COMIRB Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
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Protocol #: 20-2859

Project Title: Veterans' perspectives on emergency room based lethal means safety interventions

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I. Hypotheses and Specific Aims:

The aim of this study is to explore contextual factors that will inform development of an emergency department (ED)/ Urgent Care (UC)-based lethal means safety intervention for veterans with elevated suicide risk who seek care in VA Eds/UCs. We hypothesize that qualitative interviews with VA patients will identify perspectives and factors that will be informative for intervention development.

II. Background and Significance:

Veterans have a 20% higher risk of suicide than age- and gender-matched non-Veterans.[1] Limiting access to lethal means, such as firearms and toxic medications, is recommended to prevent suicides among those with elevated suicide risk.[2] However, little is known about ways to promote lethal means safety among at-risk adults, including Veterans. This qualitative study is expected to provide important insights into factors that could impact the development and delivery of a Veteran-centered, ED/UC-based, lethal means safety intervention.

III. Preliminary Studies/Progress Report: N/A

IV. Research Methods

A. Outcome Measure(s): We will conduct semi-structured, exploratory qualitative interviews with VHA patients. Outcomes of this exploratory study include qualitative themes that will be informative for intervention development.

B. Description of Population to be Enrolled: We will collect patient-reported data through semi-structured interviews with up to 40 Veterans who were recently discharged from a VHA ED or VHA UC. Veteran participants will be included who are ≥18 years of age, receiving or have received care in a VHA ED or VHA UC, have access to firearms and/or medications at home, and are determined to be at elevated suicide risk based on the presence of suicide risk factors, including screening positive for having elevated suicide risk at the time of admission via the Columbia Suicide Severity Rating Scale Screener. Veterans will be excluded if they are critically ill (intensive care unit requirements), are severely cognitively impaired, have severe psychiatric symptoms that would

preclude study participation, lack decision making capacity, are unable to provide informed consent, or lack reliable telephone access. No age or gender exclusion criteria will be applied.

We will stratify enrollment based on access to firearms and medications.

Deductive and inductive content analysis will occur in parallel with recruitment. We will recruit until thematic saturation is achieved. Given prior experiences conducting qualitative research, we expect to enroll approximately 30 participants.

C. Study Design and Research Methods:

RECRUITMENT: The research team will recruit veterans who recently received healthcare either at the Emergency Department or at Urgent Care at the Rocky Mountain Regional Veterans Affairs Medical Center (RMRVAMC), Grand Junction Veterans Affairs Medical Center (GJVAMC), or Cheyenne Veterans Affairs Medical Center (CVAMC).

VA electronic medical records and additional data sources including the VA Corporate Data Warehouse (CDW) will be used to obtain names and addresses of Veterans who may be eligible to participate in the study in order to send information describing the study and inviting participation by mail. Study staff will run regular reports (approximately once weekly) of Veterans who recently received care in the ED or UC at RMRVAMC, GJVAMC, and CVAMC. Staff will use electronic medical record (EMR) data to identify a subset of potential participants who have been identified as having elevated suicide risk (e.g., reports suicidal ideation, suicide attempt). Staff will pre-screen the EMR to identify additional inclusion/exclusion criteria (for this, a HIPAA waiver is being requested).

Study staff will mail potential participants a recruitment letter that describes the study. Up to two reminder letters may be sent if the participant has not responded within 4 weeks. For interested veterans, a phone number for study staff will be provided. Potential participants who respond to this letter will be screened for study eligibility using the study screening script (see appendix). Those who are eligible and interested in participating will be scheduled for a consent visit and full study visit.

SCREENING: Individuals who express interest in participating in the study will participate in a brief screening process using the study screening script (see appendix). A member of the research team will conduct the screening process via telephone. Screening will also include a review of VA medical records. Those who are eligible to participant and are willing to participate will be scheduled to complete informed consent and study procedures. Eligible participants who are scheduled for a study appointment may be sent an appointment reminder letter and consent and debriefing forms via mail or email, as appropriate and if requested.

