Managing Suicide Risk in Veteran Research Participants

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Introductions by Teresa Hudson, PhD, PharmD

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Agenda and Presentation Team

Topic	Presenter
Introduction and framework for managing suicide risk in Veteran research participants	Alan Teo, MD, MS, Physician Investigator, VA HSR&D Center to Improve Veteran Involvement in Care, Portland, OR
Case study guided by the presented framework	Mark Ilgen, PhD, Research Career Scientist, VA Center for Clinical Management Research, Ann Arbor, MI
Practical application of risk assessment in the context of research	Courtney Bagge, PhD, Research Investigator, VA Center for Clinical Management Research, Ann Arbor, MI
SPRINT Website: Location and Description of risk management resources and how to obtain additional help.	Emily Yeagley, MA, MPH, VA Center for Clinical Management Research, Ann Arbor, MI

Framework for Assessing Suicide Outcomes in Research Studies

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Alan Teo, MD, MS
Physician Investigator
VA HSR&D Center to Improve Veteran Involvement in Care
Portland, OR

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?	PHQ-8 BFRSS conversion	Not at all 0 - 1 day	Several days 2 - 6 days	More than half the days 7 - 11 days	Nearly every day 12 - 14 days
1. Little interest or pleasure in doing things		0	1	2	3
2. Feeling down, depressed, or hopeless		0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much		0	1	2	3
4. Feeling tired or having little energy		0	1	2	3
5. Poor appetite or overeating		0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down		0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television		0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual		0	1	2	3

Interpretation of Total Score/Total Score Depression Severity: 0–4 None, 5–9 Mild depression, 10–14 Moderate depression, 15–19 moderately severe depression, 20–24 severe depression.

For Researchers

self-management skills, and higher satisfaction with care. Though many close relationships appear willing to participate in patients' care, in clinical practice, they are often not formally engaged in Veterans' depression care.

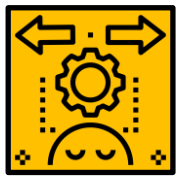
Importance (and challenge) of assessing suicide outcomes in research studies

- Studies have historically excluded patients with suicide risk
- Need suicide measures to study suicide
  - Suicide as a public health problem
  - Low base rate of suicide
  - *Value of collecting measures related to suicide even in studies not focused on suicide*
- Balancing ethical obligations with integrity of the research
  - Protection of participant safety and IRB requirements
  - Reasonable "burden" on research team and participant
  - Suicide risk assessment becomes an intervention unto itself

Framework for managing participant risk for suicide in research studies

1. Study design and informed consent

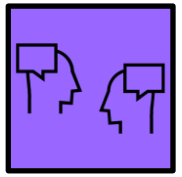
2. Collection of data related to suicide



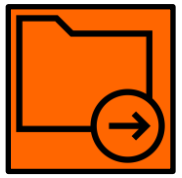
3. Determining when a more detailed suicide risk assessment is indicated

4. Assessment of suicide risk

5. Responding to suicide risk

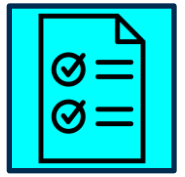


6. Reporting procedures



7. Training

1. Study design and informed consent

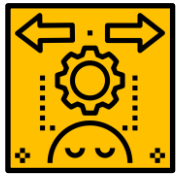


- What degree of safety monitoring is appropriate given the study design?
  - What is the *baseline risk* of suicide in the study population?
  - Could the study potentially *cause increased risk* of suicide?
- Incorporate safety monitoring related to suicide in the informed consent process
  - Inform study participants of limits to confidentiality and HIPAA in situations involving imminent suicide risk
  - May discuss procedures and clinical management plans in the case of imminent suicide risk

2. Collection of data related to suicide

- What data related to suicide are being collected as part of the study?
- Structured measures/scales (e.g., PHQ-9 I9, CSSR-S)

