

Chapter 4

From Uniform Definitions to Prediction of Risk: The Columbia Suicide Severity Rating Scale Approach to Suicide Risk Assessment

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Abstract Suicide prevention is of high national and international importance as suicide remains one of the world's greatest public health crises. Identification is the key to prevention, and therefore the ideal suicide risk assessment instrument enables identification of high risk individuals, monitors for suicide risk factors, and predicts future suicidal behavior in both research and practice. However, research and clinical practice have been challenged by nomenclature and methodological limitations regarding assessment of suicidal ideation and behavior. Systematic assessment for suicidal risk is feasible and provides more reliable outcomes, establishes operationalized criteria, and specifies parameters for triggering referrals, thereby decreasing unnecessary referral and burden. Therefore, assessment of suicidal ideation and behavior should be routinely integrated across public health settings. Knowledge of the full range of suicidal ideation and behaviors and key criteria for differentiating suicidal and non-suicidal events is paramount to the advancement of suicide risk assessment. The Columbia Suicide Severity Rating Scale (C-SSRS), a brief, standardized research-supported risk assessment tool, identifies individuals at increased risk for suicide to lower the overall disease burden and potentially the numbers of unnecessary deaths.

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4.1 Introduction

Suicide is a global public health crisis and the magnitude of its global disease burden is under-recognized. In the US alone, an adult dies by suicide every 13 min (WISQARS 2011), yet, the public health impact and disease burden of suicide are under-recognized (Insel 2010). Nearly 10 % of high school students report having attempted suicide in the past year (Eaton et al. 2012). \$141 billion in annual medical costs lost are incurred and millions of years of life globally, while in the US alone nonfatal suicide attempts cost \$6 billion a year (WISQARS 2011). Identification of individuals at high risk is crucial for any prevention effort. However, identification and detection are hampered by failure to screen adequately or at all by critical gatekeepers (See Fawcett, this volume).

A report by the U.S. Institute of Medicine concluded that “research on suicide is plagued by many methodological problems...definitions lack uniformity...[and] reporting of suicide is inaccurate” (Goldsmith 2002). Diverse terminology for identical suicidal phenomena (O’Carroll et al. 1996; Posner et al. 2007) negatively impacts instrument validity and reliability and the utility of epidemiological statistics. Across all age groups, as many as 45 % of those who died by suicide have had contact with their primary care providers within one month prior to their death; 90 % of adolescents and 77 % across all age groups visit their primary care provider within one year of their death (Luoma et al. 2002; McCarty et al. 2011). Yet, fewer than 3 % of these visit records contain a comment about suicide risk (Appleby et al. 1996). Moreover, a large number of adolescent suicide attempters present to emergency departments for nonpsychiatric reasons and can be easily missed (King et al. 2009). An even lower percentage of those who die by suicide have contact with mental health professionals (e.g., 20–25 % of adolescents within a year of suicide (Gould et al. 2003). Predictably, only 19 % of primary care providers compared with 59 % of psychiatric practitioners knew about the suicidal intentions of their patients who died by suicide (Suominen et al. 2004).

The consistent use of a standardized instrument with clinically appropriate, specific, and comprehensive terminology can greatly enhance detection, monitoring, and prediction in the suicidal patient. The ideal suicide risk assessment instrument enables identification of high-risk individuals, ongoing monitoring of risk factors for suicide (i.e., suicidal ideation and behavior) and prediction of future suicidal behavior both in research and practice.

4.2 Suicide Risk Assessment

Importantly, traditional of assessing suicide risk, which include relying on open-ended questions, have been problematic. When instructed to ask two open-ended questions about suicide, clinicians tended to over-detect suicidal ideation and under-detect suicidal behavior in adolescent patients (Holi et al. 2008). Structured

or semi-structured tools, on the other hand, improve detection in routine clinical assessments (Bongiovi-Garcia et al. 2009). In one study, the use of a structured questionnaire detected 29.7 % of patients with suicidal ideation and 18.7 % of patients with a history of a suicide attempt that were undetected by an open-ended clinician interview (Bongiovi-Garcia et al. 2009). Overall, evidence has shown that performing routine intakes identifies only 25 % of patients with a history of suicide attempt when compared to 100 % of patients identified through structured risk assessment instruments (Hawton 1987).

In a national emergency department study, a structured telephone follow-up using the Columbia-Suicide Severity Rating Scale (C-SSRS) improved detection (59 %) of suicide attempts by more than 40 % when compared to hospital chart reviews detection (18 %) (Arias et al. 2014). Furthermore, utilizing evidence-supported instruments facilitates clinical decision-making and fosters confidence in the determination of next steps for individuals identified with various levels of suicide risk. A scale with thresholds for clinical management streamlines interpretation of assessment results and when matched with triage protocols should result in more efficient use of mental health services and patient management during trials (Peña and Caine 2006).

Therefore, a comprehensive and successful implementation of structured suicide risk assessment programs should include policies and protocols that allow for assessment, intervention, and monitoring (AIM). Evidence of such implementation is apparent in the policies of various institutions and settings. The New York State Office of Mental Health has developed a comprehensive systems approach to suicide prevention for all adult and youth behavioral health care organizations in which all patients are screened using the C-SSRS. Furthermore, C-SSRS and Safety Planning online learning modules are used in training all NYSOMH staff. Additionally, the National Action Alliance, in its commitment to a vision of zero suicide, now provides a suicide toolkit that contains training in the C-SSRS and safety planning intervention. Also, Georgia has begun a state-wide dissemination and linking of systems with the C-SSRS, in which providers are implementing the C-SSRS in all services, between services, and in systems of care.

