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# Monitoring, Assessing, and Responding to Suicide Risk in Clinical Research

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## Abstract

It is essential that investigators in clinical research settings follow ethical guidelines for monitoring, assessing, and responding to suicide risk. Given the unique considerations associated with suicide risk assessment in a research context, resources informing the development of research-specific suicide risk management procedures are needed. With decades of collective experience across heterogeneous contexts, we discuss approaches to monitoring, assessing, and responding to suicide risk as a function of study sample (e.g., students, psychiatric inpatients), data collection methodologies (e.g., interview, self-report, or ecological momentary assessment), and study design (e.g., treatment research). Additional considerations include training and supervision of staff to identify suicide risk, coordination of others to respond to risk, and documentation of procedures. Finally, we attend to the impact of these procedures on the external validity of outcome data.

## General Scientific Summary

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This manuscript provides a rationale and guidelines for monitoring, assessing, and responding to suicide risk in research. These suggestions may vary as a function of study sample, methodology, and institution.

### Keywords

suicide; assessment; ethics

Suicidal ideation and behavior are serious public health problems in the United States. In 2017 alone, 47,173 people died by suicide and it is estimated that there are over one million suicide attempts per year (Drapeau & McIntosh, 2018). Clearly, research focused on identifying risk factors and treatments for suicide is critical.

Frequently cited reasons for the lack of empirical research on suicidal behaviors is the perceived liability, potential risks, and lack of training in monitoring and treating suicidal crises (Pearson et al., 2001). Despite evidence that assessing for suicide does not have prospective iatrogenic effects (see DeCou & Schumann, 2017), concerns about the potential risks do exist, among both researchers (Lakeman & Fitzgerald, 2009a) and ethics committee members (Lakeman & Fitzgerald, 2009b). Although understandable, concerns associated with these risks may serve as barriers to conducting research on the development of suicide assessments and treatments. In fact, clinical trials often *a priori* exclude individuals with suicidal ideation and/or behaviors, limiting generalizability and the clinical value of the research.

Others have reviewed the ethical issues associated with including individuals at risk for suicide in research (e.g., Fisher et al., 2002; Pearson et al., 2001). However, as there are no standard guidelines for identifying and managing suicide risk in studies, individual researchers and their ethics committees typically make these decisions idiosyncratically based on the particular sample and research methodology. With decades of combined experience with adults at high risk for suicide, we discuss our approaches to monitoring, assessing, and responding to suicide risk in clinical research as a guide for others making similar decisions in their research. When describing the assessment of “suicide risk” we refer to the likelihood that a person will make a suicide attempt or die by suicide.

## Study Sample Considerations

Proper assessment and management of suicidality in clinical research will vary depending on the study sample. Here, we discuss suicide risk assessment across clinical and nonclinical samples.

### Nonclinical samples

When conducting research with nonclinical samples (e.g., college students, community samples) the first significant question to consider is whether to assess for suicide at all. This decision point depends on multiple factors, most importantly whether suicide-related outcomes are central to the research question. Yet, even if suicide-related outcomes are not of interest, commonly used scales may include suicide-focused items. One example is item 9

of the Beck Depression Inventory-Second Edition (BDI-II; Beck, Steer, & Brown, 1996), which includes content related to a desire to end one's life. In one study of depression in undergraduates, researchers removed item 9 and prorated the scale, demonstrating high internal consistency (Weinstock & Whisman, 2007). However, researchers should consider that removing such an item may impact the psychometric properties and interpretation of the scale.

In addition, feedback from university Institutional Review Boards (IRBs) may influence whether or not a researcher specifically assesses for suicide. Many university IRBs are reluctant to approve research protocols that inquire about suicide due to concerns related to the institution's perceived ethical and legal responsibilities (Hom, Podlogar, Stanley, & Joiner, 2018). Research proposing to collect data even peripherally related to suicide in nonclinical samples should create an *a priori* protocol detailing how they will respond if any level of suicidal ideation is detected. In our experience, study participants may spontaneously report suicidal ideation and/or behavior whether or not they are asked directly. Components of a suicide risk assessment protocol for research can be found in Supplemental Table 1. These guidelines are non-exhaustive and non-prescriptive, as they may differ depending on institution, study sample, and research methods.