3. Determining when a more detailed suicide risk assessment is indicated

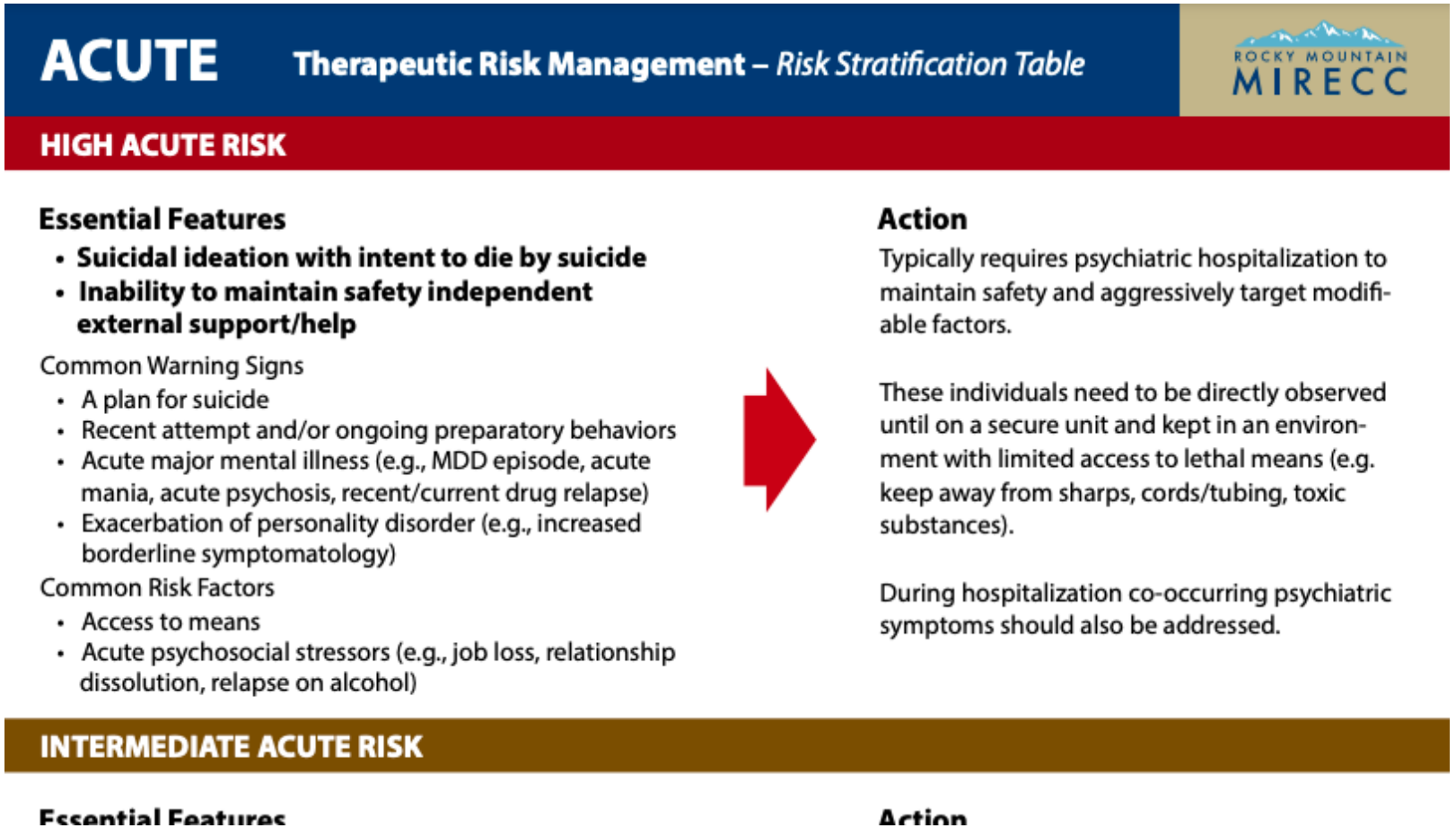


- Scenario 1: Participant above a *pre-specified threshold* for triggering detailed risk assessment
  - Score threshold on structured suicide measures/scales
  - New report of SI or suicidal behavior
  - Increase in SI or suicidal behavior
- Scenario 2: *Incidentally detected* concerns
  - Did the participant exhibit any language or behavior that raises concern?

