Guidance for Industry

Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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Revision 1

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

The purpose of this guidance is to assist sponsors in prospectively assessing the occurrence of treatment-emergent suicidal ideation and behavior in clinical trials of drug and biological products.[2] The focus of this guidance is on clinical trials conducted under investigational new drug applications, or trials that are intended for submission in a new drug application or a biologics license application. Specifically, this guidance addresses the Food and Drug Administration's (FDA's) current thinking regarding the importance of assessment of suicidal ideation and behavior in psychiatric and nonpsychiatric drug trials falling under the authority of the FDA, and the general principles for how best to accomplish this assessment during drug development. This guidance is not intended to give advice on how best to screen patients for entry into clinical trials, even though instruments used for assessing patients during the conduct of trials can also be used for screening patients. Making decisions about which patients to enter into a particular trial is a separate matter that is determined largely by the questions that the trial is intended to address.

The principles discussed in this guidance for the prospective assessment of suicidal ideation and behavior involve actively querying patients about the occurrence of suicidal thinking and behavior, rather than relying on patients to report such occurrences spontaneously, followed by retrospective classification of events into appropriate categories. This guidance offers advice about criteria that should be met for a suicidal ideation and behavior assessment instrument that can be used to conduct such prospective assessments.

[1] This guidance has been prepared by the Division of Psychiatry Products in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

[2] For the purposes of this guidance, all references to *drugs* include both human drugs and therapeutic biological products unless otherwise specified.

This guidance is intended to serve as a focus for continued discussions among the FDA, pharmaceutical sponsors, the academic community, and the public.[3] This guidance does not address the complex analytic issues involved in the analysis of the suicidal ideation and behavior data that will be derived from prospective assessments of suicidal ideation and behavior; these issues will be addressed in a separate guidance.

This guidance revises the draft guidance for industry *Suicidality: Prospective Assessment of Occurrence in Clinical Trials* issued in September 2010. This revision:

- Replaces the term *suicidality* with the phrase *suicidal ideation and behavior*
- Provides an expanded set of the Columbia Classification Algorithm for Suicide Assessment (C-CASA) categories, along with definitions and explanations
- Revises the advice on particular trials and patients that would need assessments of suicidal ideation and behavior, and the timing of such assessments
- Addresses concerns about the time burden of assessments
- Addresses questions about the possible value of the assessments providing protection for patients in the trials themselves
- Makes it clear that use of an assessment instrument that directly classifies relevant thoughts and behaviors into C-CASA categories eliminates the need for any additional coding
- Provides multiple additional references
- Revises advice on evaluation of alternative instruments

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

There has been a great deal of attention paid to treatment-emergent suicidal ideation and behavior in recent years, and to the question of how best to assess these types of events in future trials. The attention has resulted in part from findings of apparent treatment-emergent suicidal ideation and behavior caused by several different types of drugs. Meta-analyses of placebo-

[3] In addition to consulting guidances, sponsors are encouraged to contact the relevant review division to discuss specific issues that arise during the development of specific drugs.

controlled antidepressant trials, both pediatric (Hammad, Laughren, et al. 2006) and adult (Stone, Laughren, et al. 2009), revealed a signal for drug-related treatment-emergent suicidal ideation and behavior at the younger end of the age spectrum. A meta-analysis of placebo-controlled trials of antiepileptic drugs, including drugs with diverse pharmacology in studies of epilepsy as well as psychiatric indications, also revealed a signal for drug-related treatment-emergent suicidal ideation and behavior.[4] In all of the trials in these meta-analyses, the suicidal ideation and behavior events were identified and classified retrospectively; that is, the trials were not designed to identify such events prospectively. Perhaps as a result, relatively few cases were identified in this effort, the case descriptions were not complete, and baseline status was not well-defined.

The concern about treatment-emergent suicidal ideation and behavior has arisen for other drugs as well, based largely on spontaneous reports and published case reports. Drugs with such reports have included isotretinoin and other tretinoins, beta blockers, reserpine, smoking cessation drugs, and drugs for weight loss. In view of the wide range of drugs involved, it is reasonable to consider whether prospective assessments for suicidal ideation and behavior should be included in clinical trials involving at least selected drugs for nonpsychiatric indications.