## Clinical samples

Somewhat different issues arise when research is conducted using mental health patients, as it is often necessary to assess and monitor suicidality regardless of the specific psychiatric disorder targeted given suicide's transdiagnostic risk (Chesney, Goodwin, & Fazel, 2014). We therefore recommend that studies recruiting from psychiatric outpatient or inpatient settings formally assess for suicide at every encounter regardless of whether participants are recruited based on suicide history. As mentioned previously, identification of risk might come about formally through such research assessments, or informally through routine contacts at any point during the study (e.g., scheduling). Further, mental health patients may report clinical deterioration, extreme hopelessness, or other risk factors (e.g., new stressors such as job loss) during study contacts that might trigger additional assessment.

When a study is being conducted with currently hospitalized patients, the issues related to detecting and responding to suicidality are just as important, although somewhat different than with outpatients. Many patients will be in the hospital due to suicide risk prior to admission, which may or may not persist during the hospital stay. Furthermore, a small but still significant number of inpatients attempt or die by suicide during hospitalization (Bowers, Banda, & Nijman, 2010), pointing to the importance of assessing for suicide risk during study contacts even while participants are hospitalized.

As inpatients are already being monitored regularly and residing on a restricted access unit, when and how to alert hospital staff to new concerns associated with suicide is a nuanced issue. Researchers may wish to set up meetings with attending physicians prior to the onset of study procedures to discuss when and how they want to be alerted to instances of suicide risk detected through research procedures. We have found that most hospital staff want to be alerted to more active and current/recent levels of suicidality detected during research contacts in contrast to more distant instances. Communicating this risk may require the

researcher to relay the relevant information immediately to the inpatient staff member responsible for managing patient issues on the floor. In addition, the researcher may need to follow-up with the participant's attending physician to alert them to the risk. For example, if a participant reports intent to die while on the unit or following discharge, some physicians have requested to be paged immediately. Yet, some staff have become frustrated when we have alerted them to risk in cases where they considered it to be of a lower level or something they were already monitoring. Once risk is identified, hospital staff may prefer to respond to the situation themselves according to the patient's treatment plan. It is important for research staff to not interfere with this process.

One additional point of consideration is when a study is recruiting inpatients but then following-up with them post-discharge. Patients are at particularly high risk for suicide in the months following psychiatric hospital discharge; a recent meta-analysis found that the suicide rate in studies that followed patients for up to 3 months was approximately 100 times the global suicide rate (Chung et al., 2017). Spacing the intervals of assessments closer in the beginning (e.g., 6-, 12-, then 24-weeks from study start) allows for monitoring during higher risk periods. To reduce participant burden, some or all of these assessments may be conducted by phone, in which case it is important to know where emergency services should be dispatched if needed.

## Study Methodology Considerations

Researchers can assess for suicide risk using clinician-administered interviews, self-reports, and in daily life using technology such as ecological momentary assessment (EMA). Many of the measures discussed below, and others, can be found in the "Suicide Specialty Collection" in the National Institutes of Health PhenX Toolkit (Hamilton et al., 2011). These measures alone are not sufficient for a comprehensive suicide risk assessment; the addition of unstructured clinical assessment will ensure completeness.

### Interviews

The research assessments of suicide that most closely resemble clinical practice are interview-administered measures. There are a large number of interviewer-administered assessments that assess multiple aspects of suicidal behavior and risk (see Brown, 2001, for a comprehensive review).