4. Assessment of suicide risk 

- Have an SOP, template, or decision guide for research staff to follow
- Gather information on location/contact information
- Determine *acuity* of risk
  - Is it imminent suicide risk?
- Determine *level* of risk
  - Intention to act?
  - Preparatory behavior?
  - Suicide plan?

Rocky Mountain MIRECC Suicide Risk Table



ACUTE Therapeutic Risk Management – *Risk Stratification Table*

ROCKY MOUNTAIN MIRECC

HIGH ACUTE RISK

Essential Features

- **Suicidal ideation with intent to die by suicide**
- **Inability to maintain safety independent external support/help**

Common Warning Signs

- A plan for suicide
- Recent attempt and/or ongoing preparatory behaviors
- Acute major mental illness (e.g., MDD episode, acute mania, acute psychosis, recent/current drug relapse)
- Exacerbation of personality disorder (e.g., increased borderline symptomatology)

Common Risk Factors

- Access to means
- Acute psychosocial stressors (e.g., job loss, relationship dissolution, relapse on alcohol)

Action

Typically requires psychiatric hospitalization to maintain safety and aggressively target modifiable factors.

These individuals need to be directly observed until on a secure unit and kept in an environment with limited access to lethal means (e.g. keep away from sharps, cords/tubing, toxic substances).

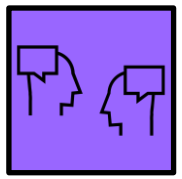
During hospitalization co-occurring psychiatric symptoms should also be addressed.

INTERMEDIATE ACUTE RISK

Essential Features **Action**

https://www.mirecc.va.gov/visn19/trm/docs/RM_MIRECC_SuicideRisk_Table.pdf

5. Responding to suicide risk



- Have an SOP, template, or decision guide for research staff to follow
- Key considerations
  - Modality of interaction (Is the participate with you in-person or remote?)
  - Menu of potential action steps
  - When to hand off to a clinician

Veterans Crisis Line
1-800-273-8255 PRESS 1

Safety Plan Worksheet

Purpose: Providers and patients complete Safety Plan together, and patients keep it with them

Step 1. Warning signs (that I might be headed toward a crisis and the Safety Plan should be used):

1.
2.
3.
4.

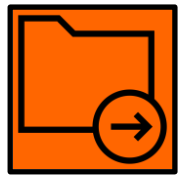
Step 2. Internal coping strategies (things I can do to distract from my problems without contacting another person):

1.
2.
3.

Step 3. People, places and social settings that provide healthy distraction (and help me feel better):

1. Name and phone number:

6. Reporting procedures



- Use a log for documentation of adverse events and serious adverse events
- Define what events are considered an AE, SAE, etc.
  - What is “expected”?
  - This will determine parameters for IRB and DSMB reporting

IRB

- Individual events
- Timeliness of reporting

DSMB

- Aggregate data
- Less frequent reporting
- Can impact study future

7. Training 

- What professional background is necessary?
- What training is needed for study staff?

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Applying the Framework for Managing Participant Risk for Suicide: Link Up Example

Mark Ilgen, PhD
Research Career Scientist
VA Center for Clinical Management Research
Ann Arbor, MI

The Link Up Study

- VA HSR&D award number IIR 14-103
- Recruited 300 Veterans from VA inpatient psychiatric units
- Inclusion criteria:
  - Hospitalized for a suicidal crisis
  - No Crisis Line use in the past year
- Randomized patients to either:
  - Crisis Line Facilitation (MI + practice call to the Crisis Line), or
  - Enhanced Usual Care
- The intervention was added onto standard care (with the goal of not changing other aspects of care, e.g., SPs, clinical team, etc.).
- Followed them at 3-, 6-, and 12-months