AUTHORIZATION: For recruitment, a waiver of consent and a HIPPA Waiver of Authorization will be obtained to allow members of the research team to view selected medical charts of patients who contact the PI or study coordinator and express interest in participating in the study. Review of the medical records allows members of the research team to screen for other criteria that would exclude participation (e.g., certain medical conditions, such as cognitive impairment).

For enrollment, all study procedures will be conducted via phone or audio conferencing. Per institutional policies, a waiver of documentation of consent will be obtained when study visits do not occur at the ECHCS. Prior to engaging in the informed consent process, a study team member will ask the potential participant if they are in a quiet and private setting to begin the process. A study team member will review the postcard consent in its entirety over the telephone or audiconference with a potential participant.

CONSENT VISIT: We will schedule initial calls with interested participants to complete study consent. During this appointment, research staff will review the postcard consent. Individuals will be informed about the study, risks and benefits to participating, and alternatives to participating. Eligible participants will be read the consent script in its entirety. For those who provide consent to participate, a VA study coordinator note will be placed in the chart. Per their request, participants may be sent hard copies or emailed copies of the consent form. A waiver of documentation of consent and a waiver of HIPAA authorization is being requested for study procedures.

ASSESSING ABILITY TO PROVIDE INFORMED CONSENT: Individuals interested in participating will be assessed for their ability to provide informed consent, based on their responses to the following questions:

Why is the study being done?
What is the study asking you to do?
What are the risks / side effects of being in this study?
What are the benefits of being in the study?
Is the study voluntary?
What do you do if you have questions or possible side effects?

If the individual is able to adequately answer these questions and decides to participate, informed consent will be obtained. Individuals who are <u>not</u> able to adequately respond to the questions above will be excluded from participation. Participants will be provided with ample time to ask questions.

STUDY VISIT: After consent is obtained, we will conduct semi-structured, exploratory qualitative interviews with VHA patients. Enrolled participants will participate in phone or teleconference interviews using VA-approved teleconferencing software (eg, Microsoft Teams) within 4 months of ED or UC discharge. To begin, the UWRAP pre-assessment (described further below, see also appendix) will be administered to assess the participant's risk for self-harm and safety to proceed with the study. A semi-structured qualitative interview will subsequently be conducted for participants (interview guides attached). Following completion of the qualitative interview, UWRAP post-assessment and study measures will be administered.

For the majority of participants, the study visit is expected to take place in a single visit. However, the study visit may be split up into multiple visits to accommodate participants' needs. For visits that take place over multiple visits, the UWRAP pre-assessment and post-assessment will be administered at the beginning and end of each visit to assess risk.

Participants who complete the study will be compensated $40 upon completion of the study visit (in the form of cash, payment vouchers, check, direct deposit, or gift cards). Individuals who choose to prematurely discontinue their participation or who are excluded from participating (e.g., due to study ineligibility) will be compensated at a prorated amount of $20 per hour (not to exceed $40). For study visits that are split into multiple visits, participants will be compensated for their time at the conclusion of each visit (not to exceed $40 total).

Protected Health Information (PHI): PHI to be collected may include: first and last name, date of birth, address, and full Social Security Number. This information is needed to access participants' medical records to collect data for this study and/or to send study recruitment letters. Because this study will collect data on participants' perspectives and experiences with healthcare, dates related to such events may also be gathered.

SAFETY MEASURE:
University of Washington Risk Assessment Protocol-Revised (UWRAP). In the present study, the UWRAP will be used to evaluate safety to participate in the study and to address potential risk associated with participating in this study. The UWRAP will be administered to all participants following informed consent, prior to administering any study measures. As noted above, for visits that take place over multiple visits, the UWRAP pre-assessment and post-assessment will be administered at the beginning and end of each visit to assess risk. Participants will be asked to articulate pre-test levels of stress, urge to self harm, intent to die, and urge to use drugs or alcohol (Pre-Assessment Risk Assessment Questions). After completing all study measures, the UWRAP post-test questions will be administered, including a debriefing checklist and protocol, as needed. Using results from the debriefing, members of the research team will be trained to evaluate responses and access additional assistance, as necessary. The UWRAP protocol has been used in over 20 years of research with potentially high-risk patients and is recommended by the National Institute of Mental Health. The UWRAP is conducted by reading items to the participant and eliciting their response. Thus, it can be conducted remotely and without video interaction.

