



The Power of Inclusion in Clinical Trials: It's Time to Study All People, Even If They Have Thought About Suicide

Chairs:

Jill Harkavy-Friedman, PhD

Manish Jha, MBBS

Disclosures

Jill Harkavy-Friedman: SVP of Research at the American Foundation for Suicide Prevention Associate Professor of Clinical Psychology, in Psychiatry Columbia University (unpaid) No paid consultations to other organizations

Manish Jha: In the past 36 months, Dr. Jha has received contract research grants from Neurocrine Bioscience, Navitor/Supernus and Janssen Research & Development; honorarium to serve as Section Editor of the Psychiatry & Behavioral Health Learning Network and as Guest Editor for Psychiatric Clinics of North America from Elsevier; consultant fees from Janssen Scientific Affairs, Sanofi, Neurocrine, Abbvie and Boehringer Ingelheim; fees to serve on Data Safety and Monitoring Board for Worldwide Clinical Trials (Eliem, Skye and Inversargo), Vicore Pharma and IQVIA (Click); and honoraria for educational presentations from North American Center for Continuing Medical Education, Medscape/WebMD, Clinical Care Options, Physicians' Education Resource, Efficient CME, and H.C. Wainwright & Co.



Speakers

Elizabeth Ballard, PhD

Evan Kleiman, PhD

John McCarthy, PhD, MPH

Kari Nations, PhD

Steven Szabo, MD, PhD

Zimri Yaseen, MD

Jill Harkavy-Friedman, PhD

Manish Jha, MBBS

Introduction: Goal of the Session and Key Issues to be Addressed

Jill Harkavy-Friedman, PhD



Disclosures and Conflicts

Jill Harkavy-Friedman, PhD
Vice President of Research
American Foundation for Suicide Prevention
New York, NY

No bias, conflict of interest or industry involvement



Objectives

- Inclusion of people with suicidal ideation and behavior in most clinical trials is a plus for clinical trials
- No longer automatically excluding people with SIB from Clinical Trials
- Demonstrate ways to safely include people with SIB
- Showcase new questions that can be addressed



A bit about suicide and SIB

Risk for suicide is not static

It's not a continuum from ideation to suicide

Ideation doesn't necessarily mean risk

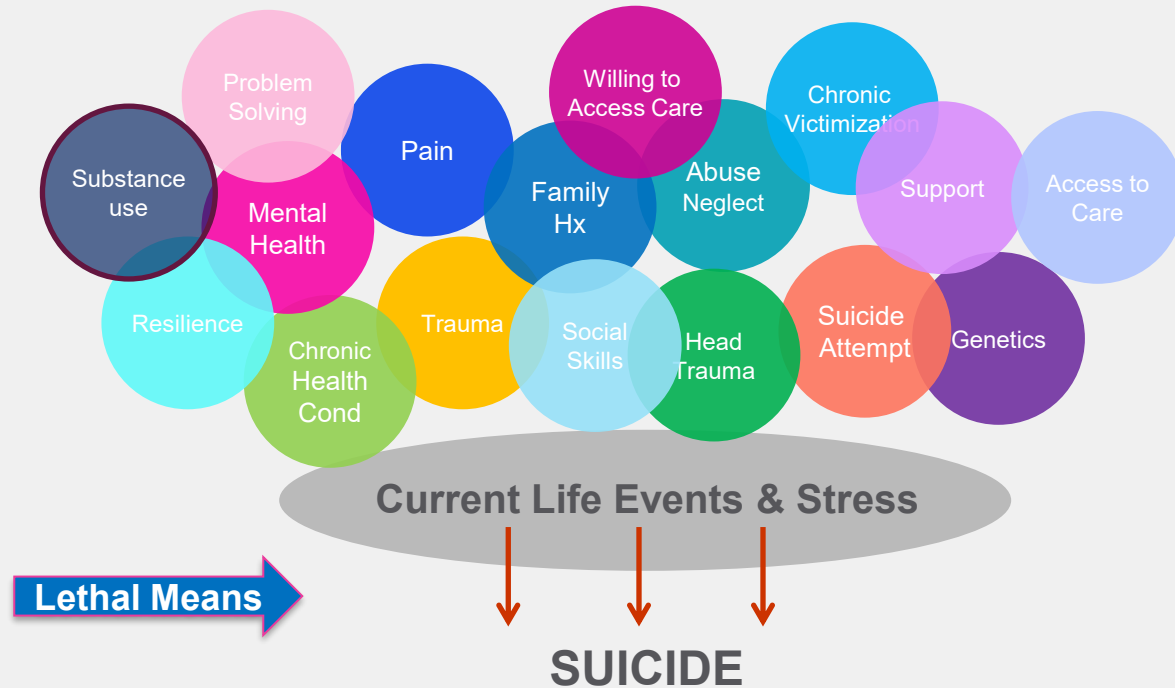
No ideation doesn't mean no risk

Mitigation of risk is possible in clinical trials

Risk is minimal



Interacting Risk & Protective Factors



Harkavy-Friedman, JM, Moutier, CY (2019) presented at the annual meeting of the American Association of Suicidology, Washington, DC. Moutier, C. National Academies of Sciences, Engineering, and Medicine.