There are two reasons for prospectively assessing suicidal ideation and behavior in clinical trials. The first is to ensure that patients in clinical trials who are experiencing suicidal ideation and behavior are properly recognized and adequately treated. The second is to ensure the collection of more timely (i.e., closer to the event) and more complete data on suicidal ideation and behavior than have been collected in the past, so that increased suicidal ideation and behavior in individual trials and in pooled analyses are easier to detect. This is important whether or not a particular drug is known to be associated with treatment-emergent suicidal ideation and behavior. Collection of such data will also provide scientifically sound evidence to evaluate concerns about a possible association with suicidal ideation and behavior for a drug that is based only on individual case reports.

The following sections provide general recommendations for prospective assessment of the occurrence of suicidal ideation and behavior, applicable to any drug, followed by a discussion of which drugs should be assessed for suicidal ideation and behavior in addition to drugs for psychiatric indications.

III. PROSPECTIVE ASSESSMENT OF SUICIDAL IDEATION AND BEHAVIOR OCCURRENCE — GENERAL RECOMMENDATIONS

A. Suicidal Ideation and Behavior Assessment Instruments

The Columbia-Suicide Severity Rating Scale (C-SSRS),[5] one of several available suicidal ideation and behavior instruments, defines five subtypes of suicidal ideation and behavior that

[4] See the Suicidal Behavior and Ideation and Antiepileptic Drugs FDA Web page at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM100190.

[5] See http://www.cssrs.columbia.edu.

we consider important to capture in any prospective assessment. In addition, we believe it is useful to capture instances of self-injurious behavior with no suicidal intent, because it is important to distinguish these behaviors from actions with suicidal intent. The ability to make this distinction helps ensure that what is labeled as a suicide attempt does in fact meet criteria for such a designation. Thus, the current preferred terms that we consider important include five levels of suicidal ideation, five levels of suicidal behavior, and the category *self-injurious behavior, no suicidal intent*. We have adopted these 11 categories as the standard for classifying suicidal ideation and behavior events. These categories are defined in Appendix A. It should be noted that the definitions provided for the five levels of suicidal behavior have been adopted by the Centers for Disease Control and Prevention (Crosby, Ortega, et al. 2011).

- Suicidal ideation
  1. Passive
  2. Active: Nonspecific (no method, intent, or plan)
  3. Active: Method, but no intent or plan
  4. Active: Method and intent, but no plan
  5. Active: Method, intent, and plan[6]

- Suicidal behavior
  1. Completed suicide
  2. Suicide attempt
  3. Interrupted attempt
  4. Aborted attempt
  5. Preparatory actions toward imminent suicidal behaviors

- Self-injurious behavior, no suicidal intent

We recommend use of a suicidal ideation and behavior assessment instrument that directly classifies suicidal ideation and behavior into the 11 preferred categories, defined in Appendix A. As stated above, the C-SSRS is a prospective assessment instrument that directly classifies suicidal ideation and behavior into these 11 preferred categories,[7] and this instrument would be acceptable for the purpose of these studies. The C-SSRS involves a series of probing questions to inquire about possible suicidal thinking and behavior, and this process is conducted at baseline (this would be a lifetime suicidal ideation and behavior assessment) and at each patient visit. Although completion of the C-SSRS is, in many instances, based entirely on the patient interview, it also allows for integration of information from other sources (e.g., family, friends, or significant others; caregivers or health professionals; hospital or emergency room records; coroner's report or death certificate). In fact, the C-SSRS is not considered complete for any particular visit until information from all potential sources has been evaluated and integrated.

Important psychometric properties of the C-SSRS have been established and reported in several papers. A recent paper reported on the instrument's construct validity (its ability to detect

[6] According to C-SSRS, the definition of *plan* includes intent (i.e., intent to complete the suicide is implicit with the concept of plan). Thus, there is no need for the category *method and plan, but no intent.* (See Appendix A.)

[7] See http://www.cssrs.columbia.edu.

suicidal ideation and behavior) based on correlation with other measures of suicidal ideation and behavior assessed in three multisite clinical trials (Posner, Brown, et al. 2011). The instrument performed well relative to other instruments, and had high sensitivity and specificity of suicidal behavior classifications relative to another behavior instrument and to assessments by an independent suicide evaluation board. Inter-rater reliability for the C-SSRS has been well-established in earlier studies (Pumariega, Millsaps, et al. 2011; Brent, Greenhill, et al. 2009).

