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Current Practices of Suicide Risk Management Protocols in Research

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Abstract. *Background:* Participant safety is an important concern in mental-health-oriented research. Investigators conducting studies in the United States that include potentially suicidal individuals are often required to develop written suicide risk management (SRM) protocols. But little is known about these protocols. It is possible that such protocols could serve as templates for suicide risk management in clinical settings. *Aims:* To elucidate common (best) practices from mental health intervention researchers. *Methods:* We conducted a systematic descriptive analysis of written SRM protocols. A convenience sample of studies funded by the United States' National Institute of Mental Health in 2005 were scanned to discover projects in which investigators were likely to identify and take responsibility for suicide risk in their participant pool. Qualitative methodology was used to create a checklist of tasks perceived to be operationally significant for insuring the safety of suicidal participants. The checklist was applied to all protocols to determine the variability of patient safety tasks across protocols. *Results:* We identified 45 candidate studies, whereof 38 investigators were contacted, resulting in the review of 21 SRM protocols. Three main categories emerged: overview, entry/exit, and process. Overall, 19 specific tasks were identified. Task frequency varied from 7% to 95% across protocols. *Conclusions:* The SRM checklist provides a framework for comparing the content of SRM protocols. This checklist may assist in developing SRM protocols in a wide range of settings. Developing guidelines and standard methodologies is an important step to further development of suicide prevention strategies. More research is necessary to determine the impact of SRM protocols on participant safety.

Keywords: suicide, suicide risk, protocol, Human Subjects Division, Internal Review Board

Introduction

Suicide and related behaviors affect both the individual and society on multiple levels and result in devastating social and financial costs (Kung, Hoyert, Xu, & Murphy, 2008; Yang, 2007). In the past decade, the utilization of psychological treatment by suicidal individuals has increased, while suicidal behaviors have *not* decreased correspondingly (Kessler, Berglund, Borges, Nock, & Wang, 2005). In the United States, public health officials, including the Surgeon General, and research funding agencies such as the National Institutes of Health (NIH) have identified prevention and treatment of suicide as a top research priority (Department of Health and Human Services, 2000; Pearson, Stanley, King, & Fisher, 2005; Pearson, Stanley, King, & Fisher, 2001; Satcher, 1999; World Health Organization, 1996). Empirically supported treatments specific to suicide are not well established or readily available (Brown et al., 2005; Hepp, Wittmann, Schnyder, & Michel, 2004; Linehan et al., 2006; Mann et al., 2005), and there exist significant deterrents to conducting research with suicidal individuals. For example, clinical researchers have traditionally excluded suicidal individuals because of safety concerns (Pearson et al., 2005, 2001), assuming that potential risks outweigh benefits. Consequently, many psychotherapy trials contain findings that may not generalize to suicidal participants.

Research studies in the United States that include suicidal participants often incorporate safeguards such as specialized suicide risk management (SRM) protocols, oversight by institutional review boards (IRB), and data safety and monitoring boards (DSMB). A SRM protocol documents procedures for identification of, and care for, suicidal participants within the context of a research study. SRM protocols should not be confused with suicide risk assessment or prevention guidelines (e.g., Rudd, Joiner, & Rajab, 2001). An SRM protocol is a specific list of actions for managing a suicidal participant (e.g., who to contact, what to document), while suicide risk assessment and prevention refer to the one-on-one nature of directly assessing risk and preventing suicide with a suicidal individual (i. e., a specific clinical intervention). An SRM protocol may include or refer to suicide risk assessment and prevention guidelines, but the reverse would not be true.

A limited body of literature exists to guide researchers in developing SRM protocols. Recognizing that insuring participant safety extends beyond assessment and prevention techniques, the NIH produced broad guidelines for including and retaining participants at increased risk of suicide within study

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Overview

Indicate where the plan is specified
1. ☐ Narrative within grant/irb
2. ☐ Separate document(s)

Indicate who is responsible?
3. ☐ Study Personnel
4. ☐ Uses specific names/numbers of clinical/supervisory contacts
5. ☐ Community Resources
6. ☐ Specific names/numbers of individuals/clinics
7. ☐ Unknown

Specify Entry/Exit from being "in" the protocol

8. ☐ Contextualization of where/when/how the risk is being identified
9. ☐ Guidelines for maintaining a participant who is at increased risk, in the study

Instrumentation

10. ☐ No specific instruments for risk assessment
11. ☐ Qualitative instrument/questions to ask
12. ☐ Use of specific instruments for risk assessment
13. ☐ Use of specific cut-off scores

Provide process guidelines

Type of instructions
14. ☐ General principles for responding
15. ☐ Specific actions for responding

Contingency Instructions
16. ☐ Once risk is identified - specify how long to wait for clinical resources before activating "emergency" procedures

Documentation
17. ☐ Specifies documenting actions taken
18. ☐ Provides a checklist for specific actions taken
19. ☐ Provides an adverse events reporting form to document the contact/action and for reporting to the IRB and/or DSMB