Because interviews will take place remotely, as an additional safety measure, participants will be asked to complete a safety locator form (see appendix). This form collects location and safety contact data in the event of an emergency which can be used to contact emergency contacts or emergency services if needed.

STUDY MEASURES: Study measures will be read to participants and responses will be recorded in electronic format (eg, Microsoft Word, Excel, CCTSI Redcap) on password secured files on password-protected and VA approved devices. All data will be entered by VA approved staff. All identifiers will be kept on VA-approved devices and services, and will not be entered into Redcap.
The MIRECC Demographics Form: A brief survey that collections sociodemographic and military service information from participants.
MIRECC lethal means safety survey: This survey assesses access to and safety practices around medications and firearms.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Adverse events

Significant adverse events are not expected given that this study does not involve an intervention. For the purposes of this study, adverse events are defined as any newly identified medical diagnoses noted by medical personnel, or symptoms reported by the participant, which are *directly related to participation in the study and occur during the administration of testing or appear shortly thereafter*. The Principal Investigator will be notified of any complaints or reports of adverse events. Any adverse event will be reported to COMIRB by the PI within 5 days. Based upon the limited risks associated with participating in this study, there will not be a Data Safety Monitoring Board.

Risks

The anticipated risks and discomfort associated with research procedures are not greater than those that would be ordinarily encountered during routine clinical care or psychological assessment. Research risks to subjects include: 1) inadvertent disclosure of personal health information (PHI) or personally identifiable information (PII) that results in psychological, social, legal, or economic consequences, and 2) time commitment required or potential discomfort related to interview participation. We feel these risks are minimal. We will mitigate risk of inadvertent information disclosure by adhering to the rigorous information security procedures in place at RMRVAMC and the VA Rocky Mountain Mental Illness, Research, Education, and Clinical Center (MIRECC). Some participants may endorse suicide-related assessment items (e.g., suicidal ideation, prior suicide attempts) during the study. For participants who reveal current active suicidal thoughts, the appropriate follow-up actions outlined in the safety monitoring plan will be implemented (See UWRAP Appendix). Participants also have the potential to become frustrated, fatigued, or distressed during the interview. Members of the research team will be trained to minimize psychological distress while assisting individuals in completing the protocol.

Benefits

This study does not involve the delivery of treatment and has no therapeutic intent. The primary benefit of this study is generalizable knowledge.

Safety Monitoring

Based on the topic of this study, it is not believed that participating in the study places participants at increased risk. However, because some participants may have a history of suicidal thoughts or suicidal behaviors, a clear and rigorous safety protocol will be implemented to assess and manage suicide risk. As described above, the UWRAP will be used to assess and address any potential risk associated with participating in the study. Participants will be asked to articulate pre-test potential stressors; following the interview, the UWRAP debriefing checklist and protocol will be administered. Using results from the debriefing, a trained member of the research team will evaluate responses and access additional assistance, if necessary.

Participants deemed to be at elevated risk for suicide may be kept on the phone while emergency services are contacted, referred to Psychiatric Emergency Services, referred to their clinician to facilitate appropriate follow-up, emergency contacts are contacted, and/or referred to appropriate VA clinical staff trained in mental health, as indicated and deemed to be appropriate by trained research personnel. For participants deemed to be at imminent risk of suicide, imminent risk may be documented in their VA electronic medical record (e.g., by entering a note into their medical record). Alternately, emergency services (911) may be contacted. (See UWRAP Appendix for a detailed Safety Monitoring Plan). All

research staff will be trained on the risk assessment protocol prior to enrolling or screening any participants.

Additionally, at the end of the study visit, all participants will be provided with the phone number for the crisis hotline.