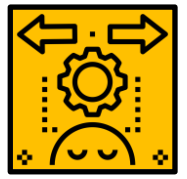
1. Study Design and Informed Consent

- Degree of safety monitoring is appropriate given the study design
  - Baseline risk: The population was chosen, in part, based on high baseline risk (and risk of re-attempt)
  - Added Risk: Limited risk of increasing suicidal thoughts/behaviors. Real risk of increased detection and need to inform care team.
  - Procedures varied based on setting:
    - Inpatient units allowed for more time and added support
    - Follow-up assessments were more variable
  - Informed consent:
    - Clear discussion about duty to warn
    - In practice – always encouraged the participant to talk with their providers

2. Collection of Data Related to Suicide

- Collection of "data" occurred in multiple ways:
  - Formal assessments:
    - Self-reported assessments
    - Structured clinical interviews
      - Determining the type of suicide-related behavior, context, method and timing
  - Incidental information:
    - Therapists discussing suicide-related content
    - Informal interactions with research team
  - Need to be prepared for all of these sources of information about suicide risk

3. Determining when a more detailed suicide risk assessment is indicated



- For self-report assessments
  - Clear pre-specified thresholds
- For interviews
  - Natural transition to in-depth conversations about risks
- Incidental
  - Ask structured questions related to suicide risk
- For each of these, inform participants of rationale/purpose of assessments (ideally, obtaining permission prior to asking)

4. Assessment of Suicide Risk

Box 1 Did the participant exhibit any language or behavior that raises concern AND / OR meet threshold on chosen suicide measures?

IF NO → -No Risk Assessment Conducted
-No Documentation needed

IF YES

Box 2 **Ask: Have you had these thoughts and had some intention of acting on them?**

Endorses active suicidal ideation with some intent to act, without a specific plan?

IF NO → LOW RISK
-Provide resource brochure and hotline card.
-Documentation needed.

IF YES

Box 3 **Ask: Have you started to work out or worked out the details of how to kill yourself? Do you intend to carry out this plan?**

Endorses active suicidal ideation with specific plan and intent?

IF NO → MODERATE RISK
-No call required; however may call supervisor if information is ambiguous.
-Provide resource brochure and hotline card.
-Documentation needed.

IF YES → HIGH RISK

ACUTE HIGH RISK

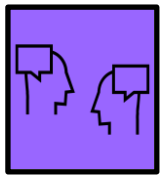
*-If the participant is in imminent, life-threatening danger, **CALL 911** or other emergency service immediately.*
-Immediate contact of supervisor while maintaining direct contact with the participant.
-Supervisor will advise next steps to be taken, which may include:
- Notification of participant's clinician, doctor, or Suicide Prevention Coordinator
- Warm handoff to the crisis line
- Warm handoff to emergency services

Ask additional questions to gather details:
- "When was the last time you had thoughts of hurting yourself?"
- "How often do you have these thoughts?"
- "How much control do you feel you have over these thoughts?"
- "When was the last time you attempted to hurt yourself?"
- "Has there been an increase in your alcohol or drug use recently?"
- "Do you have access to anything you may use to harm yourself/ a firearm?"

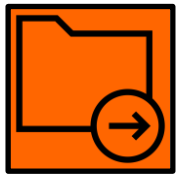
Is participant willing and able to disclose risk to clinician, crisis line, or ER?

IF NO → - Remind participant of the limit of confidentiality.
-Notify appropriate professionals.
-Documentation needed- Additional documentation in CPRS and an AE report is necessary if confidentiality is broken.

IF YES → -Stay with participant until contact with clinical professional has been established.
-Documentation needed.

5.Responding to Suicide Risk 

- When to involve a clinician/supervisor? Ideally, all decisions related to greater risk would be decided in collaboration with a supervisor. In practice, this depends on:
  - Timing/immediate safety. If no way to ensure immediate safety, research staff can act on their own.
  - The ambiguity of the scenario.
  - The willingness of the participant to self-disclose suicide-related content to clinical team (and/or lifeline)
- Setting mattered here:
  - It was easier on the inpatient unit
- **Goal – always to have the participant self-disclose**

6. Reporting Procedures 

- Being thoughtful about a priori definitions of:
  - Expected vs. Unexpected Adverse Events
  - Study related (in our case, symptom changes due to the study; not just increased detection of suicide risk).
- Have procedures for documenting any risk assessments.