For research safety assessments, the most relevant assessments are those that assess suicidal ideation and/or recent suicidal behavior. The most widely used measure in recent years has been the Columbia Suicide Severity Rating Scale (C-SSRS: Posner et al., 2011), which assesses both suicidal ideation and behavior. The C-SSRS has been adopted in a wide variety of research studies and has been recommended for use by the FDA and other national bodies. There are triage guidelines suggested for the C-SSRS; for example, a positive answer to items assessing suicidal intent or plan in the past month, or any suicidal behavior in the past three months, indicate "a clear need for further evaluation and clinical management." Other interviewer-administered measures, such as the Scale for Suicide Ideation (Beck, Kovacs, & Weissman, 1979) and the Modified Scale for Suicidal Ideation (Miller, Norman,

Bishop, & Dow, 1986), have excellent psychometric qualities but focus primarily on suicidal ideation and not past suicidal behavior, which is an indicator of future suicide attempts.

### Self-report

For studies assessing suicidal ideation and behavior using self-report measures, such as the Scale for Suicide Ideation (SSI; Beck, Steer, & Ranieri, 1988) and the Suicide Intent Scale (SIS; Beck, Schuyler, & Herman, 1974), researchers will have a quantitative measure of suicide risk. These self-report scales will most often provide a measure of suicidal ideation rather than a measure of intent to engage in suicidal behavior, but establishing appropriate cut-offs may be helpful. In one study, a cut-off of 16 on the SIS gave a sensitivity of 100% in predicting suicide death compared to suicide attempt (Stafansson, Nordstrom, & Jokinen, 2010). Researchers using the SSI may examine specific items (e.g., preparation for contemplated attempt, expectancy of actual attempt, final acts in anticipation of death) as triggers for a further risk assessment.

It is important to note that the detection of suicide risk in many instances will be an incidental occurrence during the study of some other phenomenon, clinical or not, such as mood or attitudes. Consequently, a study with no emphasis on suicide may identify what could be labelled as high suicide risk (e.g., “I would kill myself if I had the chance” on the BDI-II) without adequate procedures in place to review this item and to manage identified risk. If a measure addresses some component of suicide risk, researchers should have a protocol in place to review all self-report measures before participants leave the assessment setting (see Supplemental Table 1 for an example).

### Ecological momentary assessment (EMA)

EMA, which encompasses a set of research and assessment techniques also known as experience sampling or diary methods, is a promising methodology that allows researchers to better understand the phenomenology of suicide risk as it exists in the real world. Using EMA methods, participants are most often asked about suicidal ideation or behavior as it is occurring in the moment (i.e., “right now”) or over a recent period of time (e.g., “since the last assessment” or “in the past day”). As such, EMA is best understood as a “state” based measure of suicide risk, which may indicate short-term risk, but may not reflect longer-term risk.

There are a number of potential issues associated with EMA that may complicate risk assessment. For example, as participants may be asked to complete these assessments when they are in the presence of others, they may feel uncomfortable fully disclosing thoughts about suicidal ideation or behavior if there is any risk that others might see their responses. The quality of risk assessment is also dependent on frequency of participant compliance. As EMA methods are useful in understanding dynamic state risk, failure to regularly complete assessments may make it difficult to accurately gauge suicide risk in the moment.

Perhaps the biggest limitation in using EMA is that it is usually not feasible to regularly monitor participant responses due to limited time and resources. Yet, participants may believe that their responses will be seen by researchers in real time, who will reach out to them when they report suicidal ideation or behavior. We manage this risk using a number of

strategies. First, we inform participants that no one will observe their responses in real time. We also include disclaimers at the beginning and end of every EMA survey reminding participants that no one is monitoring their responses. We create an assessment that is always available to participants that contains emergency contact phone numbers. Finally, we establish branching logic within the protocol that identifies imminent markers of risk (e.g., specific plan, intent to act), and in the presence of these markers, they receive a message recommending the participant immediately seek help.

Although many EMA applications make it technologically feasible to "force" an emergency phone call when suicide risk is detected, the proximal and immediate predictors of suicide are poorly understood (Glenn & Nock, 2014). When assessing suicide risk, it is often preferable to respond whenever suicidal ideation is detected, due to the potential loss of life through failure to act; however, for many patients, suicidal ideation with a method and some intent to act is a chronic, recurrent, state. Forcing an emergency response might result in unnecessary psychiatric hospitalization or legal intervention, which may have a serious impact on participants' freedom and safety, as well as willingness to continue research participation. While a long-term goal of work using these methods is to develop ecologically valid measures of risk, the science is not yet sufficiently advanced to rely on technology alone to determine risk.

