality as an adverse effect in trials or in clinical practice). Page 1 of the two-and-a-half pages layout can be used as a stand-alone suicidality tracking scale for clinical practice settings. The last page (page 3) is only completed if the patient misses a follow-up appointment and is unavailable to allow completion of the scale. This section captures the best available information on the patient's disposition. This information is usually required by regulatory agencies to close the loop as completely as possible on the outcome in a clinical trial in relation to suicidality.

The Clinically Meaningful Change Measure (CMCM) version of the S-STS (Appendix B). This version is a much more expanded version developed for specific testing of the anti-suicidal effects of medications.

The main reason for developing this variant was to address an expectation of European regulators that any drug seeking regulatory approval for an anti-suicidal indication needs to demonstrate a *clinically meaningful change* in addition to showing statistically significant superiority over a placebo on a suicide ideation and behavior scale, given the risks and gravity involved in suicidality. Assessment of clinically meaningful change has become increasingly important for treatment planning, monitoring progress, and evaluating treatment response in clinical trials and in clinical practice. Minimally important change has been defined as "the difference in score on a health-related [...] instrument that corresponds to the smallest change in status that stakeholders (persons, patients, significant others, or clinicians) consider important."[7] Clinically meaningful or important change can facilitate interpretation of scores obtained on self-report measures of health status used to assess treatment effects at the aggregate and individual level.[8]

An anti-suicidal medication might show a statistically significant difference compared to placebo, but that change might not also be clinically meaningful. The effects of such an anti-suicidal 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. Appendix B shows the additional domains that should be altered by an anti-suicidal treatment and how these domains are measured, anchored, and statistically analyzed (as seen in Appendix C) in a way that any clinician could judge the extent of an anti-suicidal medication's clinically meaningful effect.

The CMCM version of the S-STS has four parts. The first section can be either patient-rated or clinician-rated. This section is identical to the first two pages of the standard S-STS.

The second section is patient-rated. It provides patients with a series of additional ratings. These include 1) an opportunity to rate a series of risk or protective factors that might be important aggravating or relieving factors in the subject's suicidal ideation and behaviors; 2) a series of 11-point (0–10) discretized visual analog (DISCAN) scales on which patients can rate 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, the extent to which it has impacted the quality of their lives, and the extent to which it has impaired their work, social, or family lives; and 3) a patient-rated global severity of suicidal impulses, thoughts, and behaviors rating and an opportunity to provide a self-assessment of treatment needs.

The third section of the CMCM version is clinician-rated. This section gives the clinician an opportunity to rate his or her judgment of the patient's suicide risk and a judgment of level of management required for the patient's suicidal ideation and behavior. It also captures a global assessment of suicidality based on all the information collected in the earlier sections of the scale with additional input from others and from any additional probe questions the clinician deems necessary to complete the assessment.

The fourth section is completed by the clinician only if the patient misses a follow up appointment and is unavailable, which allows completion of the scale. It is identical to page 3 of the S-STS standard version.

The Pediatric versions of the S-STS. The Pediatric versions of the S-STS were developed specifically for children and adolescents. There are currently three pediatric forms of the S-STS. One is for 6- to 8-year-olds, one for 9- to 12-year-olds, and one for 13- to 17-year-olds. A novel method of linguistic validation was used in the development of these versions. To our knowledge, this makes these three pediatric S-STS versions the first linguistically validated versions of a suicidality scale in children and adolescents. The Pediatric versions of the S-STS are the subject of a separate article.[9]

SCALE PROPERTIES

Response format. To capture the seriousness and intensity of each suicidality phenomenon, the S-STS uses a Likert-like response format ranging from "not at all" (0), "a little" (1), "moderately" (2), "very" (3), to "extremely" (4). This response format allows the scale to capture finer discriminations for tracking than the dichotomous yes/no format used in the suicidality module of the MINI and in the scale's most widely used alternative, the Columbia–Suicide Severity Rating Scale (C-SSRS).[10] The C–SSRS, in contrast, captures an intensity rating on the highest-rated single combination of a limited number of six of 32 possible suicidal ideation combinations. The S-STS captures the seriousness of all suicidal phenomena.

Scale structure. The C–SSRS has features of a Guttman scale structure, where the suicidal ideation items are ordered so that an individual who agrees to a particular item (e.g., suicidal method, intent, or plan) is assumed to have agreed with a lower ordered item (e.g., active suicidal ideation). In contrast, the S-STS scale structure treats each item separately without any assumptions of inherent order or cumulativeness. The S-STS structure makes it possible for the scale to capture a wider range of combinations of suicidal ideation and behavior than the C–SSRS and to assess the seriousness of each ideation item separately.

Time frames. The S-STS accommodates a wide range of time frames. In clinical trials, the frequently used variants are "in the past week," "in the past month," "since the last visit," "lifetime look back," and "in the past day." In emergency room settings, the scale can be adapted to cover all phenomena relating to "your most recent attempt" or to "what brought you here." A shorter adaptation can be used to assess suicidality in the past 15 minutes, in the past hour, or for other shorter times frames that might be needed for testing efficacy of medications with rapid anti-suicidal properties. These are all outlined in the scoring instructions (Appendix C) and in the instructions for use in acute rapid onset of action studies (Appendix D).

Administration time. In a clinical sample of 34 patients with reported suicidal ideation or behavior, the average time taken to administer the standard S-STS was 9.1 minutes.[11] While this duration was slightly longer than that reported for the C-SSRS (8.1 minutes) in the same study, it was comparable to the duration reported for suicidal subjects in another study of the C–SSRS (9.6 minutes)[12] and somewhat shorter than that for the InterSePT Scale for Suicidal Thinking-Plus (ISST-Plus) (14.5 minutes).[11] The patient-rated version of the S-STS took 8.3 minutes and the reconciliation version took 2.5 minutes in the same study. In a sample of generalized anxiety disorder patients in a clinical trial who did not have active suicidal ideation at study entry, the original eight-item version of the S-STS took 1 to 2 minutes to complete.[13]

Screening, study exclusion, and monitoring alert rules. As shown in Appendix C, the standard S-STS can be used to determine if a patient should be excluded from a study at the screening visit or alternatively after the study start and/or if a monitor should be alerted. Although different protocols have different needs, we provide suggestions based on item scores for these contingencies. Appendix E provides suggested guidelines on study stopping rules to be used with the S-STS.