4.3 Assessment of Suicidal Ideation and Behavior

The stress-diathesis model of suicidal behavior proposes that suicidal behavior may manifest through individual traits (e.g., impulsivity) that can be influenced by genetic and epigenetic effects on stress responses, mood regulation and decision-making. This array of traits is determined by genetic and early life experience resulting in a preexisting susceptibility or diathesis. The diathesis interacts with current stressors (e.g., psychosocial crisis or exacerbation of psychiatric illness) to create the risk of suicidal behavior (Mann et al. 2005; Oquendo et al. 2003; Mann 2003) (Nazem, this volume, Lopez-Castroman et al., this volume). Approximately 90 % of people who die by suicide have a diagnosable and treatable mental disorder

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

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

Fig. 4.1 Suicidal ideation and behavior categories and definitions (FDA 2012)

at the time of death (Hjelmeland and Knizek 1999). Specifically, mood, substance use, impulse control, and personality disorders and schizophrenia spectrum disorders confer the highest risk (Turecki et al. 2012; Mann and Currier 2010; Jiménez et al. 2013; Dwivedi and Mann 2012; Baca-Garcia et al. 2010; Bennett 2013) (Fig. 4.1).

Suicidal ideation and a history of suicidal behavior are among the most salient short- and long-term risk factors for suicide (Beck et al. 1999; Brown et al. 2000; Kuo et al. 2001; Nordström et al. 1995). Many individuals die from their first suicide attempt (Isometsa 1998), which underscores the importance of assessing

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

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.

Fig. 4.1 (continued)

risk for this before people make that first suicide attempt. The terminology of suicidal outcomes has historically been diverse, inconsistent and ambiguous (O'Carroll et al. 1996; Posner et al. 2007). Terms that carry value judgments such as "failed attempt," "suicide gesture," "manipulative act", "parasuicide", "deliberate self-harm" and "suicide threat" (Crosby et al. 2011) obscure appropriate identification, and ambiguity and diversity in definitions may result in both over- and under-identification of high-risk individuals. In an effort to establish a meaningful common language for suicidal behavior, the United States Centers for Disease Control (CDC) has adopted terminology developed by a group of Columbia University suicidologists and recommends a standardized scale, the C-SSRS, to elicit the required information from respondents. The C-SSRS distinguishes between the following suicidal behaviors: (a) suicide, (b) suicide attempt, (c) interrupted attempt,

Uniform Definitions

Definitions

Self-directed violence (analogous to self-injurious behavior)

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

This does not include behaviors such as parachuting, gambling, substance abuse, tobacco use or other risk taking activities, such as excessive speeding in motor vehicles. These are complex behaviors some of which are risk factors for SDV but are defined as behavior that while likely to be life-threatening is not recognized by the individual as behavior intended to destroy or injure the self. (Farberow, N. L. (Ed.) (1980). *The Many Faces of Suicide*. New York: McGraw-Hill Book Company). These behaviors may have a high probability of injury or death as an outcome but the injury or death is usually considered unintentional. Hanzlick R, Hunsaker JC, Davis GJ. *Guide for Manner of Death Classification*. National Association of Medical Examiners. Available at: <http://www.charlydmiller.com/LIB03/2002NAMEmannerofdeath.pdf>. Accessed 1 Sept 2009.

Self-directed violence is categorized into the following:

Non-suicidal (as defined below)

Suicidal (as defined below).

Non-suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is no evidence, whether implicit or explicit, of suicidal intent. Please see appendix for definition of implicit and explicit.

Suicidal self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

There is evidence, whether implicit or explicit, of suicidal intent.

Undetermined self-directed violence

Behavior that is self-directed and deliberately results in injury or the potential for injury to oneself.

Suicidal intent is unclear based on the available evidence.

Suicide attempt

A non-fatal self-directed potentially injurious behavior with any intent to die as a result of the behavior.

A suicide attempt may or may not result in injury.

Interrupted self-directed violence – by self or by other

By other - A person takes steps to injure self but is stopped by another person prior to fatal injury. The interruption can occur at any point during the act such as after the initial thought or after onset of behavior.

By self (in other documents may be termed "aborted" suicidal behavior) - A person takes steps to injure self but is stopped by self prior to fatal injury.

Source: Posner K, Oquendo MA, Gould M, Stanley B, Davies M. Columbia Classification Algorithm of Suicide Assessment (C-CASA): Classification of Suicidal Events in the FDA's Pediatric Suicidal Risk Analysis of Antidepressants. *Am J Psychiatry*. 2007; 164:1035-1043. <http://cssrs.columbia.edu/>

Fig. 4.2 CDC and Columbia uniform definitions

(d) self-interrupted/aborted attempt, and (e) preparatory acts or behavior (Crosby et al. 2011) (Fig. 4.2). The U.S. Food and Drug Administration (FDA) adopted the C-SSRS categories of both behavior and the five subtypes of suicidal ideation, for the systematic, prospective monitoring of suicidal occurrences in clinical trials (See <http://www.cssrs.columbia.edu>). Self-injurious behavior without suicidal intent was also included in the list of outcomes in order to help distinguish suicide attempts from non-suicidal self-injurious behavior. These 11 categories are the FDA standard used for the detection of pre-existing risk and treatment-emergent suicidal ideation and behavior in all clinical trials involving drugs with central nervous

system (CNS) activity (Food and Drug Administration 2012) (Fig. 4.1). Once one is assessing patients for treatment-emergent suicidal ideation and behavior, then it is also possible to detect beneficial effects of medications on ideation and behavior.

Suicide risk assessment instruments should aim to delineate suicidal ideation and behavior categories and their severity for more accurate determination of suicide risk. The following elements in a suicide risk assessment instrument are critical for the identification of high-risk individuals: a full range of suicidal behaviors and suicidal ideation.