Data security. Minimizing risks pertaining to data security will be achieved by employing safeguards built into the framework of the VA Office of Research and Development (R&D). All electronic data will be stored on a local, password and access restricted ECHCS server within the VA firewall. Data will only be able to be retrieved from within the VA network. Files will be user-restricted and/or password-protected so that only members of the research team can access the data. Any data administered on VA laptops (i.e., qualitative interview responses) will be done on VA laptops that meet the VA standards for encryption, anti-virus protection, and firewall security. Data entered into CCTSI redcap will be de-identified, and the master list of identifiers (ie, crosswalk) will be kept on secured VA servers.

Screening databases. For the purposes of this research project, one screening database will be created. The screening database will include the screening ID number, first and last name, last 4 digits of Social Security Number (SSN), date of birth, telephone number, referral source, eligibility, and relevant dates related to recruitment, screening, and scheduling.

Consented participants. Similarly, for all individuals who provide informed consent (i.e., enroll), two databases will be developed. A unique identifier (UI) will be assigned to each (e.g., #1, #2).

1. **ID Database.** The ID database will contain participant identification (i.e., UI, first and last name, SSN, date of consent, and telephone number). No other information will be stored in the ID database. The ID database will be user-restricted, with only study personnel having access to this database.

2. **Research Database.** This database will include information obtained during the study visit, including information obtained from the interview/measures and medical chart review. Only limited PHI (e.g., dates) and UI will be included in this database.

Audio files and transcripts. The research team will have each interview transcribed in its entirety. If audio files contain patient names, they will be omitted from the transcribed document (e.g., replaced with "XXX"). If other information, such as names, dates (beyond years), or additional information deemed to be identifying is provided, such information will also be omitted from the transcribed documents. Audio files and transcripts will be saved and/or labelled in their entirety with the corresponding UI. Any quotes selected will remain de-identified. Audio files will be transcribed by the VA's centralized transcription service in Salt Lake City, UT or locally at RMRVAMC. Thus, those data will remain on secure VA servers.

Paper data. No paper data are collected.

Aggregate data. Aggregate data with all PHI removed may be shared with collaborators outside of the VA. However, prior to sharing any data, appropriate data sharing agreements and memorandums of understanding will be put in place.

Staff training. Procedures designed to maintain confidentiality and data security will include training of all study personnel in regard to data security, research ethics, and study procedures, as well as formal mechanisms for limiting access to all information that can link data to individual participants.

E. Potential Scientific Problems: Potential problems include difficulty in recruitment. The VA MIRECC has a robust recruitment core with a strong track record in recruiting for VHA studies, including in ED settings. Interviews are intentionally planned by teleconference rather than in-person to increase convenience for participants and avoid risks of in-person recruitment during the COVID pandemic.

F. Data Analysis Plan: Data collection and analysis will occur concurrently. Interview guides will be iteratively adjusted if unexpected themes emerge, or if items fail to elicit relevant data. We will simultaneously perform deductive content analyses using pre-defined domains and inductive content analyses to identify emergent themes. We will convene to reach consensus regarding themes or categories/domains, and if saturation has been achieved. We will resolve coding discrepancies by consensus. We will also collect sociodemographic and clinical data from review of the electronic medical record.

G. Summarize Knowledge to be Gained: Little is known about how to develop and/or deliver lethal means safety suicide prevention interventions in clinical settings among adults, including veterans. The proposed study is expected to provide important insights into the development of a lethal means safety intervention for veterans seeking VHA ED care.

H. References:

1. 2019 National veteran suicide prevention annual report VOoMHaSP, US Department of Veterans Affairs. Available at: https://www.mentalhealth.va.gov/docs/data-sheets/2019/2019_National_Veteran_Suicide_Prevention_Annual_Report_508.pdf

2. VA. National Strategy for Preventing Veteran Suicide, 2018-2028. US Department of Veterans Affairs. Available at: https://www.mentalhealth.va.gov/suicide_prevention/docs/Office-of-Mental-Health-and-Suicide-Prevention-National-Strategy-for-Preventing-Veterans-Suicide.pdf. Accessed Aug 12 2018. 2018