Scoring. As shown in Appendix C, the standard S-STS can be used to generate a summated score (total score), individual factor scores for suicidal ideation, suicidal intent, suicidal planning, suicidal behavior, and non-suicidal self-injury. Counts for

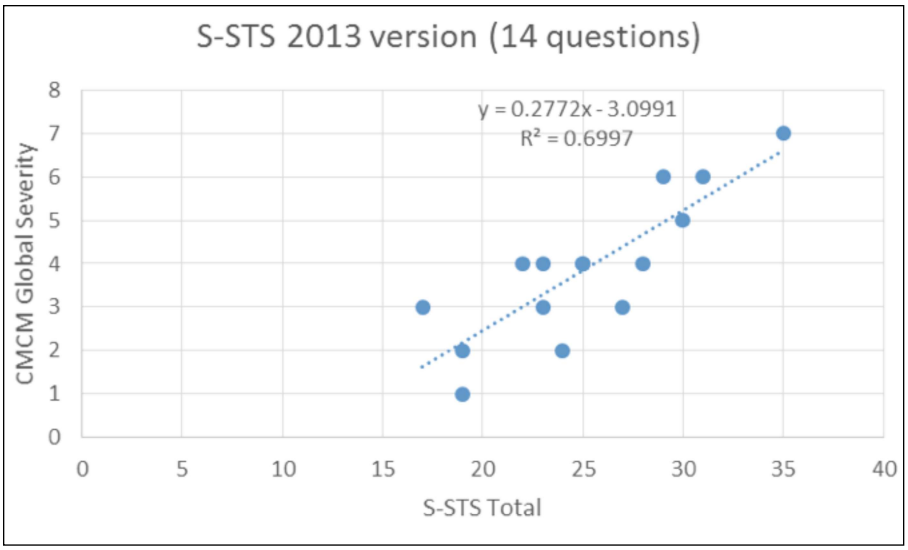

FIGURE 1. Relationship between the S-STS total score (2013 14-question version) and the CMCM global measure of suicidality from a single subject

Source: Weekly self-ratings of the 14-item 2013 S-STS total score and CMCM Global Severity score over a 15-week period.

S-STS: Sheehan-Suicidality Tracking Scale; CMCM: Clinically Meaningful Change Measure

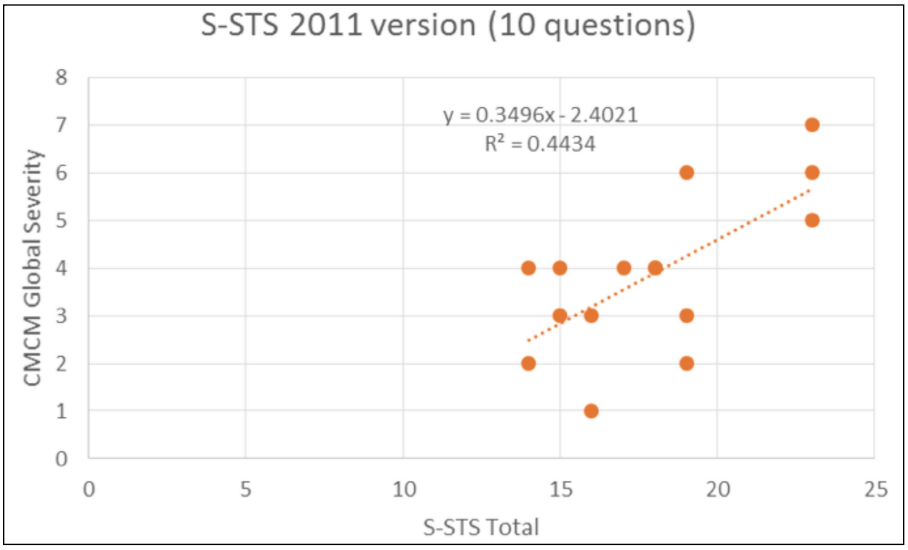

FIGURE 2. Relationship between the S-STS Total score (2011 10-question version) and the CMCM global measure of suicidality from a single subject

Source: Weekly self-ratings of 10-item 2011 S-STS total score and CMCM Global Severity score over a 15-week period.

S-STS: Sheehan-Suicidality Tracking Scale; CMCM: Clinically Meaningful Change Measure

suicidal ideation events; preparatory acts; suicide attempt events; non-suicidal self-injury events; and usual, most, and least amount of time in suicidal ideation, impulses, or behavior can also be calculated from the standard S-STS. The CMCM version generates all of the same scores and counts. In addition, it can be used to generate total risk and total protective factor scores, a total clinically meaningful impairment score, a functional impairment score, and a global severity score.

Mapping to FDA algorithms. The S-STS accommodates the definitions used in the Columbia Classification Algorithm of Suicide Assessment (C-CASA)[14] and adopted by the FDA in its 2010 Draft Guidance for assessment of suicidal ideation in clinical trials.[1] It also maps to the expanded classification algorithm for suicide assessment adopted by the FDA in its updated Draft Guidance issued in 2012 (referred to as FDA-CASA 2012).[2] (The mapping tables of the S-STS to the FDA 2010 and 2012 Draft Guidance categories are in Appendices F and G.)

Linguistic validation in other languages. The S-STS has been linguistically validated in over 20 languages by Mapi Group (www.mapigroup.com). This is expected to increase to up to 70 languages in the near future.

Changes in S-STS items from 2011 to 2013. The 2009 version of S-STS had 10 items. In 2011, the method item was disaggregated to improve sensitivity into two items: one for method (how) and one for means (with what). In 2012, we realized that this version was missing something that was captured in global suicide severity ratings and that its sensitivity could still be improved. By disaggregating one additional planning item into two questions—one for the location and another for the timing of plan—we were able to improve the relationship between the S-STS total score and the global severity of suicidality, making it more sensitive as a research tool in detecting efficacy and safety signals. As shown in Figure 1, there was a direct ascending linear relationship between S-STS total score and the global suicidality severity rating (R^2=0.6997) for the 14-item 2013 version. The relationship was less clear (R^2=0.4434) for the 10-item 2011 version (Figure 2) over exactly the same concurrent timeframe.

VALIDITY AND RELIABILITY TESTING

Evidence of validity. Coric et al[13] incorporated the self-rated S-STS into a multicenter, randomized, double-blind, placebo-controlled, and active

comparator eight-week trial examining BMS 562086, escitalopram, and placebo for general anxiety disorder (GAD). Eighty-two subjects completed 297 S-STS ratings across study time points. Of these, 61 had a baseline and at least one post-baseline follow-up S-STS. Despite the small sample and low occurrence of suicidal ideation in this study, the authors found that the sensitivity of the S-STS (its ability to detect true cases of suicidal ideation or behavior) was very high compared to the rater-administered Hamilton Depression Rating Scale (HAM-D) item #3 (suicide) and in relation to reported suicidal adverse events (AEs) and suicidal serious adverse events (SAEs). The S-STS showed 100-percent sensitivity for identifying subjects with suicidal ideation and behaviors, compared to 63 percent for item 3 (suicide) on the HAM-D. These sensitivity calculations were based on any evidence of suicidal ideation or behaviors from review of AEs, SAEs, HAM-D item #3, or a S-STS score greater than 0.