4.3.1 The Full Range of Suicidal Behaviors

Historically a suicide risk assessments or screening queried solely about lifetime or recent suicide attempts, which resulted in the omission of other types of significant suicidal behaviors. Behaviors in which steps are taken imminently before a suicide attempt or suicide would have otherwise occurred (e.g., putting a noose around one's neck and changing one's mind, being rescued by another before running in front of traffic) and behaviors in preparation of suicide (e.g., buying a knife, collecting pills, writing a suicide note) are important subtypes of suicidal behavior that often go undetected by clinicians and gate keepers. This was confirmed in a 3,776 patient sample, in which attempts comprised only 13 % of reported suicidal behaviors, while the remaining 87 % consisted of the other three types (Mundt et al. 2011). While these events were rare (approximately one percent of 35,000 assessments), it is critical to more appropriately identify high-risk individuals. This is evidenced by the fact that, over a short-term follow-up, these other lifetime behaviors significantly predicted subsequent suicidal behavior, with all behaviors being similarly predictive. Furthermore, the total number of different suicidal behaviors increased risk (Posner 2012).

While a history of a suicide attempt is the most consistent predictor of future suicide attempts or death by suicide (Brown et al. 2000; Fawcett et al. 1990; Harris and Barraclough 1997; Malone 1995; Steer et al. 1988). Other categories of suicidal behavior also predict the risk of future suicide attempts including interrupted and aborted attempts and preparatory activities (Mundt et al. 2013). Finally, the most severe lifetime suicidal ideation predicts the risk for suicide.

Importantly, interrupted attempt, self-interrupted/aborted attempt, or preparatory acts or behavior constitute the majority of suicidal behaviors engaged in by high-risk individuals (Mundt et al. 2011) and are salient risk factors for suicide or suicide attempt, with similar risk ratios (Steer et al. 1988; Barber et al. 1998; Marzuk et al. 1997; Beck et al. 1999). Lastly, ideation is also a significant risk factor: the most severe lifetime suicidal ideation is a significant predictor for future suicide. Thus, it is critical that the full range of suicidal behaviors and ideation is assessed.

4.3.2 Intent to Die

With a history of a suicide attempt being the number one risk factor for future attempts or death by suicide, improved identification of past behavior is essential. Identification, in turn, critically hinges on the clear and accurate distinction between suicidal and non-suicidal behavior. Suicidal behavior is any type of self-injurious behavior (Crosby 2010), carried out with some intent to die. A critical criterion of suicidal behavior for its distinction from nonsuicidal self-injurious behavior is the presence of intent to die. Intent to die requires the desire to bring about one's own death and is distinct from the motivations for desiring such an outcome (Hjelmeland and Knizek 1999). Such behavior is considered suicidal irrespective of the motivations surrounding the behavior, which are often affective in nature, such as ending emotional pain. A self-injurious behavior is suicidal if it is a result of any intent to die, and is strictly non-suicidal if it is not a result of any intent to die. Thus, the same behavior across individuals may be classified as suicidal or nonsuicidal depending solely on the presence or absence of intent to die. Intent to die need not be stated directly by the individual but may be inferred from additional facts such as high potential lethality of behavior (De Leo et al. 2004; Posner et al. 2011), the individuals' perception of a behavior's high potential lethality (Beck and Greenberg 1971), or additional data from informants (O'Carroll 1989) or medical records (Posner et al. 2007).

4.3.3 Distinction of Suicidal Ideation and Behavior

The prognosis and outcome of suicidal ideation and behavior are different. Suicide attempts are both less common and more closely related to suicide as an outcome. A widely used term "suicidality", conflates ideation and behavior and FDA has recommended to discontinue its use. Distinct, non-overlapping definitions of suicidal ideation and suicidal behavior are critical for accurate assessment of prior ideation and behavior as predictors of future risk and for prospective detection of suicidal phenomena in the context of treatment. In a large multi-trial study lifetime severe suicidal ideation with at least some intent to die was associated with a five-fold increase in the risk of suicidal behavior on trial and a lifetime history of suicidal behavior without severe ideation was associated with a four-fold increase in risk of on trial behavior. Importantly, patients with a history of severe ideation and behavior were nine times more likely to have behavior during trial (Mundt et al. 2013). In an adolescent emergency department follow-up study, ideation was predictive of subsequent suicidal behavior even when a history of attempts was not predictive, reinforcing the need to identify suicidal ideation.

In general, the extant literature suggests separation of ideation and behavior because: (1) suicidal ideation and behavior do not always co-occur (Fawcett 1992), (2) gene variants associated with treatment-emergent suicidal ideation in clinical

treatment trials of SSRIs appear to be unrelated to genes primarily associated with suicidal behavior (Laje et al. 2007; Meyer et al. 2010; Perlis et al. 2007; Perroud et al. 2009), (3) suicidal ideation is predictive of or a precursor to suicidal behavior (Posner et al. 2011; Kessler et al. 1999), and (4) ideation and behavior might be more predictive of suicide depending on other factors such as age (Brent et al. 1993; Fergusson et al. 2005; Lewinsohn et al. 1994; Pfeffer et al. 1993; Wichstrom 2000; Brown et al. 2000; Conwell and Thompson 2008; Vannoy et al. 2007; King et al. 2012). Moreover, suicidal ideation may add incremental validity to the prediction of future suicide attempts relative to a history of past suicide attempts alone (Horwitz et al. 2014). Treatment may affect risk of ideation without affecting risk of nonfatal suicide attempts or suicide. These findings confirm the importance of assessing suicidal ideation independently of suicidal behavior.