The information pertinent to suicidal ideation and behavior collected in the C-SSRS interview is classified into the set of 11 preferred categories described above as the interview is conducted. The direct classification of information collected in the C-SSRS interview into these 11 categories, along with integration of information about the event from other sources, renders it unnecessary to conduct any other classification step (i.e., this process replaces the retrospective classification of data that was needed for the FDA's meta-analyses of suicidal ideation and behavior). For example, after it is determined, based on the C-SSRS interview and information from other sources, that a potentially self-injurious event was an actual suicide attempt, this fact is noted on the C-SSRS form, and no further classification is needed. It is important to note that the C-SSRS form is not complete until all available relevant data have been accessed and integrated into the assessment. Data entries for C-SSRS classified events then become the basis for analyses of future trials focused on suicidal ideation and behavior.

The C-SSRS is a detailed interview, but the full interview is needed only if the initial screening questions about suicidal ideation and behavior are positive. Although the screening questions should be completed at baseline and at every visit for every patient, they are not by themselves burdensome, typically taking only 1 to 2 minutes for patients who have no positive findings. Even for a patient with multiple positive findings, the full interview typically takes less than 10 minutes. Data from almost 15,000 administrations of an electronic self-report version of the C-SSRS (i.e., the eC-SSRS) found an average completion time of 3.5 minutes for patients without positive findings, and about 7 to 8 minutes for patients with positive findings (Mundt, Greist, et al. 2010a). The eC-SSRS uses probe questions similar to those used by a human interviewer in the paper form of the C-SSRS. It is an alternative approach to obtaining data on suicidal ideation and behavior (Mundt, Greist, et al. 2010b).

The following information can be used by sponsors to evaluate the appropriateness of other proposed instruments:

- *<u>Categories</u>: The instrument ideally should include all the categories of suicidal ideation and behavior identified in the 11 preferred terms defined in Appendix A.*

- *<u>Definitions</u>: The instrument should include definitions for all of these categories (these definitions ideally should coincide with the definitions in Appendix A).*

- *<u>Probes/Questions</u>: The instrument should include probes or questions that permit determination of whether or not each of these ideas or behaviors occurred.*

- *<u>Other information</u>: The instrument should provide for integration of information from other sources (e.g., family, friends, or significant others; caregivers or health*

professionals; hospital or emergency room records; coroner's report or death certificate) to permit accurate completion of the assessment.

- *Direct classification into the 11 preferred terms (see Appendix A): Use of the C-SSRS instrument accomplishes this goal directly, and other instruments used for this purpose ideally would be capable of doing this as well. Other instruments that do not accomplish this classification directly can still be useful for the purpose of protecting patients in a trial. In these instances, however, it may not be possible to use data from these trials in future meta-analyses exploring for treatment-emergent suicidal ideation and behavior in multiple treatment programs.*

- *Training: There should be provisions for formal training of raters to ensure accuracy and consistency in application of the instrument.*

Although we consider the C-SSRS an acceptable prospective suicidal ideation and behavior assessment instrument, other instruments, as noted above, could also be acceptable if they directly classify events of interest into the 11 categories of suicidal ideation and behavior described above. Sponsors should, however, discuss the acceptability of alternative instruments with the FDA before using them in clinical trials. Although alternative instruments could be acceptable, it should be noted that the use of different assessment instruments in different programs is likely to increase measurement variability across programs, decreasing the opportunity to identify potential signals in future meta-analyses that include data from multiple programs. This type of imprecision is particularly problematic in dealing with events that have a low incidence, as is the case for suicidal ideation and behavior occurring in clinical trials.

B. Managing Suicidal Ideation and Behavior Data

This section provides general advice regarding management of data from prospective assessments of suicidal ideation and behavior in clinical trials. Detailed advice about the structure of data tables and other data recommendations for preparing a suicidal ideation and behavior submission to the FDA will be addressed in a separate guidance, as will analytic and statistical considerations. Although a composite of suicidal ideation and behavior was the primary endpoint in previous FDA meta-analyses, it is likely that future meta-analyses will consider suicidal behavior and ideation separately, because they may have different predictive value for subsequent suicidal behavior.