Figure 1. Identified tasks.

procedures (Pearson et al., 2005). These guidelines, along with a related article in the *Journal of Clinical Psychiatry* (Pearson et al., 2001), describe a range of issues related to protecting suicidal participants and recommend the formulation of SRM protocols. Although the specifics of SRM protocols are not discussed, Nierenberg et al. (2004) provide an example of how these guidelines were applied in the STAR*D trial (see www.star-d.org). Oquendo, Stanley, Ellis, and Mann (2004) provide guidelines for applying the principles of respect for persons, beneficence, and justice to study design. We know of no direct evidence supporting the efficacy of SRM protocols in insuring patient safety (Beck, Brown, Steer, Dahlsgaard, & Grisham, 1999; Brown, Beck, Steer, & Grisham, 2000). As such, the purpose of the present research is to elucidate best practices and to develop research tools for SRM protocol assessment.

Methods

Participants and Collection of SRM Protocols

Participants were primary investigators of National Institute of Mental Health (NIMH)-funded studies focused on mental health interventions. The unit of analysis was a study and its SRM procedures. We sought a representative sample of U.S. clinical treatment projects in which study personnel would be likely to both identify and assume responsibility for suicide risk in their participant pool. Studies such as secondary data analyses, survey studies, and observational studies, were excluded. The Computer Retrieval of Information on Scientific Projects (CRISP) database was used to review mental health intervention studies funded during 2005, including adult participants and study mechanisms of R01, R21, and R34. Studies were filtered first based on title and then from a review of their abstract. Participants were approached by telephone, given a description of the study, and asked to participate. Interviewers requested a description of the study and a copy of any written protocol used for responding to suicide risk.

Development of Qualitative Analyses for Research Protocols

Methods drawn from grounded theory were used identify the breadth of content and processes used in SRM protocols (Glaser & Strauss, 1968; Starks & Brown-Trinidad, 2007). Two members of our team (S.V. & J.U.) reviewed the protocols and identified categories of content and process. From these categories we developed organizing themes, which correspond generally to a subset of those presented in published guidelines for protecting participants (Pearson et al., 2005, 2001). A total of 19 tasks were identified. All protocols were then "rated" by two members of the research team (S.V. & U.W.) using a checklist containing the 19 tasks (Figure 1). We compared ratings, discussed discrepancies, and refined the category definitions. The review-and-refine process continued until we were confident that the categories were defined well enough to be an effective tool for facilitating new proto-

col development. All procedures were approved by the local institutional review board.

Results

Participation

An initial list of 1075 studies was reduced to 283 by scanning titles. We retrieved the 283 abstracts and identified 45 that appeared to meet our criteria. Of these, 38 study representatives were contacted, while 7 could not be reached; 3 of the remaining representatives refused participation, and 1 agreed to participate, but we were unable to collect the data. Hence, 27 studies met the inclusion criteria and were enrolled in the investigation. Of these, 21 had a written protocol and were included in our analyses.

The Studies

The 27 studies included clinical trials addressing a wide range of mental illness including depression (22), psychosis (1), severe mental illness (1), homelessness with severe mental illness (1), mental health needs (1), and dementia (1). The majority (22) were randomized controlled trials, while there was one pilot, one qualitative, one feasibility, and two observational designs. Studies varied in participant enrollment, (median = 216, range 45 to 4000). Studies were conducted in various settings, including academic outpatient (6) and inpatient clinics (3), primary care (3), health organizations (3), in-home (2), community health center (2), specialty mental health clinic (2), senior center (1), community dwellings for those with severe mental illness (1), ophthalmology clinic (1), assisted-living facility (1) medical center (1), and telephone (1).

Suicide Risk Management Protocols

The length and format of the SRM protocols varied greatly. Some were as short as a single paragraph embedded in an IRB application. Other formats included flow diagrams, reporting forms, general guidelines, and detailed lists of information and procedures. Research team members (S.V. & U.W.) independently applied the derived checklist to each protocol. We applied the kappa statistic as a heuristic guide for approaching a reasonable level of agreement (McGinn, 2004). After each round of evaluation we identified items with poor agreement, discussed the discrepancies, and either retained or modified the item definition. When the definition was modified, we re-examined all protocols against the new definition. We terminated the process when kappa's for all 19 identified tasks reached a level greater than or equal to 0.8 (range 0.81 to 1.00, $M = 0.90$, $SD = 0.07$), as well as being subjectively satisfied that others would be able to correctly infer our intended categorical descriptions.