## Training and Supervision of Research Assistants

Many of the widely used suicide risk screening measures are designed to be used by non-clinicians and can be easily administered by research assistants and research staff with adequate training and supervision. Due to the sensitive nature of the assessments and the implications of a positive screen, licensed clinical staff should be available during all assessments to provide clinical coverage in the event that suicide risk is identified.

Prior to the start of a project involving suicide risk assessment, investigators should create a safety manual that outlines the expectations for assessments, threshold for contacting clinical staff for risk assessment, and common issues that can arise during assessments. Initial training should involve review of the manual, review of the assessment measure, any training (e.g., C-SSRS online training: http://cssrs.columbia.edu/training/training-research-setting/), role-plays, supervised practice assessments, and regular clinical supervision of assessments. All assessments should be audio or video recorded for later review. Researchers should set up parameters for determining when a research assistant is sufficiently proficient in conducting a risk assessment before moving from the training to supervision phase. The parameters will vary depending on factors such as prior clinical experience, comfort level, adherence ratings, and investigator expectations.

Within clinical research protocols, unlicensed study staff function as gatekeepers by assessing suicidal ideation and behavior, and following clear guidelines for when to contact a clinician. For protocols recruiting patients with chronic suicidal ideation, contacting a clinician for every reported instance of suicidal ideation may be unnecessary. For example, in one of our suicide risk assessment studies, in which we recruit individuals recently hospitalized for suicidal ideation and behavior, research assistants are trained to contact

clinicians when they report any intent or plan to act on suicidal thoughts, any suicidal behavior (i.e., actual, interrupted, aborted attempts, preparatory behavior), or significant increases in suicidal ideation or distress during the protocol. In contrast, in protocols that do not directly target high-risk patients, staff may be required to contact a clinician if *any* suicidal ideation is present.

However, it is important to remember that most people who report suicidal ideation do not attempt suicide (ten Have et al., 2009). Therefore, researchers should consider assessing for other markers of acute risk, such as those described in Suicide Crisis Syndrome (i.e., entrapment, affective disturbance, loss of cognitive control, hyperarousal, social withdrawal; Galynker, 2017) or Acute Suicidal Affective Disturbance (i.e., a sudden surge in suicidal intent over minutes, hours, or days, severe social withdrawal, marked self-alienation; Tucker et al., 2016). While all self-reported suicidal ideation and behavior must be taken seriously, this potential risk should not be grounds to avoid or prevent the conduct of research that might possibly identify suicide risk. Indeed, the identification of this risk might be beneficial to research participants in the long run by providing them the help they need.

Other considerations for training and supervision include using common nomenclature for consistency across assessments, the degree to which staff deviate from assessment prompts, and staff comfort talking about suicide. Supervision should include regular reliability meetings with all assessment staff, clinicians, and principal investigators. This will prevent rater drift and allow for discussion of ethical and clinical issues that arise during the assessment. Finally, it is essential that clinicians make themselves available to debrief with research staff, especially following particularly difficult risk assessments.

## Coordinating with Others to Respond to Risk

Response to suicide risk may require one or more of the following actions: 1) escorting or arranging transportation for the participant to the local ED for further evaluation; 2) contacting a family member or close friend to assist in monitoring the individual or transporting them to the hospital; 3) calling the participant's outpatient treatment providers to alert them to the risk (after obtaining releases of information for this purpose); 4) calling local police to assist when a person is judged to be at imminent risk but is not accepting of help; and 5) following up with the participant by contacting him/her in the upcoming days to re-assess risk level.