4.3.4 Suicidal Ideation

Suicidal ideation is a heterogeneous construct. The National Institute of Mental Health (NIMH) Developing Centers for Intervention and Prevention of Suicide specified that wish to die, thoughts of killing oneself, and intent to kill oneself constitute types of suicidal ideation (Brown et al. 2008). Suicidal ideation may be passive (i.e., having a wish to die as opposed to thoughts of killing one self) or active, which can range from range from non-specific thoughts of killing oneself to thoughts with a specific method or plan for killing (Brown et al. 2008). The distinction of passive and active suicidal ideation was first described by Beck et al. (1979) to separate thoughts of desiring one's own death from thoughts of actively killing oneself (Beck et al. 1979). Intent to act demarcates the difference between thoughts of a suicide attempt where the person feels sure they would never act and where they believe they could act on those thoughts of killing themselves. A more severe stage is when the thoughts have a compulsive, or hard to resist quality, and the person may describe a struggle to resist the thoughts of suicide. The evidence base examining predictive properties of these ideation subtypes is growing (Mundt et al. 2013; Posner et al. 2011; Arias 2014; Hesdorffer et al. 2013; Katzan et al. 2013; Posner 2013) which was likely a result of the C-SSRS delineating ideation types more clearly.

4.3.5 Wish to Die

Thus, the PHQ-9 combines a large range of severity of suicidal ideation, blurring and eliminating the distinction between higher and lower risk ideation indicators, making the predictive value of this item poor.

Passive suicidal ideation includes any internal experience that indicates a wish or desire to die (“wish to die”) and excludes thoughts of being better off dead, thoughts

of one's own death, or that life is not worth living. This definition represents the consensus of the National Institute of Mental Health (NIMH) Developing Centers for Intervention and Prevention of Suicide conference (Brown et al. 2008). Evidence has shown that people with a high wish-to-die/wish-to-live index are six times more likely to die by suicide than those with lower indices (Brown et al. 2005). In turn, these research findings played a pivotal role in the development of the C-SSRS. Prior to this, assessment of suicidal ideation failed to distinguish true passive suicidal ideation (i.e., the wish to die) from other thoughts of death or dying that are not passive suicidal ideation and not predictive of future suicidal behavior. This historical muddling of definitions is evident in the Patient Health Questionnaire (PHQ-9), which spuriously equates thoughts of being "better off dead" with passive suicidal ideation, effectively eliminating the distinction between higher and lower risk indicators. Unsurprisingly, the predictive value of this item is poor. The observed point prevalence of suicidal ideation, behavior, or both was 6.2 % on the C-SSRS compared to 23.8 % on item 9 (the "suicide" item) on the PHQ-9 a nearly four-fold increase in false positive screens (Katzan et al. 2013). The Cleveland Clinic similarly compared the PHQ-9 suicide item to the electronic screening version of the C-SSRS, and found that the PHQ-9 yielded more than three times as many false positives as true positives (Katzan et al. 2013).

4.3.6 Intent to Act

Intent to act depends on the extent to which one is ready to act on thoughts of killing oneself. Suicidal thoughts without intent to act are characterized by having thoughts of killing oneself but not feeling that one might do anything about them. The distinction is clinically important because the presence of intent to act confers higher risk for subsequent suicidal behavior, as shown in a study of adolescent suicide attempters, where a lifetime history of severe ideation with at least some intent to die was associated with a 50 % increase in the risk of on-trial suicidal behavior (Posner et al. 2011; Currier et al. 2009).

4.3.7 Intensity and Worst-Point Ideation

In addition to types of suicidal thoughts, assessing their intensity and time frame is also very important. Although researchers and clinicians have assumed that one needs to query about current levels of ideation to identify risk, worst point lifetime ideation has been shown to be a better predictor of death by suicide (Beck et al. 1999). Unlike severity, ideation intensity is best seen as a continuous characteristic consisting of five dimensions: duration of thoughts, frequency of thoughts, controllability of thoughts, deterrents from acting on thoughts, and reasons for ideation. Duration of the most severe ideation predicts subsequent suicidal behavior among

adolescents (King et al. 2012). In an adolescent emergency department follow-up study, it was demonstrated that duration of thoughts was predictive of subsequent suicidal behavior, while suicide attempts and lifetime attempts were not predictive, thus reinforcing the importance of ideation assessment (King et al. 2012). Significantly, all items on the C-SSRS intensity of ideation subscale (i.e., frequency, duration, controllability, deterrents, and reasons for ideation) were shown to be significantly predictive of suicide on Beck's SSI. Large trial data across multiple indications show that total score on ideation intensity incrementally is associated with a greater risk of suicidal behavior during trial, while minimal intensity of ideation was associated with a six-fold increase in the odds of suicidal behavior on-trial, very severe intensity was associated with a thirty-fold increase in risk (OR=34.39; 95 % CI: 9.23-128.09) (Posner 2014).

4.4 Instruments: Utility and Feasibility

Utilizing an evidence-based and research-supported instrument, such as the C-SSRS, for risk assessment can minimize false negatives and false positives, enable the redirection of scarce resources, and efficiently guide appropriate care to at-risk individuals. To determine whether a particular instrument is optimal and ideal for assessment, monitoring, or screening, consideration should be given to the following administration parameters: administration time, administration methods and delivery, the type of raters, and the level of training required for administration.

4.4.1 Administration: Time

The optimal administration time for any risk assessment instrument should be brief (minutes), which may be facilitated by the instrument's structure. In particular, guided interpretation of patient responses during risk assessment in the form of a decision tree allows for briefer administration time and quicker and more reliable decision-making.