7. Training 

- Professional background
  - Investigators were doctoral level clinicians
  - Therapists were masters-level clinicians
  - RAs were bachelor's level
- Training involved
  - Education about suicide and suicide risk – dealing with misperceptions
  - Determining acuity of risk – as well as how much time is available to make the decision.
  - Culturally:
    - Balancing collaboration and autonomy (sometimes RAs need to make immediate decisions).
    - Balancing accuracy/completeness of the data with compassion
    - Always encourage non-judgmental curiosity

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Practical Application of Risk Assessment in the Context of Research

Courtney L. Bagge, Ph.D.
Research Scientist
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Ann Arbor, Michigan

University of Washington Risk Assessment Protocol

UWRAP

- Assessment protocol for managing risk in high-risk samples
- Protocol that wraps around study assessment
  - Pre-Assessment: Face Sheet and Mood Improvement Protocol
  - Post-Assessment: Debrief Protocol and Risk Assessment
- Recommended by NIMH
  - Pearson J, Stanley B, King C, Fisher C. NIMH. Issues to Consider in Intervention Research with Persons at High Risk for Suicidality Available from: http://www.nimh.nih.gov/health/topics/suicide-prevention/issues-to-consider-in-intervention-research-with-persons-at-high-risk-for-suicidality.shtml

Linehan et al, Cognitive and Behavioral Practice, 2012

Face Sheet: Pre-Study Assessment

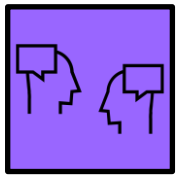
- Assess current state

On a scale of 1 to 7, what is your level of stress right now?

Low 1 2 3 4 5 6 7 High

On a scale of 1 to 7, what is your intent to kill yourself right now?

Low 1 2 3 4 5 6 7 High

Begin Mood Improvement Protocol 

- Interview can be stressful- Prepare how to handle stress
- What might be helpful if the interview is stressful?
  - Anything you could do or I could do to make it easier?
  - Prepare for two time points: During interview and after interview
- Examples:
  - Deep breathing; Chit-Chat
  - Music; Walking outside
  - Funny You-tube clips; Soothing pictures
- Tips
  - Can text links to participant's cell phone
  - Can encourage participant to describe what seeing and hearing around them

Debrief Protocol: Post-Study Assessment

- Ask for feedback on experience during study assessment
- Assess current state and *changes* since Pre-Study Assessment

On a scale of 1 to 7, what is your level of stress right now?

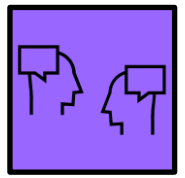
Low 1 2 3 4 5 6 7 High

On a scale of 1 to 7, what is your intent to kill yourself right now?

Low 1 2 3 4 5 6 7 High

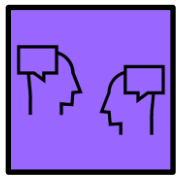
- Ask
  - how will cope with any negative feelings?
  - if any fun activities are planned for rest of the day?
- End-If no distress or subject's plan to manage distress appears sufficient

Finish Mood Improvement Protocol



- Offer the mood induction activity (previously chosen)
- Examples:
  - Deep breathing
  - Chit-Chat
  - Music
  - Walking outside
  - You-tube clips
- After participant leaves, document
  - What activity was used (if any)
  - Effect on mood