Preti et al[15] evaluated the reliability (internal consistency and test-retest stability) as well as the convergent validity and divergent validity of the self-rated S-STS using a cross-sectional study in a nonclinical sample of 303 college students aged 18 to 40 years (mean age of 23.5 years). Within this sample, 29.4 percent had experienced passive suicidal ideation, 20.4 percent had experienced active suicidal ideation, 4.3 percent had planned a suicide attempt, 1.9 percent had engaged in preparatory suicidal behavior, 5.9 percent had engaged in self-injurious behavior without intent to kill themselves, and 2.6 percent had made a suicide attempt. Sixty subjects were contacted for retesting 4 to 6 weeks later, and 58 complied. Overall, the authors found "promising evidence on the convergent, divergent, internal consistency, and test-retest stability of the S-STS."

Youngstrom et al[16] presented an analysis of the concordance of the S-STS with the C–SSRS in a clinical sample of 196 suicidal subjects drawn from inpatient and emergency room settings at Penn State Milton S. Hershey Medical Center in Hershey, Pennsylvania, USA. The analysis mapped each scale to the C-CASA categories that were adopted in the 2010 FDA Draft Guidance[1] for suicidal assessment. The authors found acceptable concordance between the S-STS and the C–SSRS using Kappa scores. A further analysis using the updated 2012 FDA classification categories suicide ideation and behavior categories is underway by this group from this dataset.

The University of Alabama at Birmingham (UAB) conducted a validation study comparing the S-STS and the ISST-Plus[17] with the C-SSRS (treated as the gold standard) in 40 adult subjects identified as having suicidal ideation or behavior with varying degrees of severity recruited from inpatient, outpatient, and emergency room settings. The data were analyzed using mapping to both the 2010 and the 2012 FDA Draft Guidances[1,2] suicidality categories. The results were reported at five national scientific meetings in poster and oral presentations[11,18] and have generated one published article so far.[11] Subjects were rated on all three scales on the same day and were assigned to each scale in a random sequence order. The S-STS clinician-rated, S-STS patient-rated, and S-STS reconciliation versions were used in this study and were part of this validation analysis. In essence, the S-STS and ISST-Plus were very similar to each other in the agreement scores and diverged very little from each other, although the two scales appear different on face inspection and method of use and are derived from very different sources (Figure 3). However both the ISST-Plus and S-STS (in all 3 versions) showed marked differences with the C-SSRS on most of the suicidal ideation items, which are the essential core of most suicide assessments. The reasons for these differences are the subject of of another paper.[11]

The problem here is the flawed navigation instruction for suicidal ideation on the C–SSRS relating to item 2, the flawed application of a Guttman Scaling procedure on the C–SSRS, and the related type I and type II errors on the C–SSRS that lead to under-endorsement of some suicidal phenomena and over-endorsement of others.[19] For example, the true rates of non-specific active suicidal ideation are inflated on the C-SSRS compared to reality. The Guttman Scaling assumption as used in the C–SSRS is not an optimal, comprehensive, reproducible, or generalizable assumption to model suicidal ideation and behavior. See Appendix H for further details on why Guttman scaling is not optimal for use in the design of a suicidality scale. C-SSRS datasets *cannot* be merged with ISST-Plus and S-STS datasets because of these design flaws.

Evidence of reliability. To date, there are no published data supporting inter-rater reliability of the S-STS; however, the UAB clinical research team conducted a test-retest reliability and inter-rater reliability study in conjunction with the previously described validation study,[11] which confirmed the S-STS reliability. This study is currently being prepared into a manuscript for publication.[18]

COMPARISON OF CLINICIAN-RATED, SELF-REPORT, AND RECONCILED VERSIONS OF THE S-STS

The correspondence between the clinician-rated, self-report (patient-rated), and reconciled versions of the S-STS appears to be high. As shown in Figure 4, the three versions showed similar patterns in the way they mapped or failed to map to the C–SSRS and the FDA-CASA 2012 categories in the UAB study described above.[11] The reconciliation version was more similar to the clinician-rated version than to the self-rated version, but the interpretation of this finding is complex. While it is tempting to assume that the clinician-rated and the reconciliation versions best reflect what actually occurred, one should not assume this is always or even usually the case.

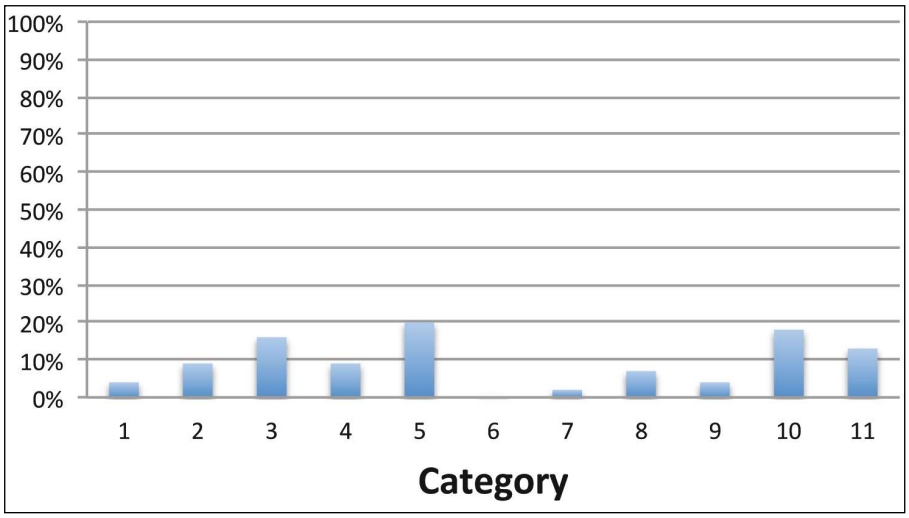

FIGURE 3. Percentage disagreement between the clinician-rated version of the S-STS and the ISST-Plus using FDA 2012 CASA categories

Category 1: Passive suicidal ideation: wish to be dead; Category 2: Active suicidal ideation: nonspecific (no method, intent, or plan); Category 3: Active suicidal ideation: method, but no intent or plan; Category 4: Active suicidal ideation: method and intent, but no plan; Category 5: Active suicidal ideation: method, intent, and plan; Category 6: Completed suicide; Category 7: Suicide attempt; Category 8: Interrupted suicide attempt; Category 9: Aborted suicide attempt; Category 10: Preparatory acts toward imminent suicidal behavior; Category 11: Self-Injurious Behavior Without Suicidal Intent

S-STS: Sheehan-Suicidality Tracking Scale; ISST-Plus: InterSePT Scale for Suicidal Thinking-Plus; FDA-CASA 2012: United States Food and Drug Administration-Classification Algorithm for Suicide Assessment