4.4.2 Administration: Methods and Delivery

The most common methods for suicide risk assessment by gate-keepers and clinicians involve a general interview and no systematic questions about ideation, behavior or family history of suicidal behavior. A much better approach involves systematic questioning guided by a checklist or rating scale (Malone 1995).

Self-report instruments have the advantage of making self-disclosure of sensitive issues easier. These types of instruments may facilitate the admission of suicidal

ideation and behavior, or any suicide-related phenomena, which may be denied in an in-person, face-to-face interview. As mentioned previously, a telephone follow-up assessment, which used the C-SSRS, improved detection (58 %) of suicide attempts by more than 40 % when compared to hospital chart reviews (18 %) (Arias 2014).

Risk assessment instruments for suicide are available in a variety of paper and electronic formats. Importantly, innovative delivery formats enable a greater number of individuals to be screened, facilitating broader implementation. Timing of assessment is crucial after an at-risk patient is discharged from a hospital, particularly from a psychiatric inpatient unit, as there is an increased risk for suicide in the first week after discharge (Roy 1982).

4.4.3 Administration: Gatekeepers

Suicide risk assessment is not limited to medical settings, even though primary care physicians often see individuals shortly before they attempt suicide, but should include educational, religious, workplace, legal, and forensic settings. As such, settings may include diverse populations, it is crucial that nonmental health professions be able to ask appropriate screening questions. Training in the administration of a risk assessment tool enhances implementation efforts in these settings. In a juvenile justice setting nonclinician raters (gatekeepers) showed good inter-rater reliability when administering a structured risk assessment questionnaire to adolescent girls (Kerr et al. 2014). In the U.S. Marines, all support workers, such as chaplains, family advocacy workers and attorneys, are trained to be aware of suicide risk and warning signs and to administer and utilize the C-SSRS. In rural communities, where access to a mental health professional or practitioner may be limited, the ability of nonmental health professional gatekeepers to screen is essential.

4.4.4 Multiple Sources of Information

In many risk assessment contexts, situational factors render obtaining information directly from a patient impossible. Examples of clinical populations that are challenging span dementias, cognitive impairment, and autism. In all of these cases, collecting information from other reporters and its integration into an overall clinical picture is crucial. The ability of a risk assessment tool to obtain and integrate information from a variety of sources of information provides the necessary flexibility and accuracy.

4.4.5 Risk Management

Assessment scales should have operationalized thresholds that differentiate levels of risk and aid in determining patient disposition. A patient management protocol that specifies next steps after the risk assessment may include referrals to mental health professionals for low-to-moderate risk patients or hospitalization and suicide watch, for high-risk patients. Without a systematic assessment to determine suicide risk level that drives the next steps, providers are less able to properly triage patients. This can lead to overestimation of risk, or a tendency to err on the safe side, resulting in increased burden for mental health professionals, hospitals, and other healthcare facilities and diminished resources to offer the right quality of patient care for those who are most in need.

4.4.6 Generalizability

Suicide risk assessment instruments require parallel forms developed for specific populations. Modifications may include developmentally appropriate questions or addition of population-specific risk factors (e.g., the military) (Peña and Caine 2006).

4.4.7 Triage

Operationalized thresholds that distinguish higher levels of risk are an essential component of assessment scales, so that appropriate triage steps can be taken. In cases of low-to-moderate risk, such steps may involve referral to mental health professionals for further evaluation, while high-risk cases may require hospitalization or suicide watch. In the absence of built-in thresholds that link to specific triage protocols, providers are forced to worry about every person screened. This could lead to problematic situations such as clinicians believing more patients require one-to-one observation than there is staff available to provide it. In other words, over-estimation of risk leads to misallocation of resources and poorer quality of care. Whether at a hospital or a correctional facility, it is essential for assessment administrators to have access to a screener with research-based next-step protocol, which will in turn impact care delivery and service utilization.

4.5 Risk Factors: Suicidal Behavior and Ideation-Specific Mediators and Moderators and Corresponding Instruments

A thorough evaluation of the benefits and risks of therapeutic interventions and suicide-related outcomes should include a consideration of known risk factors as well as mediating and moderating variables. Mediators are intervening variables that help clarify the nature of and represent potential mechanisms that underlie the relationship between independent and dependent variables. Moderators are characteristics that affect the direction and/or strength of the relationship between the independent and dependent variables. Suicidal behavior and ideation-specific mediators and moderators to be considered include: biological factors (genetic, stress responsivity, developmental anomalies, altered neural circuitry), psychological factors (aggressive and impulsive traits, negative inferential styles, cognitive rigidity, hopelessness, decision-making, problem-solving, mood regulation), psychiatric illness (e.g., major depressive episode), and social support systems (see Hudzik and Cannon, this volume). Knowing mediating and moderating relationships affecting the risk of suicide enhances the understanding of factors that play a role in mitigating or increasing that risk and creates a context for evaluating the effects of treatment. Table 4.1 lists examples of instruments assessing some of these risk factors.

4.6 How Should Instruments Measure Suicide Risk: Characteristics Important for Detection and Prediction

Suicidal behavior occurs in many psychiatric disorders (e.g., depression, schizophrenia) and in many medical conditions (e.g., strokes, epilepsy, head injury and AIDS) (Harris et al. 1994). Thus, monitoring of suicidal ideation and behavior should be part of clinical practice for nonpsychiatrists including neurologists, internists and primary care physicians. In the evaluation of new medications that affect the brain and other systems such as endocrine, measuring the impact of new drugs on suicidal ideation and behavior has been made a requirement by the FDA for all clinical trials. For accurately assessing the comparable importance of risk and protective factors from a clinical and public health perspective.