Evaluating and Managing Risk

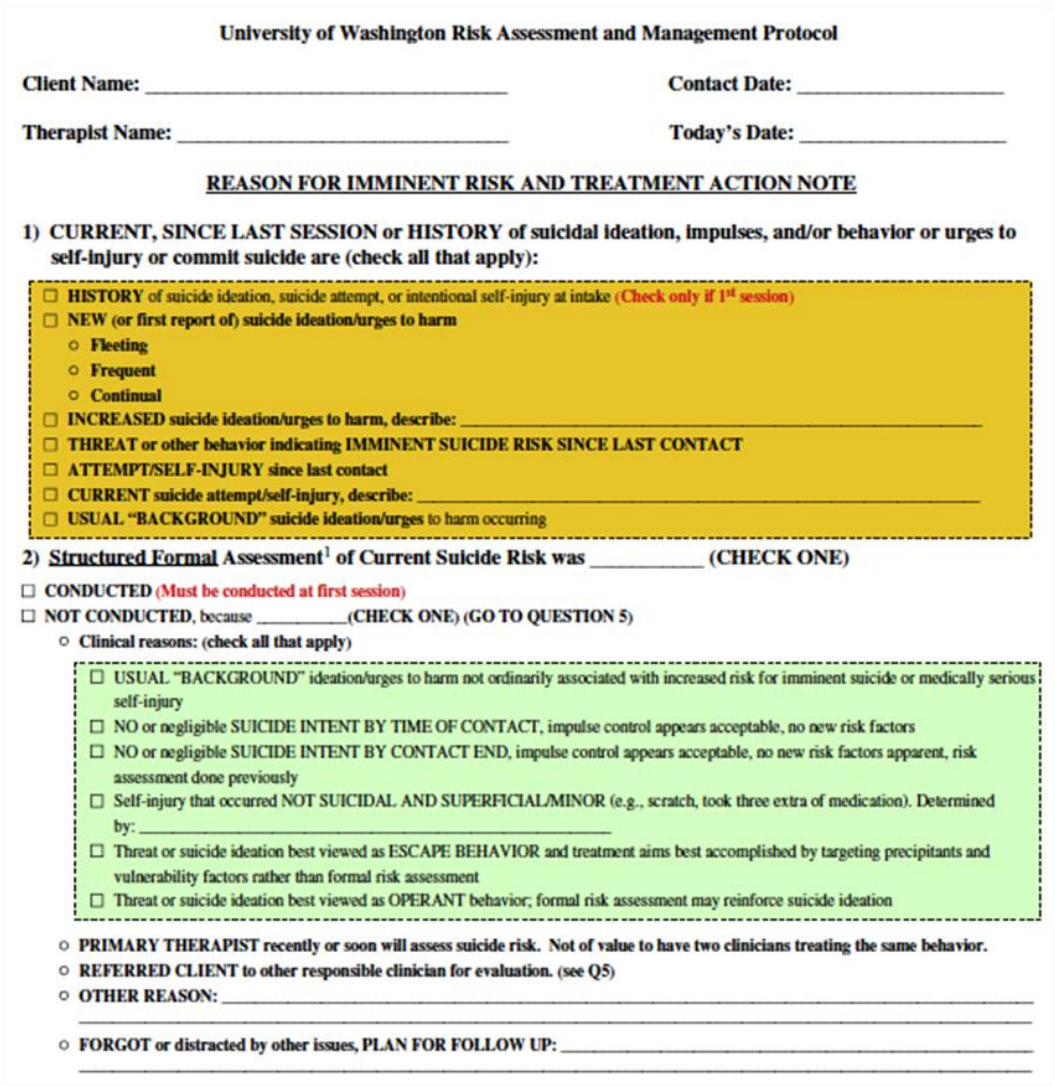


- Thresholds-Minimum *required* to conduct a suicide risk assessment
  - If higher than a 3 on intent to kill self
  - Participant is uncertain that can control suicidal impulses
- Assessment of suicide risk (and determination of risk level)
  - Suicide Risk/Protective Factors Assessment
  - Or the SRA of your choice
- Responding to suicide risk (management)
  - Depends on level of risk
  - Use lowest level of intervention as appropriate and then move to higher-levels
- All can vary across studies
  - Thresholds; who conducts an SRA; and how risk is managed

