

Implementation of suicide research into clinical settings

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Disclosures

- I have no actual or potential conflict of interest in relation to this program/presentation.
- Any opinions expressed are my own and do not represent the opinions of the US Government



Research Support and Off-Label Use

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Background

- Experimental medicine research including people with suicidal thoughts and behaviors involves consideration of screening and assessment, physical environment, and clinical response.
- Case example: Suicide research conducted in a clinical research setting
 - Institutional Approval
 - Screening and Assessments
 - Physical Environment

NIH Clinical Center

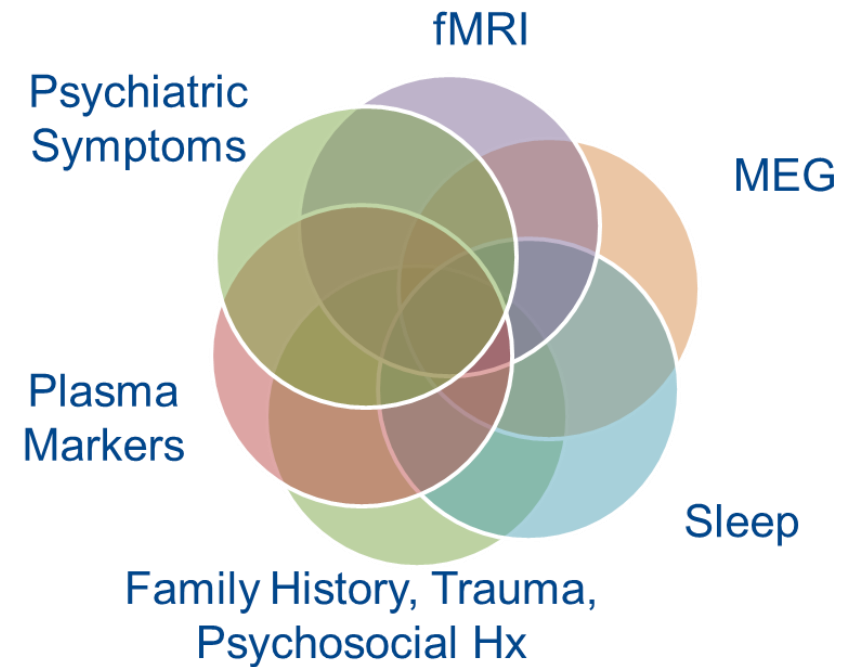
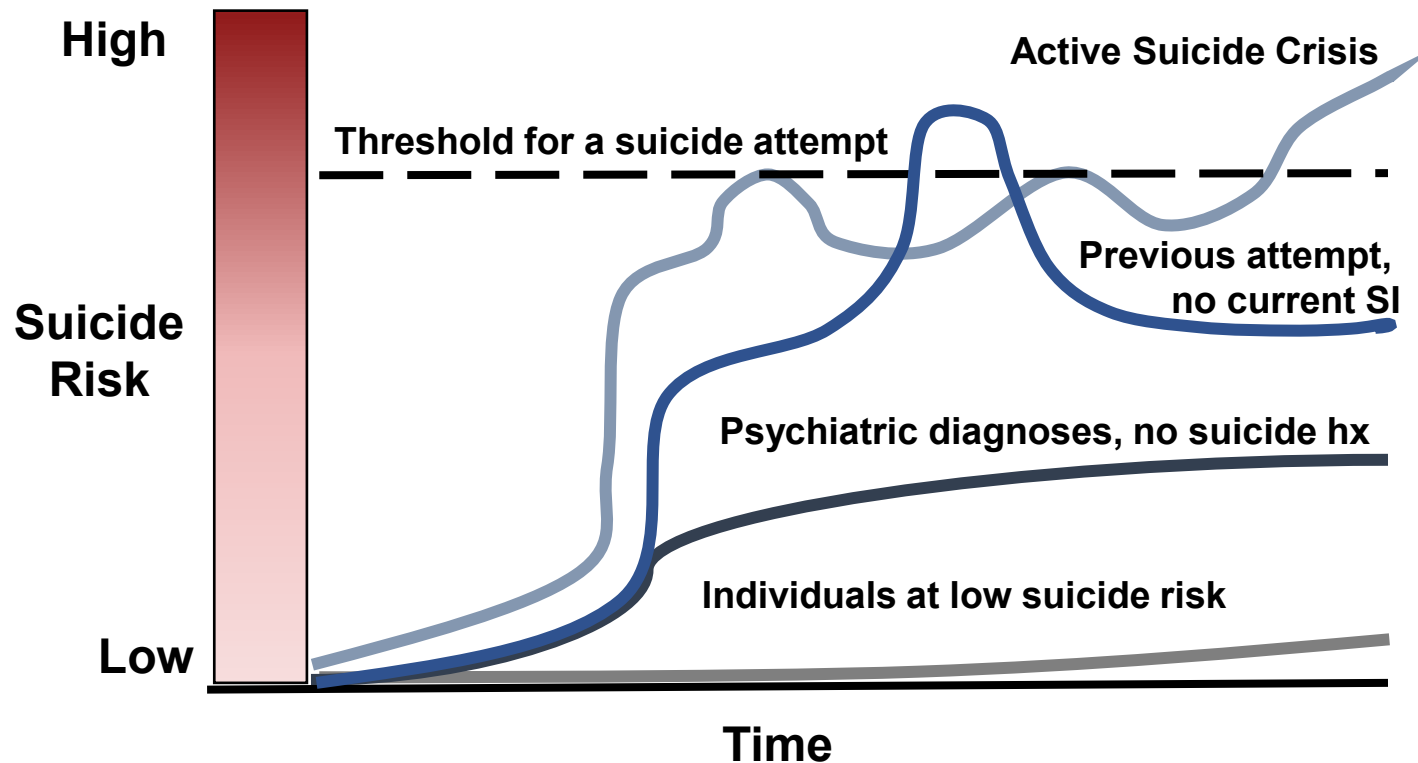