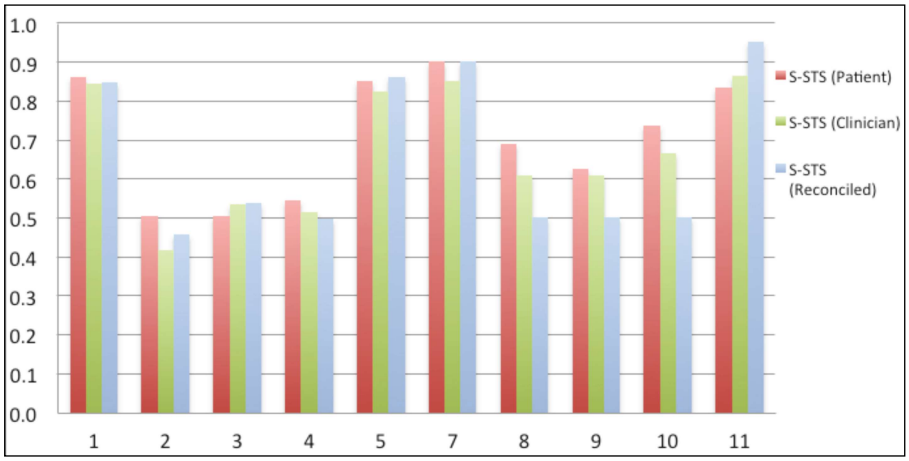

FIGURE 4. Comparison of the self-rated, clinician-rated, and reconciliation versions of the S-STS by FDA-CASA 2012 category using AUC by FDA-CASA 2012 categories

S-STS: Sheehan-Suicidality Tracking Scale; ISST-Plus: InterSePT Scale for Suicidal Thinking-Plus; FDA-CASA 2012: United States Food and Drug Administration-Classification Algorithm for Suicide Assessment; AUC: area under the curve

SUICIDE SIGNAL DETECTION TESTING

There is a growing recognition of the need for signal detection in pharmacovigilance.[20] While the S-STS is used to detect suicidal signals as adverse events, it has also been used to identify an anti-suicidal efficacy signal in randomized, double-blind, controlled efficacy studies, including the study that compared BMS 562086, escitalopram, and placebo for treatment of GAD (as previously discussed);[13] a study that compared citalopram augmented by lithium to citalopram with placebo in a four-week study of suicidality in major depressive disorder (MDD), dysthymia, and depressive disorder not otherwise specificed (NOS);[21] and a study that examined a new investigational compound in pre-dementia Alzheimer's disease.[22]

In the Coric et al study[13] comparing BMS 562086, escitalopram, and placebo (n=82, 61 with a post-baseline S-STS assessment) for treatment of GAD, there was a positive signal on the S-STS over eight weeks of treatment. A power analysis in this study showed that a sample size of 123 per treatment arm would be needed to detect this anti-suicidality efficacy signal for escitalopram on the S-STS at $p<0.05$ level in an adult GAD study. This sample size is less than the usual sample size per treatment arm in a typical multicenter clinical trial in central nervous system (CNS) research. It offers hope that the S-STS could be used as an efficacy signal detector in many CNS clinical trials searching for anti-suicidal effects from future investigation drugs.

Khan et al[21] used the S-STS to study the anti-suicidal effects of citalopram augmented by lithium versus citalopram with placebo (n=80). The subgroup of patients on lithium with a blood level of 0.5mEq/L or higher showed significantly higher S-STS remission rates (45% compared to 19%, $p<0.05$). In this same study, the Beck Suicide Scale did not have adequate sensitivity to detect this signal at a $p<0.05$ level.

Figure 5 shows the percent symptom reduction in suicidal thoughts and behaviors and depressive symptoms as measured by the S-STS and the Montgomery Asberg Depression Rating Scale (MADRS) in the Khan et al[21] study. It shows that the anti-suicidal effects of lithium (as measured by the S-STS)

can be disaggregated from any anti-depressant effects (as measured by the MADRS). According to Khan et al,[21] "The reduction of S-STS scores was large (43%) and twice that seen in MADRS scores (25%) among the 80 patients in the trial. Both response (χ^2=8.8, p<0.01) and remission rates (χ^2=4.6, p=0.03) showed similar patterns."

Comparison of S-STS to C-SSRS. The S-STS differs from the C–SSRS in several respects. First, the C–SSRS uses a hierarchical Guttman-like scale structure for suicidal ideation items and combinations. As Mundt et al[12] observe, the presence of suicidal ideation on the C–SSRS is ascertained at five levels of increasing degrees of ideation severities. These include passive ideation and four levels of active ideation (thoughts of killing self, thoughts of method for killing self, intentions to kill self, and development of plans for committing suicide). The last three levels of ideation are only evaluated on the C–SSRS if thoughts of killing oneself are first endorsed.[12] Effectively this means that if the patient does not have non-specific, active suicidal ideation, the rater cannot inquire about method, plan, or intent. This is not the case with the S-STS. The S-STS does not assume nor make use of a Guttman scaling procedure or assumptions in evaluating suicidal ideation and or behaviors. Second, the C–SSRS uses a yes/no response format for the suicidal ideation items, whereas the S-STS allows finer tuned ratings on an ordered scale from 0 to 4. While the C–SSRS does provide for an intensity rating, it is categorical (not ordered) and only applies to the most severe category endorsed, based on its 1 to 5 hierarchical categorization. This means that other categories, even though they may be experienced as more severe, are not rated for intensity because they are ranked lower on this *a priori* hierarchy. Third, the C–SSRS is generally clinician-rated, whereas the S-STS can be patient-rated or clinician-rated.

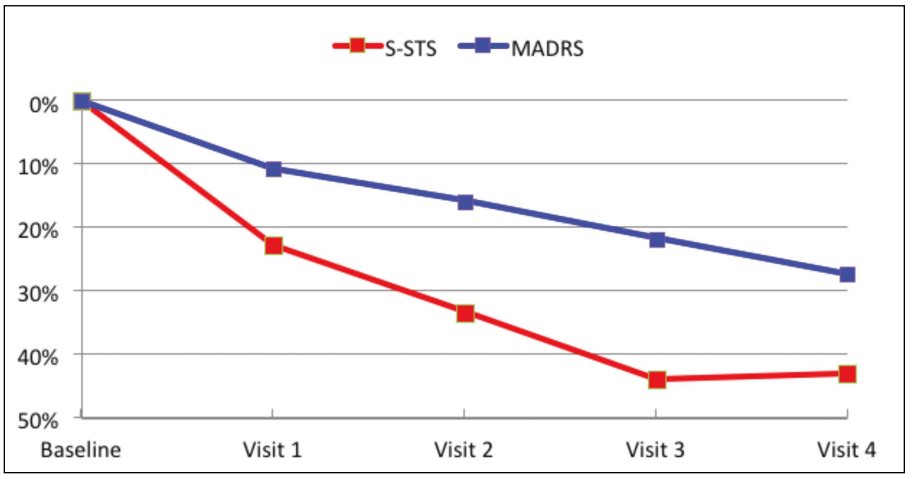

FIGURE 5. Use of the S-STS in detecting an efficacy signal with lithium

Data adapted from Khan et al (2011)[21]

S-STS: Sheehan-Suicidality Tracking Scale; MADRS: Montgomery Asberg Depression Rating Scale

TRAINING, CURRENT USE, AND APPLICATIONS

Training. The FDA requires training before suicidality instruments are used in clinical trials. Sponsors, rater training agencies, and clinical research organizations can handle the training on the S-STS as long as they adhere to the FDA's expectations on the FDA-CASA 2012 definitions. Training is not required for licensed practitioners using the S-STS in clinical practice.

