Safety and Ethical Considerations in EMA Research with Participants with Suicidal Thoughts & Behaviors

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Disclosures & Conflicts

Disclosures: Dr Nock receives publication royalties from Macmillan, Pearson, and UpToDate. Has been a paid consultant in the past three years for Microsoft Corporation, the Veterans Health Administration, Compass Pathways, and for legal cases regarding deaths by suicide. Has stock options in Cerebral Inc. He is an unpaid scientific advisor for Empatica, Koko, and TalkLife.

Conflicts of Interest: None

Safety & Ethical Issues

(1) Key safety and ethical concerns

(2) What have we been doing (systematic review)?

(3) What should we strive to do (consensus statement)?

(4) Future considerations

Digital Monitoring of Suicidal Thinking

- Early studies: palm pilots

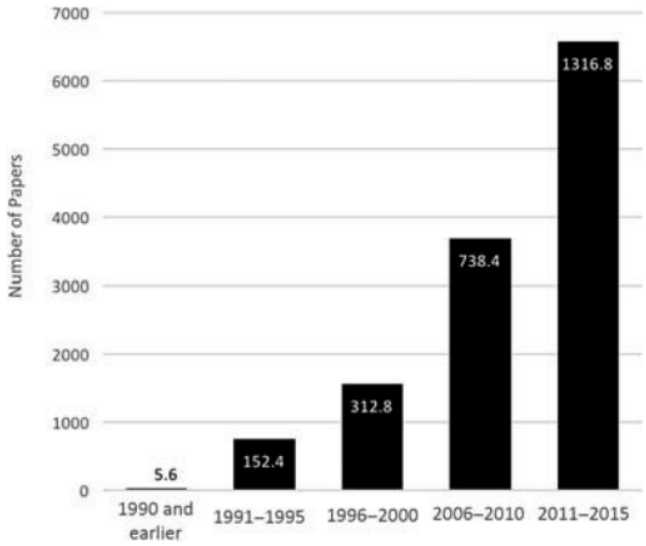
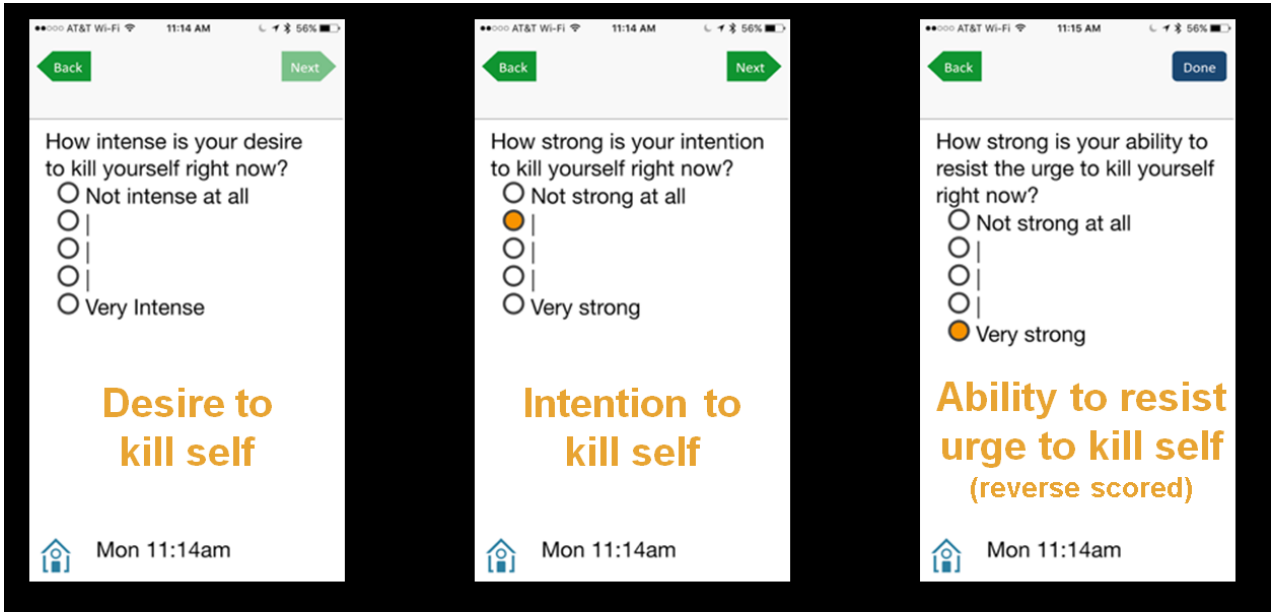


FIGURE 1. Total number of publications in Web of Science using real-time monitoring across five-year periods. *Note*. Search results in Web of Science were based on all English-language, peer-reviewed empirical articles using the terms (*real-time monitoring* OR *ecological momentary assessment* OR *experience sampling* OR *ambulatory assessment*). Inset number is average number of publications over the five-year period.