Prior to FDA mandating prospective monitoring of suicide-related events in drug trials, all previous antidepressant, anticonvulsant, and other non-psychiatric trials were not set-up to adequately assess these events. Suicide risk analyses were based on spontaneously generated adverse events and the higher risk estimates from these analyses may have been a product of ascertainment bias rather than a reflection of a true association.

The choice of a suicide risk assessment instrument and interpretation of the results obtained from the assessment depend on the degree to which the instrument is able to capture concepts of interest (Fig. 4.1). From this point of view, an

Table 4.1 Select risk factors and associated instruments

Risk factor	Assessment instrument	References
Aggression and impulsivity	<ul style="list-style-type: none"> • Barratt impulsiveness scale • Buss–Durkee hostility inventory • Brown–Goodwin aggression history (AGGHx) 	Stanford et al. (2009), Buss and Durkee (1957), Kelip et al. (2006)
Substance abuse	<ul style="list-style-type: none"> • Mental health screening form-III (MHSF-III) • Simple screening instrument for substance abuse (SSI-SA) • CAGE questionnaire (alcohol) • Drug abuse screening test (DAST) • Michigan Alcoholism Screening test (MAST), • Psychiatric research interview for substance and mental disorders (PRISM) 	Sacks et al. (2005), Ewing (1984), Skinner et al. (1982), Selzer et al. (1971), Samet et al. (1996)
Hopelessness	<ul style="list-style-type: none"> • Beck hopelessness scale (BHS) 	Beck et al. (1990)
Distress/mental pain	<ul style="list-style-type: none"> • Mental pain scale • Self-defeating personality questionnaire (SDPQ) • Self-critical cognition scale • Self-derogation scale • The guilt inventory 	Orbach et al. 2003, Shneidman et al. (1993), Schill (1990), Kugler and Jones (1992), Kaplan et al. (1969), Orbach et al. (1991)
Neurocognitive factors	<ul style="list-style-type: none"> • Iowa gambling task (decision-making) • Stroop task (interference scores; attention) (adapted) • Buschke selective reminding task (SRT) test (memory and learning) 	Bowman et al. 2005), Keilp et al. (2014)

instrument which incorporates clear definitions and examples of behaviors that reflect those concepts minimizes variability in clinical judgment.

Science demands uniformity in measurement: moving away from a single instrument inherently degrades the precision of the signal, compounding existing imprecision across research sites and raters (Gibbons, 2010). The impact of imprecision grows when incidence rates are low, such as with death by suicide. At the same time, imprecision with low frequency events is incredibly problematic, as misclassification of one or two cases can have a profound impact on risk estimates and substantially alter conclusions. Even if you assume two measures are equally valid, more measurement variability still equals more noise. This has a particularly large impact when trying to combine studies. The 2012 FDA Guidance echoes this sentiment, stating that “the use of different instruments is likely to increase measurement variability... decreasing the opportunity to identify potential signals” that would inform future analyses and clinical trials. Uniform measurement with a validated instrument like the C-SSRS is crucial for prevention, research, and clinical practice.

Research has shown that systematic monitoring and consistent application of well-operationalized suicidal ideation and behavior criteria result in lower and more precise risk estimates. In a classic example of controversy surrounding safety of antidepressants, analyses commissioned by the FDA showed that consistent

application of the C-SSRS' empirically supported definitions of ideation and behavior led to significantly better estimates of risk, with 50 % fewer ascertained suicide attempts (Posner et al. 2007). Similarly, in a large nonpsychiatric trial with 14,000 subjects, systematic monitoring sourcing the C-SSRS revealed 12 suicidal adverse events (AEs) compared to 452 reported spontaneously (Posner January 2009). Reducing false positives is as important as identifying risk in the effort to improve detection and better allocate limited or scarce resources. An initiative organized by the CDC, Department of Defense, National Institute of Mental Health, and the Department of Veterans Affairs is recommending the C-SSRS as one of the consensus measures to be incorporated into large-scale biomedical studies involving human subjects to facilitate data sharing and comparison (<http://www.phenxtoolkit.org>).

Accuracy and validity of clinical judgment about suicidal ideation and behavior, whether in research or practice, improve when validated measures are used in assessment, which in turn increase their treatment utility. The critical parameters of a valid clinical suicide risk assessment in addition to construct/conceptual validity include sensitivity to clinical change and predictive validity. Scales that take classification in consideration for the measurement of ideation and behavior and incorporate definitions of ideation and behavior subtypes have shown robust sensitivity to change in symptoms as well as predictive validity (Posner et al. 2011). The Beck Scale for Suicide Ideation, a continuous scale, has shown predictive validity for death by suicide in adults in long-term follow-up studies (Brown et al. 2000) but has not performed as well in predicting near-term nonfatal suicidal behavior, whereas the C-SSRS has demonstrated such predictive qualities (Posner et al. 2011). Identifying specific types of suicidal ideation and including the full range of behaviors (including preparatory acts or behavior and self and other interrupted attempts) instead of aggregating characteristics along a continuum may be more useful for risk stratification. In support, research on the SSI has shown that empirically derived factors such as “plans” and “desire” have different predictive patterns using past attempts and suicide as outcomes (Beck et al. 1997; Joiner et al. 2003). Lifetime history of a specific *type* of ideation—with intent to act—has been shown to be a stronger predictor of subsequent suicidal behavior than ideation without intent to act (Mundt et al. 2013; Posner et al. 2011).