Could use L-RAMP

Linehan Risk Assessment and Management Protocol (L-RAMP)

- A protocol for study clinicians
- Obtain from same website as U-WRAP



University of Washington Risk Assessment and Management Protocol

Client Name: _____ **Contact Date:** _____

Therapist Name: _____ **Today's Date:** _____

REASON FOR IMMINENT RISK AND TREATMENT ACTION NOTE

1) CURRENT, SINCE LAST SESSION or HISTORY of suicidal ideation, impulses, and/or behavior or urges to self-injury or commit suicide are (check all that apply):

- ☐ **HISTORY** of suicide ideation, suicide attempt, or intentional self-injury at intake (Check only if 1st session)
- ☐ **NEW (or first report of) suicide ideation/urges to harm**
  - ○ **Fleeting**
  - ○ **Frequent**
  - ○ **Continual**
- ☐ **INCREASED suicide ideation/urges to harm, describe:** _____
- ☐ **THREAT or other behavior indicating IMMINENT SUICIDE RISK SINCE LAST CONTACT**
- ☐ **ATTEMPT/SELF-INJURY since last contact**
- ☐ **CURRENT suicide attempt/self-injury, describe:** _____
- ☐ **USUAL "BACKGROUND" suicide ideation/urges** to harm occurring

2) Structured Formal Assessment[1] of Current Suicide Risk was _____ (CHECK ONE)

- ☐ **CONDUCTED** (Must be conducted at first session)
- ☐ **NOT CONDUCTED**, because _____(CHECK ONE) **(GO TO QUESTION 5)**
  - ○ **Clinical reasons: (check all that apply)**
    - ☐ USUAL "BACKGROUND" ideation/urges to harm not ordinarily associated with increased risk for imminent suicide or medically serious self-injury
    - ☐ NO or negligible SUICIDE INTENT BY TIME OF CONTACT, impulse control appears acceptable, no new risk factors
    - ☐ NO or negligible SUICIDE INTENT BY CONTACT END, impulse control appears acceptable, no new risk factors apparent, risk assessment done previously
    - ☐ Self-injury that occurred NOT SUICIDAL AND SUPERFICIAL/MINOR (e.g., scratch, took three extra of medication). Determined by: _____
    - ☐ Threat or suicide ideation best viewed as ESCAPE BEHAVIOR and treatment aims best accomplished by targeting precipitants and vulnerability factors rather than formal risk assessment
    - ☐ Threat or suicide ideation best viewed as OPERANT behavior; formal risk assessment may reinforce suicide ideation
  - ○ **PRIMARY THERAPIST recently or soon will assess suicide risk. Not of value to have two clinicians treating the same behavior.**
  - ○ **REFERRED CLIENT to other responsible clinician for evaluation. (see Q5)**
  - ○ **OTHER REASON:** _____
  - ○ **FORGOT or distracted by other issues, PLAN FOR FOLLOW UP:** _____

Linehan et al, Cognitive and Behavioral Practice, 2012

Acknowledgements

- Katherine Comtois, University of Washington
- See website for UWRAP and LRAMP:
  - https://depts.washington.edu/uwbrtc/resources/assessment-instruments/?msclkid=4722973dc7d111ec9234b513ab32a1a5