Current use. The most current data on usage of the S-STS in clinical trials comes from the 2013 International Society for CNS Clinical Trials and Methodology (ISCTM) survey. This survey assessed use of different suicidality instruments by 1,447 industry employees at 178 companies large and small. In a study examining these survey results, Chappell et al[23] received back 129 responses from 50 companies, but analyzed only the data on the subset of 86 respondents who indicated direct involvement with suicidal ideation and behavior. Results of the survey indicated that the C–SSRS was used for tracking suicidality by 94 percent of the participants, the S-STS by 22.4 percent, and the ISST-Plus by 10.4 percent. Some respondents noted that they had used more than one instrument.

In addition, the S-STS is currently being used in a national initiative assessing suicidality in South African Veterans mandated by the Parliament of South Africa.[24] The National Institute of Mental Health and Neuro Sciences (NIMHANS) in India is using an adapted version in its 2014 India national mental health epidemiology study.[25,26] It is difficult to get a precise estimate on the number of studies that have used the S-STS. The first author of this article (D.S.) has given permission for its use in many studies, including those investigating biomarkers and genetic linkage, where the S-STS disaggregated suicidal phenomena may provide the fine-grained phenotyping needed in such studies.

Applications. Careful suicidality assessment and tracking are needed and indeed increasingly mandated and have become routine in psychiatric research, mental health, and medical as well as other settings.[2]

Clinical trials. In clinical trials, the S-STS is a potentially powerful tool to detect anti-suicidal signals from new medications.[13,21,22] It also offers a valuable alternative to the C–SSRS for assessing suicidal ideation and behavior

as an adverse event (AE) or serious adverse event (SAE).[13] As we observe in a companion paper, the S-STS captures a more complete range of suicidal ideation and behavior, reducing potential type II error (not capturing suicidal phenomena that do exist), and it is likely to have less type I error (identifying suicidal phenomena when they do not exist) because the S-STS avoids the flawed navigation instructions and hierarchical scaling assumptions inherent in the suicidal ideation section of the C–SSRS.[19]

Clinical practice. With increasing media attention to recent high profile suicides, incidents of "death by cop," suicides associated with conjoint homicides or school killings, and the call for proper screening of those buying guns, suicide assessments cannot be haphazard. They need to be systematic, careful, and thoughtful, with the aim of helping the vulnerable in a humane, understanding way. The S-STS provides a useful screening and tracking tool in mental health, primary care, and emergency room settings. It allows clinicians to collect the documentation recommended in the prescribing information for most psychiatric medications for assessing and monitoring suicidality before and during the course of treatment. This serves both to protect patients and to protect clinicians and healthcare provider groups and institutions medico-legally. Unlike alternative scales, such as the C–SSRS, the S-STS can be self-rated on paper or by computer before each visit while the patient waits to see a clinician. This assists the clinician in routinely monitoring the patient's suicidality.

Health maintenance and managed care organizations. Health maintenance and managed care organizations are taking increasingly active roles in suicide prevention to promote health and to contain costs associated with suicidal behaviors. The S-STS, with its sensitivity to signal detection and change,[13,21,22] has a potential role in this effort and can be integrated easily into an electronic medical record.

Epidemiology research. The S-STS has applications in national epidemiology studies to investigate national suicide statistics beyond the usual reporting of deaths by suicide. This may provide national health policy advisors with information to better plan and allocate funding in national efforts to reduce suicide. For example, S-STS is currently being used in adapted form, as noted above, in two major epidemiology initiatives—one in South Africa[24] and one in India (one of the largest epidemiology studies ever carried out in psychiatry[25,26]).

Military and military veterans. The increasing rate of suicide among members of the armed forces and veterans is another growing concern and has led to the implementation of programs to more carefully detect and monitor suicidality in these groups.[27] The ability to use the paper-based or electronic self-rated S-STS one page form provides a way to screen those from waiting lists with higher suicidality scores and to ensure they get higher priority and more urgent care.

Criminal justice. It is estimated that more than 400 suicides occur each year in local jails at a rate three times greater than in the general population, and, according to some estimates, suicide is now the third leading cause of death in prisons.[28,29] The S-STS, with its companion the Sheehan-Homicidality Tracking Scale (S-HTS),[30] is a potentially valuable tool for screening and follow-up of the incarcerated and those on parole. The S-STS can be used to detect suicidality and the S-HTS can detect both homicidality alone and combination homicidality/suicidality (e.g., murder-suicide) in these populations. The S-HTS is the only scale the authors are aware of that tracks these homicidal or homicidal/suicidal impulses, ideations, or behaviors with the necessary level of detail.

International security. The frequency of suicide terrorism is a growing concern internationally. While the determinants of suicide terrorist acts are complex, there is increasing evidence that antecedent suicidality may play a role in this phenomenon.[31] Surviving perpetrators are increasingly being apprehended and detained in hotspots, such as Israel, Palestine, Afghanistan, and Iraq, and some are being sent to rehabilitation programs (e.g., in programs in Saudi Arabia).[31] The third author of this article (I.S.) has called for international cooperation and sharing of information about this population as a preventative measure.[32] Consistent, systematic data collection on suicidality within this population using a tool such as the S-STS may be useful in detecting the extent to which antecedent and ongoing suicidality contributes to these acts. This could enable the international sharing and analysis of such data in order to better understand the suicide terrorist and to lead to better methods of prevention of such behavior. Because of its systematic collection of data[11] and its sensitivity to signal detection and change,[13,21,22] S-STS also has potential uses as a screening tool for victims of human security catastrophes, including war, famine, and displacement.

Schools and colleges. High profile suicides at schools and colleges/universities have alerted the public to the need for sensitive evaluation of students at all levels. As discussed earlier, as many as one fifth of college students have suicidal ideation, 4.3 percent had made a suicide plan, and 2.6 percent have made a serious suicide attempt.[15] The probability of a suicide attempt among subjects who had suicidal ideation and had made a plan captured on the self-rated S-STS was 46.2 percent.[15] Routine tracking of suicidality in this population when they come to the attention of college counselors is prudent, and the S-STS provides a useful tool for this purpose because it can be self-rated.

Concern about the need to monitor suicidality in vulnerable samples of children and adolescents, both on and off medications, persists. Indeed a recent study of automated healthcare claims from 11 health plans for 1.1 million adolescents, 1.4 million young adults, and 5 million adults from 2000 to 2010 found a significant, relative

increase in psychotropic drug poisonings in adolescents and young adults since the FDA mandated boxed warnings on antidepressants used in this population.[33] The Pediatric versions of the S-STS have been linguistically validated for 6- to 8-year olds, 9- to 12-year olds, and 13- to 17-year olds, making them potentially useful tools for screening and tracking suicidality by school counselors.[9]

CONCLUSION

The S-STS has evolved to meet higher expectations for a safety and efficacy scale to assess and monitor suicidality in clinical, research, educational, and security settings. This update and the related appendices should provide clinicians, researchers, and those charged with the responsibility to assess and monitor suicidality in institutional settings, simple and clear answers to frequently asked questions on the current (2014) status of the scale.