Mark O. Hatfield Clinical Research Center

- **NIH Clinical Center**
 - Dedicated research facility
 - CORE facilities
- **Dedicated Inpatient Unit**
 - Multidisciplinary team model
 - Equipped for the study of unmedicated subjects

NIH Research: Neurobiology of Suicide Protocol

Multi-modal biomarkers of acute as compared to chronic suicide risk
Preliminary identification of biomarkers of SI response to intervention
Longitudinal follow-up to track outcomes
Malleable design to integrate new techniques and interventions



NIH Research: AFSP Grant

Funding from American Foundation for Suicide Prevention to evaluate MEG response to movie clip mood induction and LD-IAT pre/post ketamine as surrogate markers of suicide risk.



Day -1



Ketamine



Day +1

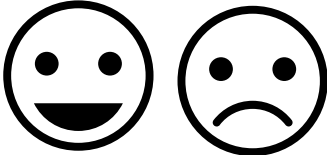
Other Potential Markers under Investigation



Sleep



Ecological Momentary Assessment (EMA)



Emotional Expression and Word Production



Future Thinking



Resting State MEG

Stock Images from Power Point; Gerner 2021

Institutional Approval of Suicide Research at NIH

- Department of Bioethics consultation
- Extensive consultation with IRB
- Ethics Grand Rounds, “Research on suicide: Is it ethical to enroll individuals in crisis?”
- Extensive training of staff
- Failure Modes and Effects Analysis (FMEA) with Clinical Center leadership to identify potential risk



Screening Instruments

- Columbia Suicide Severity Rating Scale (C-SSRS) for study inclusion
- Regular assessment with items from C-SSRS, Scale for Suicidal Ideation (SSI), suicide items from MADRS and HAMD
- ASQ, developed at NIMH, used across hospital



Enhanced Consenting Process

- Multiple Informed Consents
 - Neurobiological procedures and ketamine consented separately
- Pre-Consent “quiz”
 - Check understanding of participant
- Clinical Research Advocates
 - Advocates for participant that are not involved in research process who witness consent and check-in with participants during the trial



Beyond the Inpatient Environment



Sleep Studies

- Participant is isolated in sleep study room
- Many wires
- Light restrictions so that opening door for safety checks are not feasible



MRI

- Participant is isolated in scanning room
- Materials in pre-scanning room



MEG

- Participant is isolated in scanning
- Many wires
- Materials in pre-scanning room including scissors

Environmental Considerations



- Assessment of physical environment
- Meetings with imaging and sleep staff
- Enhanced monitoring during off-unit procedures
- Safety checklists for off-unit procedures
- Debriefing sessions after difficult procedures, i.e. mood inductions or stress tasks

Enhanced Clinical Discussions

- Safety plan **specific to research participation**
 - Included in research participation binder

Safety Plan

****Please keep with you throughout research participation****

Warning signs for suicidal thoughts:

1. _____
2. _____
3. _____

Helpful coping strategies if my suicidal thoughts or other symptoms get worse:

1. _____
2. _____
3. _____

Activities to refocus my attention:

1. _____
2. _____
3. _____

People who I can ask for support:

1. _____
2. _____
3. _____

Professionals to contact in a crisis:

7-SE Staff, number of unit: 301-451-0851 _____

Name of physician: _____

Names of nurses: _____

Names of psychologist/social workers: _____

Name of Independent Medical Monitor: _____

Summary and Lessons Learned

- Consider a Failure Modes and Effects Analysis if starting a major initiative
- Training benefits all staff members regardless of their level of mental health training
- Integrate standardized suicide assessment with clinical judgment and use language consistently
- Maintain constant checks of the physical environment

For more information

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Review article

Neurobiological research with suicidal participants: A framework for investigators



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Patients and their families

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