4.7 Inclusion/Exclusion of Suicidal Individuals in Clinical Trials

Cross-national studies suggest that suicidal ideation and suicide attempts are relatively common (Nock et al. 2008). In fact, suicidal ideation and behavior are prevalent across all medical disorders; in those with one or more general illnesses, 25.2 % have suicidal ideation and 8.9 % make a suicide attempt (Druss and Pincus 2000). Consequently, there exists the expectation that increased suicide risk may be

present in psychiatric and nonpsychiatric clinical trials and that such risk should be assessed and managed. The various approaches to any suicidal phenomena in clinical trials have included: (a) exclusion of those at risk for suicidal behavior from participation, (b) removal from trial if suicidal ideation or behavior emerge during the trial, (c) management of suicidal issues in the context of the trial, or (d) any combination of these approaches (Pearson et al. 2001). Possible exclusion of those at risk for suicidal behavior from participation may have been the result of active and/or significant past suicidal ideation, a recent suicide attempt, or a history of suicidal behavior. Seventy-seven antidepressant (SSRI) clinical trials of fluoxetine, citalopram, paroxetine, and sertraline (Prozac, Celexa, Paxil, and Zoloft, respectively) between 1984 and 2001 were reviewed for inclusion and exclusion criteria for suicidal phenomena (Stanley 2009). Approximately 10 % (8 out of 77) of these trials allowed some level of suicidal ideation, history of behavior but excluded those with recent suicidal behavior in their research subjects; thus, these trials told very little about how antidepressants would affect suicidal patients (Stanley 2009).

The issue of exclusion of suicidal patients from clinical trials arises in relation to the balancing of scientific and safety concerns. Understandably, exclusion of suicidal individuals offers the advantages of minimizing risk to participants and investigators, lowering costs for monitoring, and maintaining homogeneity of the sample. However, exclusion is potentially unfair to a segment of the population that is in need of treatment. It leads to the false assumption that treatments found effective for nonsuicidal persons with certain mental disorders can be effective in reducing suicidal behavior among persons with that disorder as well. Exclusion hampers generalizability, as the desired applicability for a study is usually an entire diagnostic group and not just a specific segment of the group (Stanley 2009). Protection by exclusion has a cost and may not be protective; expert consensus has consistently indicated that suicidal patients should not be excluded from clinical trials (Meyer et al. 2010). Suicidal individuals have been deprived of access to effective treatments tailored to their needs, similar to the effects of the historical exclusion of women of childbearing age, children and adolescents, and ethnic minorities. Thus, the optimal approach would include the active management of suicidal ideation, behavior, and attempts through the addition of risk-mitigating procedures (Pearson et al. 2001). Such procedures would include additions to the study planning process, alteration in the consent process, increased staff training, and managing increased suicidal risk via increased monitoring and crisis intervention procedures. Managing suicidal ideation and behavior in the context of clinical trials will allow for increased generalizability as both suicidal and non-suicidal individuals will be included.

Studies have demonstrated the ethical and clinical feasibility of including individuals with suicidal ideation and/or recent suicidal behavior as participants in clinical trials (Liu 2009; Safer and Zito 2007). Therefore, it is difficult to argue for the exclusion of individuals considered at risk for suicide from clinical trials as many individuals with these symptoms will be receiving these medications, after FDA approval, in the absence of systematic premarketing data on the associated risks and benefits related to suicidal ideation and suicidal behavior (Meyer et al.

2010). Clinical trials in which suicide is the primary outcome measure will need to be so much larger and longer than the usual 8-week study (Meyer et al. 2010) that such studies are not practical. Nonfatal suicide attempts are a higher base rate outcome that is more realistic in terms of sample size and study duration. Informed consent forms for such a study must explain that suicidal ideation and behavior are outcome variables and the limits of confidentiality should an individual become suicidal, and describe the assessment and treatment individuals will receive if they withdraw from the study (Meyer et al. 2010). A balance between research assessment and clinical care can be established to preserve patient safety and the validity of the clinical trial results.

4.8 The Columbia-Suicide Severity Rating Scale (C-SSRS)

The Columbia-Suicide Severity Rating Scale (C-SSRS) maximizes feasibility of suicide risk assessment. It is a semi-structured, rater-based interview that prospectively assesses the severity and frequency of suicidal ideation and behaviors. The C-SSRS was developed by leading experts and researchers at the University of Pennsylvania and Columbia University, in collaboration with Aaron Beck's research group, over 10 years ago in the context of a National Institute of Mental Health (NIMH) research effort, in response to the need for a measure to assess outcome, change, and severity. The C-SSRS identifies the full range of suicidal ideation and behavior, monitors change from visit to visit, and predicts safety referral criteria derived from studies.

The C-SSRS was designed to (1) provide definitions of suicidal ideation and behavior and corresponding probes; (2) quantify the full spectrum of suicidal ideation and suicidal behavior and gauge their severity over specified periods; (3) distinguish suicidal behavior and nonsuicidal self-injurious behavior; and (4) employ a user-friendly format that allows integration of information from multiple sources (e.g., direct patient interview, family and other interviews, and medical records). As reviewed by Meyer et al. (2010), these criteria are considered essential for judging the utility of scales assessing suicide-related phenomena. The C-SSRS is unique among rating instruments in meeting all of these criteria. The C-SSRS has received wide acceptance in the US and worldwide. It has been translated into 116 languages and is also used in clinical trials to screen for suicide and prevention efforts across the US. The C-SSRS is used in many county and state screening and prevention programs, in the military, and by many large private medical centers and health care networks. The C-SSRS provides reliable outcomes, establishes operationalized criteria, specifies parameters for triggering referrals, which decreases unnecessary burden, and impacts care delivery and triage.