We believe that an important feature of an instrument used for prospective assessment of suicidal ideation and behavior, especially with regard to future meta-analyses, would be that it directly classifies events of interest into the 11 categories of interest as part of the assessment process. Such instruments would not require the creation of narratives for blinded assessment of suicidal ideation and behavior by experts, as was the case for previous FDA meta-analyses. The databases generated from use of the C-SSRS or other assessment instruments judged to be acceptable for this purpose would serve directly as the basis for any subsequent analyses.

It is possible for a patient to have more than one type of event during an interval. For example, during a reporting interval, a patient might have experienced separate instances of suicidal

ideation, self-injury without suicidal intent, suicide attempt, and completed suicide. We acknowledge that it is often difficult to determine whether a sequence of such events represents a continuum of related events, in which case it would be most reasonable to classify such a continuum according to the most serious event, or whether these are really distinct events, in which case it would be reasonable to consider them separately. This is a judgment best made by the interviewer, or if a self-reporting approach is used, by the patient. If the events are discrete, they can still be captured in a single C-SSRS interview and rating form. In previous meta-analyses, we counted only the most serious suicidal ideation or behavior event during an interval, and this may still be the optimal approach. Nevertheless, different approaches might also be used in future analyses. Consequently, all events that can be determined to be discrete events should be separately classified and recorded for the interval being assessed.

C. Specific Trial Considerations

1. Identifying Trials in Which Suicidal Ideation and Behavior Assessment Should be Carried Out

In general, suicidal ideation and behavior should be assessed in every trial after it has been determined that the drug is appropriate for this assessment (see section IV). The full assessment of suicidal ideation and behavior generally should involve a pooled analysis of all controlled trials, so that it will not be possible to conclude that a drug has no effect on suicidal ideation and behavior until a substantial database is available for this analysis. A separate guidance on statistical issues involved in the analysis of suicidal ideation and behavior will address general principles to consider in reaching a judgment on this issue. Sponsors who believe they have sufficient data to address this issue should seek advice from the relevant review division.

2. Populations in Which Assessment of Suicidal Ideation and Behavior Would be Difficult

It is reasonable to omit, or consider alternative assessments in, trials involving patients with cognitive impairment so substantial as to interfere with an understanding of the concept of suicide. Such populations can include certain patients with Alzheimer's disease (those with severe cognitive impairment), other dementias, mental retardation, and autism. Critically ill patients would also be difficult to assess for suicidal ideation and behavior.

Instruments such as the C-SSRS have been used successfully in children and adolescent patients with various psychiatric disorders that do not involve cognitive impairment. Nevertheless, assessing young children also can be challenging because many may not have reached sufficient cognitive maturity to understand the concept of death.

A sponsor considering the omission of standard suicidal ideation and behavior assessments (where these generally would be conducted) from a specific clinical trial in a particularly challenging population should discuss this omission with the review division to obtain prior agreement. In certain instances, alternative instruments may permit the assessment of suicidal ideation and behavior or other adverse psychological events.

3. Dosing Considerations

a. Single-dose trials

Because the time course of the risk for drug-induced suicidal ideation and behavior is unknown and likely differs by drug or drug class, it cannot be assumed that short-term trials pose no risk to patients and healthy volunteers. However, treatment-emergent suicidal ideation and behavior have rarely been reported in relatively short-term multiple-dose phase 1 trials in healthy volunteers. The risk of such an event would be even lower in single-dose trials in healthy volunteers. In addition, such trials are generally conducted in well-controlled settings with almost continuous observation, so that any treatment-emergent events would be readily detected. Therefore, we have concluded that multiple-dose trials in healthy volunteers should include such assessments, but that it is reasonable to omit such assessments from single-dose trials in healthy volunteers.

b. Microdose trials

It is reasonable to omit suicidal ideation and behavior assessments in microdose trials involving low doses that are not expected to have any measurable pharmacological effects. Microdose trials are typically employed for imaging agents in the assessment of receptor occupancy.

4. Timing of Assessments

In general, in outpatient trials for which assessment of suicidal ideation and behavior are considered appropriate, assessments should be conducted at baseline (the lifetime suicidal ideation and behavior assessment) and at all planned visits at which other clinical assessments are to be carried out.[8] For certain drugs (e.g., those with particularly long elimination half-lives), it may make sense to include follow-up assessments even after dosing has stopped. These assessments should also be conducted at any unplanned visits at which other clinical assessments are needed.