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APPENDIX A. Sheehan-Suicidality Tracking Scale (S-STS) (In the past (timeframe))

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 the past (timeframe):

1. did you have any accident? NO ☐ YES ☐
(this includes taking too much of your medication accidentally)
IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:

	Not at all	A little	Moderately	Very	Extremely
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?	0	1	2	3	4

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:

1b. did you intend to die as a result of any accident? NO ☐ YES ☐

In the past (timeframe), **how seriously did you:**	Not at all	A little	Moderately	Very	Extremely
2. think (even momentarily) that you would be better off dead, need to be dead or wish you were dead? How many times? ____	0	1	2	3	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: ☐ to kill yourself ☐ to plan to kill yourself mark either or both: was this: ☐ largely unprovoked ☐ provoked	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[1,2]). * 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? dd/MMM/yyyy	How?	How serious was each attempt? 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.			0	1	2	3	4	

Add rows as needed.

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? dd/MMM/yyyy	How?	How serious was each preparation? 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.			0	1	2	3	4	

Add rows as needed.

Levels of Preparation
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 ONLY

	NO	YES
17. Missed appointment - reason: subject died from a completed suicide?	0	100
18. Missed appointment - reason: subject died, but not enough information to code as a suicide?	0	0
19. Missed appointment - reason: subject died from cause(s) other than suicide?	0	0
20. Missed appointment - reason: subject alive, but not available because of a suicide attempt?	0	4
21. Missed appointment - reason: subject alive, but not available for known reasons other than suicide?	0	0
22. Missed appointment - reason: subject alive, but not available, for uncertain reasons, or "lost to follow up"?	0	0

Total Scale Score Add scores from Questions 1a + 2 through 11 + [the highest of 12 or any row of 16] + [the highest of 14 or any row of 15] + 17 + 20 [on page 3].

TOTAL ☐

☐ I have reviewed the answers on Pages 1 and 2 with the patient.

_____ _____

Clinician Signature dd/MMM/yyyy

☐ I have reviewed the answers on Pages 1 and 2 with my doctor or clinician.

_____ _____

Patient Signature dd/MMM/yyyy

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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.

APPENDIX B. Sheehan-Suicidality Tracking Scale (S-STS) CMCM Version (In the past (timeframe))

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 the past (timeframe):

1. did you have any accident? NO ☐ YES ☐
(this includes taking too much of your medication accidentally)
IF NO, SKIP TO QUESTION 2. IF YES, GO TO QUESTION 1a:

	Not at all	A little	Moderately	Very	Extremely
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:	0	1	2	3	4

1b. did you intend to die as a result of any accident? NO ☐ YES ☐

In the past (timeframe), **how seriously did you:**	Not at all	A little	Moderately	Very	Extremely
2. think (even momentarily) that you would be better off dead, need to be dead or wish you were dead? How many times? ____	0	1	2	3	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: ☐ to kill yourself ☐ to plan to kill yourself; mark either or both: was this: ☐ largely unprovoked ☐ provoked	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[1,2]). * 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? dd/MMM/yyyy	How?	How serious was each attempt? 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.			0	1	2	3	4	

Add rows as needed.

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? dd/MMM/yyyy	How?	How serious was each preparation? 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.			0	1	2	3	4	

Add rows as needed.

Levels of Preparation
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								
1	Any suicidal impulses, ideation and behavior from pages 1 & 2 of the S-STS	☐	☐	☐	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐	☐	☐	☐
18	First or second degree relative with a history of suicidal impulses, ideation or behavior (including attempts or completed suicide)	☐	☐	☐	☐	☐	☐	☐	☐

	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	☐	☐	☐	☐	☐	☐	☐	☐
24	Witnessed or caused serious 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	History of risk taking	☐	☐	☐	☐	☐	☐	☐	☐
30	Male over 55	☐	☐	☐	☐	☐	☐	☐	☐
	Health								
31	Depression or bipolar disorder	☐	☐	☐	☐	☐	☐	☐	☐
32	Panic attacks or high anxiety or agitation	☐	☐	☐	☐	☐	☐	☐	☐
33	Schizophrenia or schizoaffective 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	☐	☐	☐	☐	☐	☐	☐	☐
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)

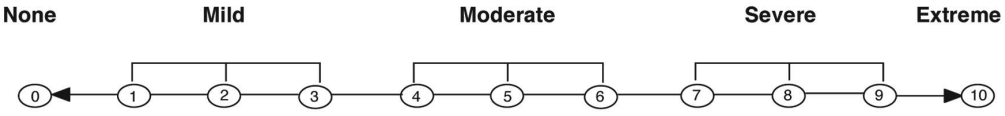
CLINICALLY MEANINGFUL CHANGE MEASURES (PATIENT RATED)

(Please mark ONE circle for each category.)

In the past (timeframe):

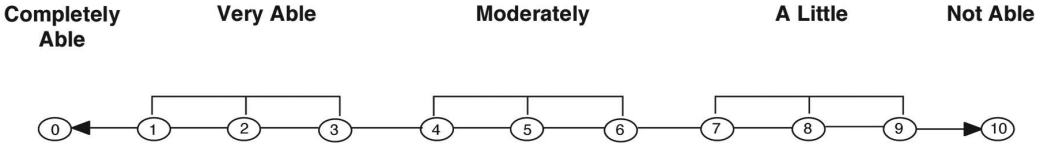
HOPELESSNESS

Rate your level of hopelessness:



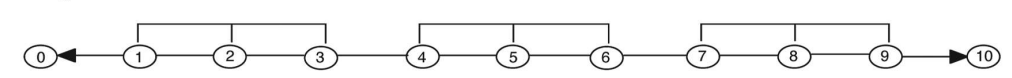
ABILITY TO COPE

Rate your ability to cope with your suicide impulses, thoughts, and behaviors:



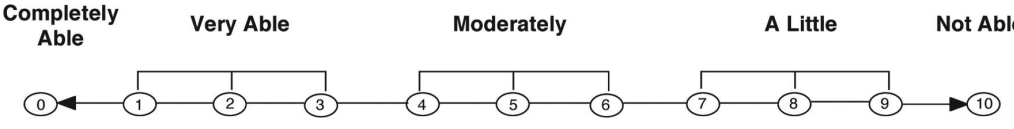
WILLINGNESS TO COPE

Rate your willingness to cope with your suicide impulses, thoughts, and behaviors:



ABILITY TO STAY SAFE

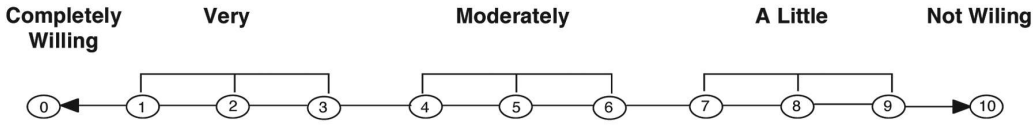
Rate your ability to keep yourself safe:



In the past (timeframe):

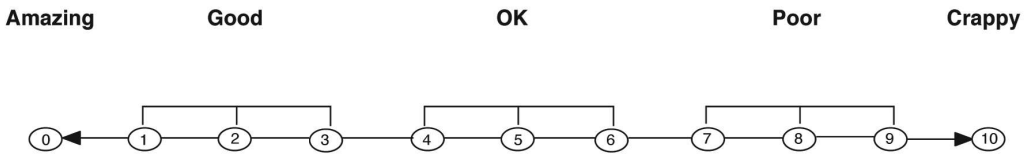
WILLINGNESS TO STAY SAFE

Rate your willingness to keep yourself safe:



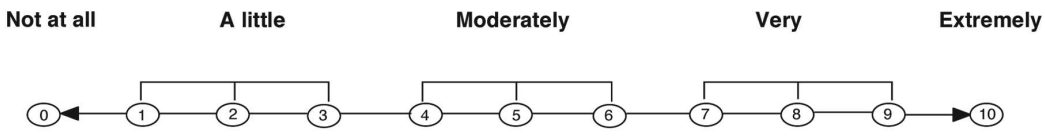
OVERALL QUALITY OF LIFE

Rate your current overall quality of life:



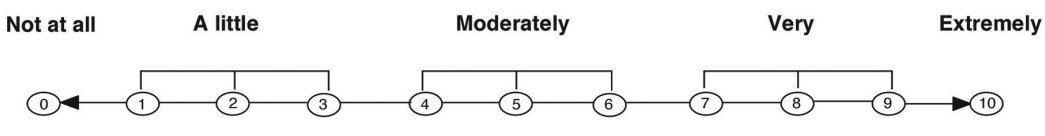
DELIBERATE SUICIDALITY

How deliberately were you thinking about or planning to kill yourself:



IMPULSIVELY SUICIDAL

How strong was the impulse to act in any suicidal way:



SHEEHAN - SUICIDALITY TRACKING SCALE (CMCM Version)

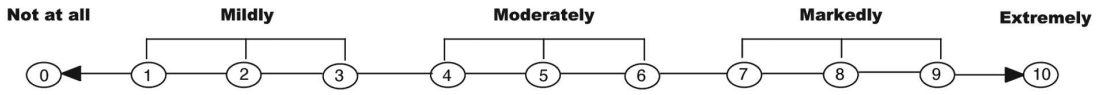
LIFE IMPAIRMENT FROM SUICIDALITY (PATIENT RATED)

Please mark ONE circle for each category.

In the past (timeframe):

WORK* / SCHOOL

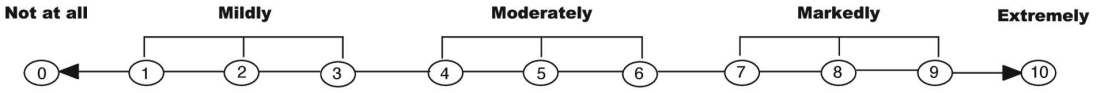
The suicide symptoms have disrupted your work / school work:



☐ I have not worked /studied at all during the past timeframe **for reasons unrelated to the suicide symptoms**.
* Work includes paid, unpaid volunteer work or training. If your symptoms interfered with your ability to find or hold a job or contributed in any way to your currently not working, you must give a score on this scale.

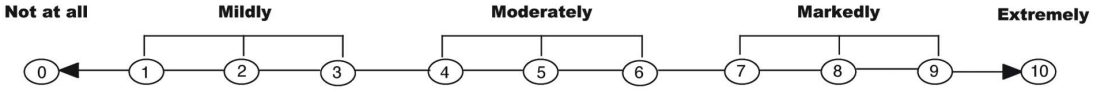
SOCIAL LIFE

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? _____

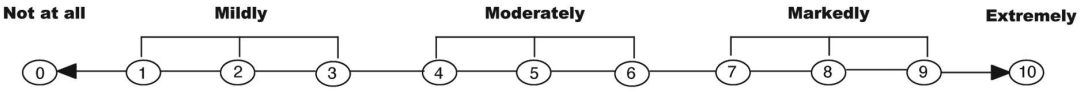
DAYS UNDERPRODUCTIVE

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):

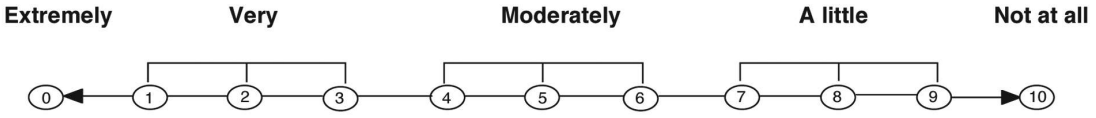
QUALITY OF LIFE DISRUPTION BY SUICIDALITY

The suicide symptoms have disrupted the quality of your life:



DESIRE TO RECOVER FROM SUICIDALITY

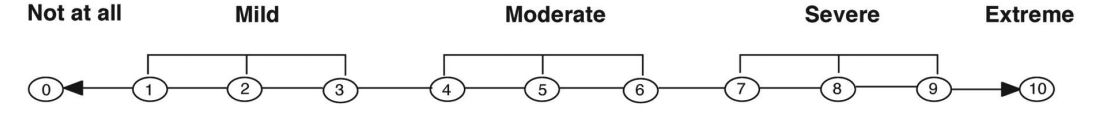
Rate your desire to recover from your suicide impulses, thoughts and behaviors:



If you can't imagine the possibility of recovery, choose "10"

GLOBAL SEVERITY OF SUICIDAL IMPULSES, THOUGHTS, AND BEHAVIORS

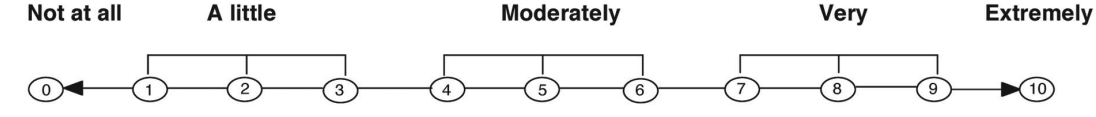
Rate the overall severity of all your suicide impulses, thoughts, and behaviors:



Over the next (timeframe):

HOW LIKELY ARE YOU TO TRY TO KILL YOURSELF?