As a result, the C-SSRS has been endorsed and adopted into policies across a variety of national and international settings and institutions. In particular, the Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources Service Administration's jointly funded Center for Integrated

Health Solutions has endorsed the C-SSRS as one of three screening tools that should be utilized to assess suicide risk; the other two are the Suicide Assessment Five-Step Evaluation and Triage (SAFE-T) and Suicide Behaviors Questionnaire (SBQ-R).

In the US Army, all providers must consider suicide risk for all soldiers evaluated in an emergency department and must administer the C-SSRS if there is a suicide risk concern. Also, acute care hospitals, such as Reading Hospital, have integrated the C-SSRS Screener (with additional triage points) as part of a hospital suicide screening protocol and policy. Overall, the C-SSRS has been endorsed or adopted into policies by approximately 30 US states, several countries, and many national and global institutions, and is about to become the primary measure used in all NIMH suicide research (PhenX toolkit).

4.9 Reporting of Adverse Events

The number of empirically validated treatments aimed at reducing suicidal ideation and behaviors remains small. According to Oquendo et al. (2011), there have been fewer than 30 studies that focused on assessing psychosocial and pharmacological interventions that may benefit individuals at risk for suicidal behavior (Oquendo et al. 2011). Intervention research in most of medicine focuses on conditions associated with the greatest morbidity and mortality. Although suicidal patients, a majority of whom have a psychiatric or substance use disorder, constitute such a population there is a dearth of intervention trials in suicidal individuals. Two barriers that may explain the small number of intervention trials for suicidal individuals include ethical issues, such as the decision of whether to enter vulnerable populations into randomized trials, and the expectation of lethal outcomes in treatment trials for conditions with high mortality (Oquendo et al. 2004).

Therefore, the foreseeable occurrence of a fatal or near-fatal event in intervention clinical trials, for which suicide reduction is the outcome of interest, requires a consideration of adverse event (AE) or adverse drug event (ADE) identification and reporting standards. Across different institutions and agencies that conduct and/or supervise intervention trials, definitions of adverse events are often too general and too variable to allow for comparability between studies and meaningful interpretation of study results (Czaja et al. 2006, Santiago et al. 2003). Consequences of the lack of clarity and consistency in defining adverse events include the potential for underreporting during clinical trials, which poses a threat to the safety of trial participants. One clinical- and nonresearch-setting study found that voluntary reporting only yielded 1 in 20 adverse drug events (Cullen et al. 2003), while others have found that medical adverse events were underreported at varying rates, ranging from 50 to 96 % (Barach and Small 2000). This underreporting may originate from a variety of sources that may include, but are not limited to, fear that the study will be terminated, deterrence posed by time-consuming paperwork

necessary for reporting an adverse event, and population characteristics (Oquendo et al. 2011) (see also Ratcliff et al., this volume).

Regarding adverse event reporting, Gandhi et al. (2000) identified methods of detecting ADEs that include voluntary reporting, chart review, and computerized monitoring (Gandhi et al. 2000). Common types of voluntary reporting used to detect ADEs include spontaneous voluntary reporting and stimulated voluntary reporting. Spontaneous voluntary reporting has been a common mechanism utilized by institutions to identify ADEs, but this form of reporting identifies only a small portion (approximately 5 %) of ADEs (Cullen et al. 2003). Relatedly, stimulated voluntary reporting, a real-time verbal inquiry, made reporting quick and easy, but a problem arose as ADEs were reported verbally, yet only a small fraction of these ADEs were filed on a reporting system (Weingart et al. 2000). Another common ADE identification method, chart review, looks retrospectively for ADEs documented in an individual's medical chart. Importantly, conducting chart reviews usually requires a substantial amount of training and is costly and time-consuming (Gandhi et al. 2000). Accordingly, research has demonstrated that only a very small percentage of events actually make it to the medical chart (Gandhi et al. 2000) and that there can be significant variation in the review of ADE data (Bates et al. 1998; Sanazaro et al. 1991). Computerized monitoring, which can screen administrative and clinical databases and identify certain events, appears to be promising. Computerized monitoring identified 731 ADEs in an 18month period, an eightfold increase in ADE identification when compared to spontaneous voluntary reporting alone (Classen et al. 1991). However, chart reviews are able to detect 20 % more ADEs when compared to computerized monitoring; of note, computerized monitoring required 11 person-hours per week, while chart reviews required 55 person-hours per week (Jha et al. 1991).

To improve adverse event identification and reporting, unified and consistent definitions and systems of reporting must be developed. Suicide research and terminology has been plagued by a lack of conceptual clarity and a large variability in nomenclature, and developing universally applied definitions can allow for comparability of adverse events across clinical trials and research studies. Furthermore, systematizing adverse event reports into a database can provide researchers and investigators with a method to compare safety results (Califf et al. 1998). Ultimately, developing comprehensive and accurate systems of reporting will allow for prevention opportunities as certain patterns may be noticed.

4.10 Conclusion

Suicide prevention is of high national and international importance and identification of at-risk individuals is the first necessary step toward prevention. Research and clinical practice have been challenged by methodological limitations regarding assessment of suicidal ideation and behavior. Such issues have undermined confidence in epidemiological findings and have had a profound impact on drug safety

questions. Systematic assessment for suicidal risk is feasible and provides more reliable outcomes, establishing operationalized criteria for inclusion and exclusion of trial participants, and specifying parameters for triggering referrals, thus decreasing unnecessary referral and burden. Therefore, assessment of suicidal ideation and behavior should be routinely integrated across public health settings. Knowledge of the full range of suicidal ideation and behaviors and key criteria for differentiating suicidal and nonsuicidal events is paramount to the advancement of suicide risk assessment. Brief, feasible, research-supported risk assessment tools can identify individuals at increased risk for suicide.

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