Determining what constitutes a visit generally is straightforward for an outpatient trial, but not necessarily for an inpatient trial. For an inpatient trial, suicidal ideation and behavior assessments ordinarily would be done at the same times as other symptom assessments, but would not be needed at the times of nonsymptom assessments (e.g., vital signs). Sponsors should seek advice from the review division if there are questions about the appropriate frequency and timing of assessments for particular trials.

[8] Some have argued that there is no evidence that these types of assessments in the context of clinical trials provide any protection for patients in these trials, but are only useful for making population decisions about drugs over relatively long periods of time. Although earlier trials looking at suicidal ideation overall (without regard to severity) did not find evidence for the predictive value of detecting ideation for suicidal behavior over the short-term, two recent analyses from independent sources found that severity of suicidal ideation detected in baseline C-SSRS assessments predicted suicidal behavior over a relatively brief follow-up period (Posner, Brown, et al. 2011; Mundt, Posner, et al. 2011). These recent findings support the use of assessments for suicidal ideation and behavior in clinical trials as a way of providing additional protection for patients in the context of such trials.

5. Implementation During Ongoing Trials

Determining how to implement suicidal ideation and behavior assessments in ongoing trials may involve some discussion with the FDA. Suicidal ideation and behavior data derived from a trial in which suicidal ideation and behavior assessments were added after the trial was well along would not be optimal for inclusion in a meta-analysis. It should be noted, however, that there is a version of the C-SSRS that is specifically designed for already-enrolled patients. Whether or not such data will be useful in a meta-analysis, it may still be important to add suicidal ideation and behavior assessments for the protection of patients involved in the ongoing trial. For a trial that is well along, it would not be feasible to go through the formal process of amending the protocol and obtaining investigational review board concurrence. Nevertheless, even in these instances, it may be useful to alert investigative sites of the general concern about possible drug-induced suicidal ideation and behavior, so they can individually decide how to address this issue.

6. Prospective Assessments in Large Simple Trials

The question has been raised as to whether prospective assessments for suicidal ideation and behavior would be needed in certain trials (e.g., a large simple phase 4 trial for which data collection is minimized). An instrument such as the C-SSRS adds little burden to such a trial, as long as visit frequency is not altered, and increasingly these types of assessments are becoming part of clinical practice. Nevertheless, sponsors who have questions about what might be needed in a particular trial should ask the relevant review division about this.

IV. PROSPECTIVE ASSESSMENT OF SUICIDAL IDEATION AND BEHAVIOR OCCURRENCE — SPECIFIC INDICATION RECOMMENDATIONS

Past experience specifically indicates that assessment of suicidal ideation and behavior should be a regular part of development programs involving antidepressants and antiepileptic drugs. But the heightened risk of suicide in most psychiatric illnesses strongly suggests that suicidal ideation and behavior should be assessed as part of the evaluation of any drug being developed for a psychiatric condition (i.e., those indications managed in the Division of Psychiatry Products). There are no data to support the view that patients with nondepressed psychiatric disorders have any lesser vulnerability to treatment-induced suicidal ideation and behavior than patients with overt depression. On the contrary, based on limited exploratory analyses of the trials using antidepressants in adults, including many trials in psychiatric patients with disorders other than depression, there is some evidence that the relative risk may actually be greater in nondepressed psychiatric patients (Stone, Laughren, et al. 2009). Moreover, in the meta-analysis for suicidal ideation and behavior with antiepileptic drugs, the odds ratio for suicidal ideation and behavior was greater for epilepsy patients than it was for the psychiatric patients treated with these drugs, even though the absolute rates were higher in psychiatric patients compared to epilepsy patients.[9]

[9] See the Suicidal Behavior and Ideation and Antiepileptic Drugs FDA Web page at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM100190.

Therefore, other than the exceptions noted in section III.C., prospective suicidal ideation and behavior assessments should be carried out in all clinical trials involving any drug being developed for any psychiatric indication, as well as for all antiepileptic drugs and other neurologic drugs with central nervous system (CNS) activity, both inpatient and outpatient, including multiple-dose phase 1 trials involving healthy volunteers. Questions about what constitutes CNS activity should be addressed to the Division of Neurology Products.