In general, it is best to include communication from the research team to a clinical team in addition to a family member or contact person identified by the research participant. In the context of acute risk, confidentiality surrounding release of clinical information does not apply. This should be explained to participants as part of the informed consent process, both explicitly and in writing. Whether or not a family member is present, the research team should determine what level of escort to provide to clinical evaluation; if possible, research staff escort to a clinical evaluation area can work well, supplemented by security or police if there is concern regarding the participant's imminent risk of dangerous behavior or strong disinterest in clinical evaluation. Provision of a clear and concise written description of the research team's concerns regarding risks and/or a verbal communication in which the

receiving intake coordinator or clinician completes written notes is ideal. The research team can provide contact information so the treating clinician can reach out with questions.

## Documentation

Suicide researchers are often left with the question of how suicide-related serious adverse events (SAEs) should be classified when suicide can be both an SAE and a study outcome. The anticipated occurrence of fatal or near-fatal events in intervention trials where suicidal behavior is the outcome of interest requires careful consideration of the standards used to document and report SAEs (Oquendo et al., 2011). These events may also occur in non-intervention research where suicide is an outcome. Suicidal behavior and suicide death can be considered *expected* SAEs, events that may be reasonably anticipated to occur as a result of the study procedure and are described in the consent form. These definitions for suicidal ideation and behavior conform to the Columbia Classification Algorithm for Suicide Assessment (C-CASA) that was developed to systematize definitions of suicidal behavior (Posner et al., 2007).

The procedures for documenting and reporting events related to patient safety in suicide research are determined by identifying meaningful events for assessing patient safety. Within our team's suicide intervention trials, events determined to be relevant for assessing patient safety during a suicide intervention trial have included: ED visit (for ED-based studies), suicide or potentially suicide-related inpatient hospitalization (i.e., visits related to suicide/self-injury, mental health, ingestion, or traumatic injury), actual suicide attempt, or suicide death. Consideration of study-specific IRB and Data and Safety Monitoring Board (DSMB) requirements also play a part in the formation of protocols associated with how to effectively track suicide risk. It is recommended that each study develop a structured protocol for internal AE documentation and reporting which will help detect study-relevant AEs to accurately monitor and assess patient safety in suicide research (Arias et al., 2014). This documentation should include the steps research staff took to assess and respond to participants' safety and the associated rationale for the response.

## Minimizing the Impact of Suicide Assessment on Study Outcomes

Responding to suicide risk may alter outcomes for research in which suicidal ideation or behavior is a dependent variable. If a participant meets a certain risk threshold, action is required to ensure patient safety, but it is important to avoid introducing a potential contaminating effect (Boudreaux et al., 2013; Nierenberg et al., 2004; Oquendo, Stanley, Ellis, & Mann, 2004; Pearson et al., 2001). When conducting clinical trials, it is important to acknowledge that intervening in the presence of suicide risk as part of the research procedure is introducing another level of clinical intervention that participants may not otherwise receive if they were not enrolled in the research study. This is also the case for non-treatment research, where regular assessment that could trigger a clinical response may not actually be part of the natural course of the illness.

In suicide prevention research, study teams must develop approaches that maintain patient safety while at the same time conduct a study with credible treatment conditions (Pearson et

al., 2001). One important consideration is the frequency and timing of follow-up assessments. Assessments must occur frequently enough to avoid memory bias, but not so frequent that it diminishes the study's ecological validity (Boudreaux et al., 2013; Oquendo et al., 2004). Another consideration is how to address suicide crises (i.e., imminent risk, active suicidal ideation with plan/intent) during follow-up assessments. Several suicide intervention studies (e.g., ED-SAFE; Miller et al., 2017) have used the Boys Town National Hotline (2013) to ensure that there will always be a mental health counselor on call during the interview-based follow-up assessments (Arias et al., 2014). Integrating these types of procedures into the study design are key factors in limiting unintended effects of introducing a secondary intervention and impacting the study outcome, while ensuring patient safety.

## Conclusion

Given the high and increasing rates of suicide, it is essential to conduct research focused on identifying, preventing, and safely and effectively treating suicidal ideation and behavior. We believe that having a proactive plan to ethically assess, monitor, and respond to suicide risk in a manner that ensures institutional IRB and funding agency compliance will remove barriers that stand in the way of including individuals at increased suicide risk in clinical research.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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