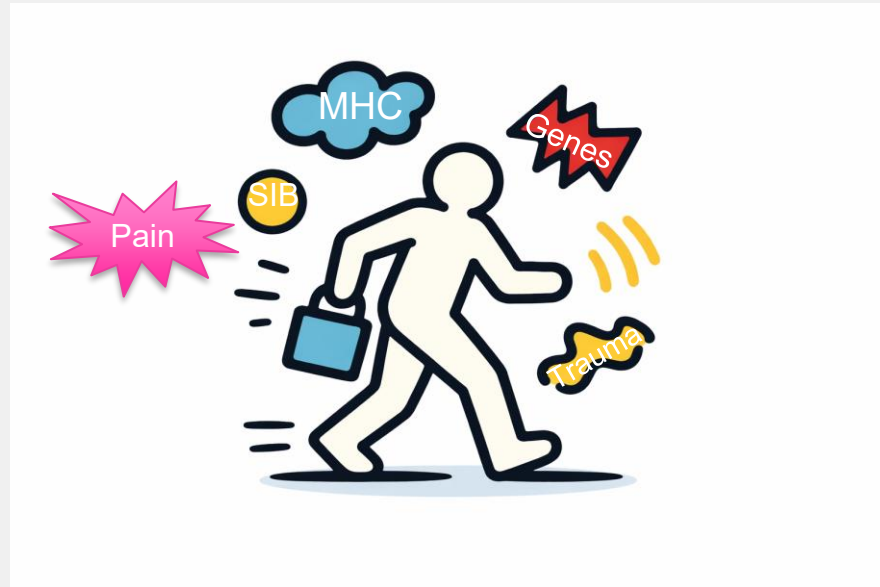
2019. *Improving care to prevent suicide among people with serious mental illness: Proceedings of a workshop*. Washington, DC: The National Academies Press. doi:<https://doi.org/10.17226/25318>.

©2021 AFSP. All rights reserved

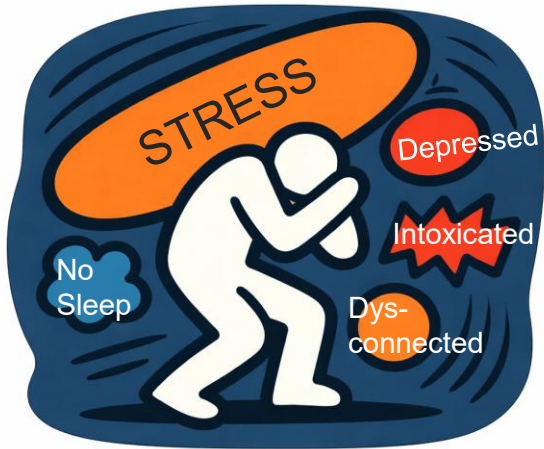
Is this person “at risk”



With Risk



“At Risk”



With risk \neq At Risk



Talk

Killing themselves
Having no reason to live
Being a burden to others
Feeling trapped
Unbearable pain
Hopelessness
Soon it won't be a problem

Behavior

Alcohol or drugs
Looking for a way to kill themselves
Acting recklessly
Withdrawing from activities
Isolating from family and friends
Sleep changes
Saying goodbye
Giving away prized possessions
Aggression or agitation

Mood

Depression
Loss of interest
Rage
Irritability
Humiliation
Anxiety
Hopelessness



Effects of Exclusion

Eliminating people with SIB in depression studies reflect only a subtype of people

Excluding people with SIB does not ensure that no one in the trial will be at risk

Discrimination against people with a mental health conditions from trials

Participation in clinical trial often feel like it's the last resort for patients and they want to participate



Is it ethical to exclude people who may benefit from treatment?

- **Risk of suicide is high without treatment**

There are scientific and clinical costs to excluding people with SIB



Impact and Benefits of Inclusion

Broader representation of who can receive the treatment

Opportunity to learn about real world efficacy

Death by suicide is a rare event

- **Cancer trials do not exclude people who may die by cancer and now lives can be saved**

We can save lives



Today's Presentations

Voice of person with LE

Meeting the goals of a clinical trial with inclusion

Considerations for assessment and inclusions

Inclusion elevates and this is how it is done

FDA Perspective

Real-time methods

Psychometric considerations

Systemic monitoring is not a risk



Thank You!

afsp.org

©2021 AFSP. All rights reserved



**American
Foundation
for Suicide
Prevention**



@afspnational