Table 1. Frequency of categories across all protocols

Category	Rater 1		Rater 2		Mean %
	%	(*n*)	%	(*n*)	
1	29%	(6)	19%	(4)	24%
2	76%	(16)	86%	(18)	81%
3	86%	(18)	100%	(21)	93%
4	71%	(15)	71%	(15)	71%
5	81%	(17)	71%	(15)	76%
6	67%	(14)	52%	(11)	59%
7	5%	(1)	10%	(2)	7%
8	71%	(15)	86%	(18)	79%
9	19%	(4)	24%	(5)	21%
10	29%	(6)	24%	(5)	26%
11	33%	(7)	33%	(7)	33%
12	62%	(13)	62%	(13)	62%
13	43%	(9)	48%	(48)	45%
14	14%	(3)	19%	(4)	17%
15	90%	(19)	95%	(20)	95%
16	14%	(3)	10%	(2)	12%
17	57%	(12)	62%	(13)	60%
18	14%	(3)	24%	(5)	19%
19	14%	(3)	0%	(0)	7%

Table 1 presents the frequencies of the 19 tasks as assessed by each rater. There was significant variance in the frequencies (7% to 95%). Three major themes were created from our list of categories: Overview, Entry/Exit from the Protocol, and Process.

Themes

Overview

The Overview included two tasks: (1) where the plan was documented, and (2) who was specified as having clinical responsibility. Specifying study personnel as having clinical responsibility was common (93%), with 71% specifying names and telephone numbers. Use of community resources was also common (75%), but in these cases only 57% identified specific names and telephone numbers. Use of both study-personnel and community resources was very common (76%), in the event that a patient's distress could not be resolved.

Entry/Exit from the Protocol

Six tasks were included in Entry/Exit from the Protocol. While 79% of protocols provided some context regarding where, when, or under what circumstances suicide risk

might be identified, only 21% gave instructions for how to decide if a participant should remain within the study.

Process

The process theme was subdivided into three categories: (1) the type of instructions provided for interacting with patients, study staff, and clinicians (2 tasks); (2) presence of contingency instructions (1 task); (3) type and content of documentation (3 tasks). Contingency instructions (item 16) were present in only 12% of the protocols. A few (7%) provided a specific form for communicating the identification actions taken to either a DSMB, or an IRB (item 19).

Discussion

This descriptive review of written protocols in mental-health-intervention studies indicates significant variation in the length, format, and content of SRM protocols used in NIMH-funded mental-health-intervention research. Although the majority of our sample relied on some form of written protocol, 22% had none. Our goal was to describe and communicate common practices for protecting research patients in mental-health-oriented treatment studies, with the hope that this information would inform future protocol development and ultimately stimulate research on the impact of such protocols on participant safety. We stress that the intention of this study was descriptive and not evaluative.

Themes

Overview

The issue of where the protocol is documented may seem trivial; however, our subjective experience indicated that protocols embedded within IRB or grant documentation were more difficult to analyze, which in turn could inhibit effective implementation of the protocol.

Entry/Exit from the Protocol

Our subjective response to protocols that were more specific in detailing entry and exit was a sense of context for circumstances in which the protocol would be applied. Such context was helpful in mentally reviewing various scenarios that might occur. We theorize that this may provide significant benefit in planning for the occurrence of suicidality.

Process

Many protocols appeared to be targeted at research staff conducting assessments who were not mental health clinicians. The presence of general principles for responding (e.g., remain calm, reassure the patient) appeared appropriate and helpful. The types of specific instructions were broad. We coded the presence of any instructions (e.g., inform patient you are contacting your supervisor for additional assistance) as positive, noting that the level of detail between protocols varied immensely. In our experience it is not always clear to participants that research staff may not be trained clinicians, and that interactions with such staff do not constitute clinical assessments. This was only clearly addressed in a few protocols.

Flow charts were rare, but they are particularly helpful in providing a clear view of specific actions to be taken, when, and by whom. Forms were also helpful providing clear steps to take, which information to collect, and whom to involve. The lack of contingency instructions appeared particularly problematic, especially for protocols intended for nonclinical staff. Instructions on how to reach the on-call psychiatrist are useful, but what if there is no response? How long should staff wait to escalate the process to the next level – and what would that be?

Documentation

The variation in length, format, and specificity of documentation was dramatic. For example, "make a note in the patient record" would code positive for "specify documenting actions taken" (item 17). More reassuring were actual forms listing documents to be generated within a protocol (varying depending on level of risk), with checkboxes for notating completion (item 18).

Limitations/Future Directions

We utilized a convenience sampling frame. It is possible that there are common practices being utilized that were missed because of unintended sampling bias? The ultimate purpose of suicide risk management protocols in intervention studies is to identify and protect participants at risk of suicidal behavior. This observational study provides no empirical evidence regarding whether or not SRM protocols actually achieve this goal. Hence, a next step would be to gather information on outcomes of protocol invocation.

Conclusions

Our investigation has resulted in the development of checklist of common tasks found in SRM protocols utilized by NIMH-funded researchers in the United States. Developing SRM protocols for mental-health-intervention studies is a ubiquitous process that is recreated frequently, and it is done so in the absence of empirically based research into content, process, and outcomes. Creating SRM protocols involves a large amount of human and capital resources that

could otherwise be invested in study activities. This process deserves an empirical foundation to guide researchers and we hope the development of the checklist will assist in the development of further research.

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