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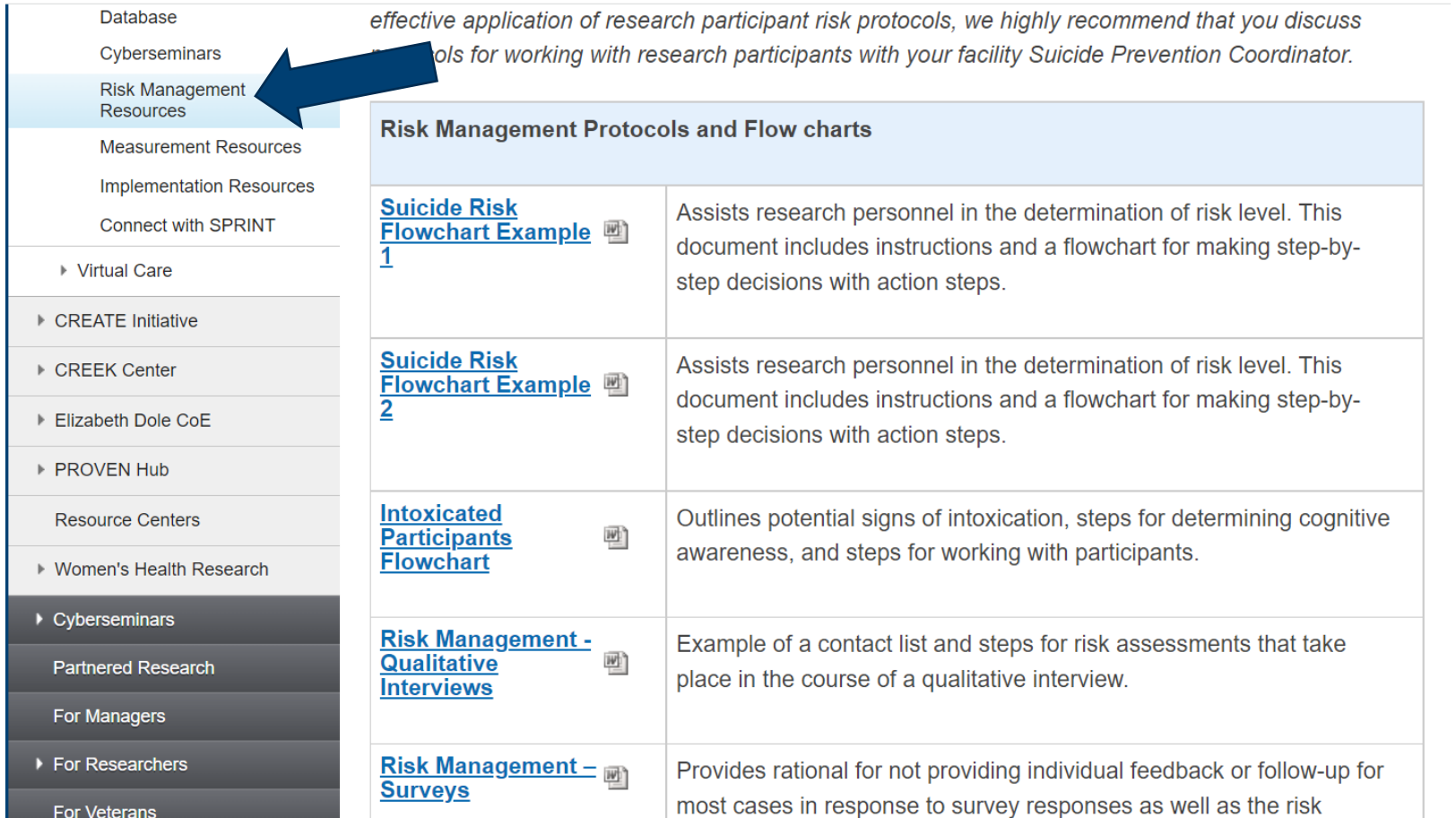
Risk Management Resources

Emily Yeagley, MA, MPH
VA Center for Clinical Management Research
Ann Arbor, MI

Resources Location

- https://www.hsrd.research.va.gov/centers/core/sprint/



About SPRINT Resources

- Examples collected from various research teams and must be tailored to fit with your study protocols and population
- Study teams my choose different approaches for assessment, tracking, and training
- Highly suggest coordination with your site Suicide Prevention Coordinator
- The resources that you use will likely need to be approved by your local RD/IRB

Resource Organization

- What is available?
  - Resource Guides
  - Templates
- Topics covered:
  - Risk Management/Assessment Protocols and Flow Charts
  - Risk Documentation
  - Participant-Facing Resources
  - Regulatory Resources

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Q&A

Additional Questions/Comments:
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