Tempting as it may be to think that patients without a psychiatric condition receiving nonpsychiatric drugs would not be at risk for drug-induced suicidal ideation and behavior, experience suggests that this belief may be erroneous. Although there are few controlled trial data in these settings, there has been long-standing concern about a variety of drugs, including isotretinoin and other tretinoins, beta blockers (especially those entering the brain), reserpine, drugs for smoking cessation, and drugs for weight loss, for which possible signals of risk for suicidal ideation and behavior have already been identified. Therefore, at a minimum, we recommend that prospective suicidal ideation and behavior assessments be carried out in all clinical trials for all drugs that are pharmacologically similar to drugs in the above list. These assessments, however, might reasonably be used more broadly, perhaps with any drug that appears to have a CNS effect. Sponsors are encouraged to contact the relevant review division to discuss whether these assessments are recommended for an individual drug.

Assessments should be conducted in both inpatient and outpatient trials, and even multiple-dose phase 1 trials involving healthy volunteers, with the exceptions noted in section III.C. This list of suspect drugs will expand if new possible signals are detected, and it is plausible that certain drugs and pharmacologic profiles will prove not to be inducers of suicidal ideation and behavior. This cannot be known if the drugs are not studied. One of the advantages of conducting suicidal ideation and behavior assessments more broadly is that future meta-analyses may either confirm the signal or provide reassurance that the signal is false. The possibility that suicidal ideation and behavior assessments should be conducted as part of essentially all drug development programs, even for drugs not yet recognized as having CNS effects, has also been considered, but this guidance does not recommend that approach. Further experience may change our view on this issue and comments on this current recommended approach are welcome. Questions about whether a particular drug under development would need assessments for suicidal ideation and behavior should be directed to the review division that has responsibility for the indication in question.

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APPENDIX A: SUICIDAL IDEATION AND BEHAVIOR CATEGORIES AND DEFINITIONS (Posner, Oquendo, et al. 2007)[10]

Suicidal Ideation

Passive suicidal ideation: wish to be dead

Patient has thoughts about a wish to be dead or not alive anymore, or wish to fall asleep and not wake up.

Active suicidal ideation: nonspecific (no method, intent, or plan)

General nonspecific thoughts of wanting to end one's life or commit suicide (e.g., "I've thought about killing myself") without general thoughts of ways to kill oneself/associated methods, intent, or plan during the assessment period.

Active suicidal ideation: method, but no intent or plan

Patient has thoughts of suicide and has thought of at least one method during the assessment period. This situation is different than a specific plan with time, place, or method details worked out (e.g., thought of method to kill self but not a specific plan). Includes person who would say, "I thought about taking an overdose but I never made a specific plan as to when, where, or how I would actually do it . . . and I would never go through with it."

Active suicidal ideation: method and intent, but no plan

Active suicidal thoughts of killing oneself, and patient reports having some intent to act on such thoughts, as opposed to "I have the thoughts but I definitely will not do anything about them."

Active suicidal ideation: method, intent, and plan

Thoughts of killing oneself with details of plan fully or partially worked out and patient has some intent to carry it out (i.e., some degree of intent is implicit in the concept of plan).

Suicidal Behavior

Completed suicide

A self-injurious behavior that resulted in fatality and was associated with at least some intent to die as a result of the act. Evidence that the individual intended to kill him- or

[10] See http://www.cssrs.columbia.edu.

herself, at least to some degree, can be explicit or inferred from the behavior or circumstance.

Suicide attempt

A potentially self-injurious behavior, associated with at least some intent 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.

Interrupted suicide attempt

When the person is interrupted (by an outside circumstance) from starting a potentially self-injurious act (if not for that, actual attempt would have occurred).

Aborted suicide attempt

When person begins to take steps toward making a suicide attempt, but stops before actually engaging in any self-destructive behavior. Examples are similar to interrupted attempts, except that the individual stops before being stopped by something else.

Preparatory acts toward imminent suicidal behaviors

This category can include anything beyond a verbalization or thought, but it stops short of a suicide attempt, an interrupted suicide attempt, or an aborted suicide attempt. This might include behaviors related to assembling a specific method (e.g., buying pills, purchasing a gun) or preparing for one's death by suicide (e.g., giving things away, writing a suicide note).

Self-Injurious Behavior Without Suicidal Intent

Self-injurious behavior associated with no intent to die. The behavior is intended purely for other reasons, either to relieve distress (often referred to as *self-mutilation* (e.g., superficial cuts or scratches, hitting or banging, or burns)) or to effect change in others or the environment.