Rate how likely you are to try to kill yourself:



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 or if I need to be admitted to the hospital ward or 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 or partial hospitalization or 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:

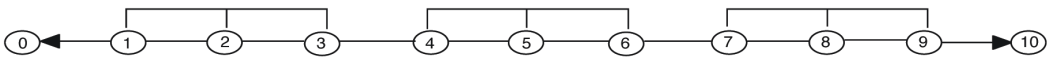
- Suicidal ideation
- Suicidal planning
- Suicidal intent and patient's perception of how likely they are to attempt suicide again in the future
- Suicidal behaviors (including impulsive suicidality)
- Suicide risk / protective factors
- Ability and willingness to cope with and to stay safe from suicidality
- 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

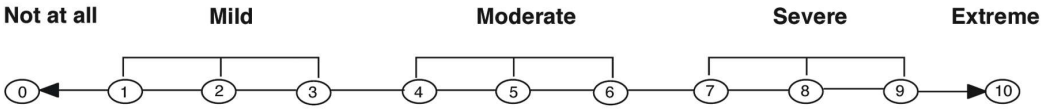
Anchor your judgment of the suicide risk and level of clinically meaningful management needed, with a single score, based on the table below:



Score	Judgment of Suicide Risk	Judgment on Level of Management Needed for Suicidality
10	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 or 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.

FOR CLINICIAN USE ONLY

	NO	YES
17. Missed appointment - reason: subject died from a completed suicide?	0	100
18. Missed appointment - reason: subject died, but not enough information to code as a suicide?	0	0
19. Missed appointment - reason: subject died from cause(s) other than suicide?	0	0
20. Missed appointment - reason: subject alive, but not available because of a suicide attempt?	0	4
21. Missed appointment - reason: subject alive, but not available for known reasons other than suicide?	0	0
22. Missed appointment - reason: subject alive, but not available, for uncertain reasons, or "lost to follow up"?	0	0

Total Scale Score Add scores from Questions 1a + 2 through 11 + [the highest of 12 or the aggregate of 16] + [the highest of 14 or the aggregate of 15] + 17 + 20 [on page 13].

TOTAL ☐

☐ I have discussed the answers above with the patient.

_____ _____

Clinician Signature dd/MMM/yyyy

☐ I have discussed the answers above with my doctor or clinician.

_____ _____

Patient Signature dd/MMM/yyyy

References

1. 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. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/ 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

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.

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
10 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 the aggregate of 16), (highest of 14 or the aggregate 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 NOT 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:

1. 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. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/ 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.

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:"

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.

The **S-STS CMCM version** (**C**linically **M**eaningful **C**hange **V**ersion) assesses the following domains:

1. Suicidality **phenomena**
    - passive ideation and impulses
    - active ideation and impulses
    - method and means (how and with what)
    - plan (when & where)
    - intent
    - preparatory suicidal behaviors (aborted, interrupted and neither aborted nor interrupted)
    - non-suicidal self harm behaviors
    - suicide attempts (halted by self or by another person or event or completed as intended)
    - accidents involving any suicidality
    - death from suicide or other causes
2. Suicide **risk / protective factors**
3. Suicidality **Confounding** Features
    - method and means (how and with what)
    - hopelessness
    - ability & willingness to cope and to stay safe from suicidality
    - overall quality of life
    - deliberate suicidality
    - impulsive suicidality
    - quality of life disrupted by suicidality
    - desire to recover from suicidality
    - Patient's judgment on Likelihood of a suicide attempt (Use the same timeframe in looking forward as used in the look-back for the assessment. This timeframe will vary by study or clinical setting, based on the goals).
4. **Functional impairment** from suicidality
5. **Clinician's judgment of suicide risk**
6. Clinician's and patient's **judgment of needed treatment / disposition**
7. **Global severity of suicidality** (clinician's and patient's judgment)
8. 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.

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

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 completed 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 suicidal 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

S-STS to C-CASA 2010 Mapping Table

Status Update on the Sheehan - Suicide Tracking Scale (S-STS) 2014

Appendix F

Sheehan-Suicidality Tracking Scale (S-STS) Standard version

Mapping Table to categories in Columbia-Classification Algorithm for Suicide Assessment (C-CASA)

and for 2010 FDA Guidance Document for Suicidality Assessment

12/12/12

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 $\geq$ 1 on that question.

12/12/12

S-STS to FDA-CASA 2012 Guidance Document Mapping Table

Status Update on the Sheehan - Suicide Tracking Scale (S-STS) 2014

Appendix G

Sheehan-Suicidality Tracking Scale (S-STS)

Mapping Table to categories in the 2012 FDA Guidance Document on

Assessment of Suicidal ideation and Behavior

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

11/12/13

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 $\geq$ 1 on that question. All the above "Suicidal Ideation and Behavior Category" definitions are based on and should fully reflect and follow the definitions outlined in

1. 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. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm/ 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.

* 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.

11/12/13

Appendix H

Why the S-STS avoids the Guttman Scaling structure and assumptions of cumulativeness associated with the C-SSRS and the FDA-CASA 2012 categories

A Guttman scale is a cumulative scale, designed to measure progressively higher levels of a single unidimensional trait, attribute, concept or phenomenon. It typically uses a dichotomous yes/no response format. The C-SSRS appears to use Guttman scaling to investigate to what degree 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 4. Agreement with the presence of a suicide plan assumes agreement with the presence of intent. There is an inherent assumption that patients progress from passive ideation, to active ideation, to method, to intent and finally to plan, as if progressively going higher on a stairs. Arriving on any stair assumes that the subject has stepped on the prior stairs. While this model of suicidal ideation may apply to some cases of suicidality, it is by no means generalizable to all cases or comprehensive as a model of the movement of suicidal phenomena over time.

Usual practice in the development of a Guttman scale calls for the arrangement of all reasonable items investigating the trait along a hierarchy of cumulativeness. A scalogram analysis on a sample of subjects examines how closely the set of items corresponds with the cumulativeness of the trait along the dimension identified. If a scale item is out of synchrony ("an error") with the perceived cumulative nature of the dimension, it is dropped. If a scale had less than 10% "erroneous data", Guttman considered it acceptable. However, if too many items that are associated with a high number of errors are dropped to achieve an error rate of less than 10%, the resulting reduced number of scale items gives an overly optimistic impression of the reproducibility and generalizability of the scale and this is not acceptable.

This appears to be the issue with the final choice of the 5 FDA-CASA 2012 and the 5 corresponding C-SSRS *categories*. A starting point in developing such a Guttman scaling procedure for suicidal ideation would be the arrangement of all the combinations of the 5 suicidal ideation *phenomena* of passive ideation, active ideation, method, intent and plan (32 combinations). Testing all of these in an adequate sample of suicidal subjects would find "errors" in the theorized cumulativeness (i.e. combinations that were exceptions to the theorized order of cumulativeness). The "errors" would be dropped, leaving 5 combinations, on a scale that now has less than 10% errors. However the deleted items reflect clinical combinations that do exist, but which are now ignored. This gives an overly optimistic impression of the reproducibility, the generalizability and the comprehensiveness of the hierarchy of categories and of the associated scale. Instead in reality, the true reproducibility of how well the five chosen suicidal ideation *categories* correspond with cumulativeness is below an acceptable coefficient of reproducibility.

7/7/14

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.[1]

In contrast, the S-STS uses no such Guttman scaling structure or assumptions of cumulativeness along a single dimension of suicidal ideation, and can capture all possible combinations that occur. This makes it more comprehensive and generalizable.

1. 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):xx–xx.