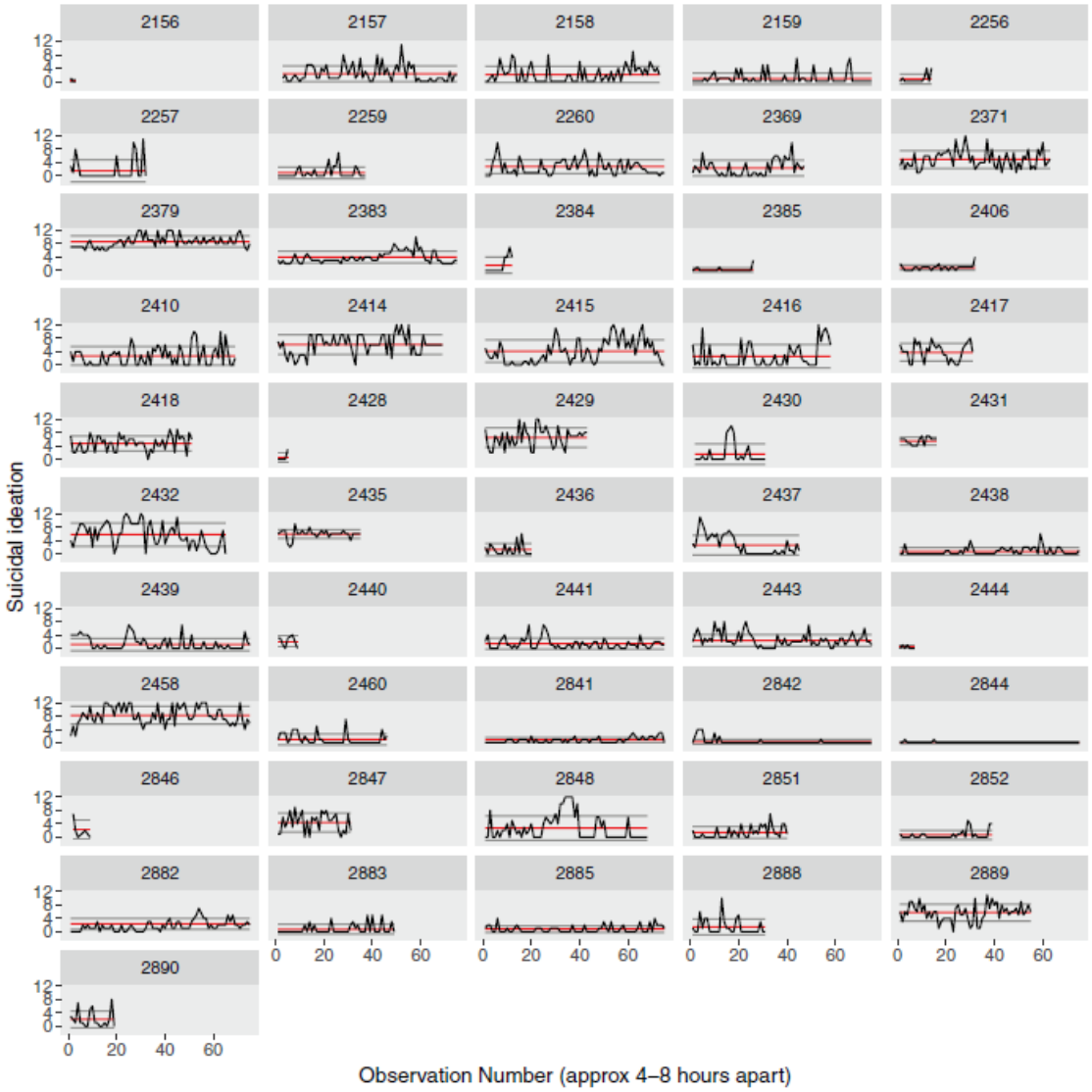
Nock et al. (2009). J Abnormal Psychology.

Kleiman & Nock. (2017). Psychiatry.

Digital Monitoring of Suicidal Thinking

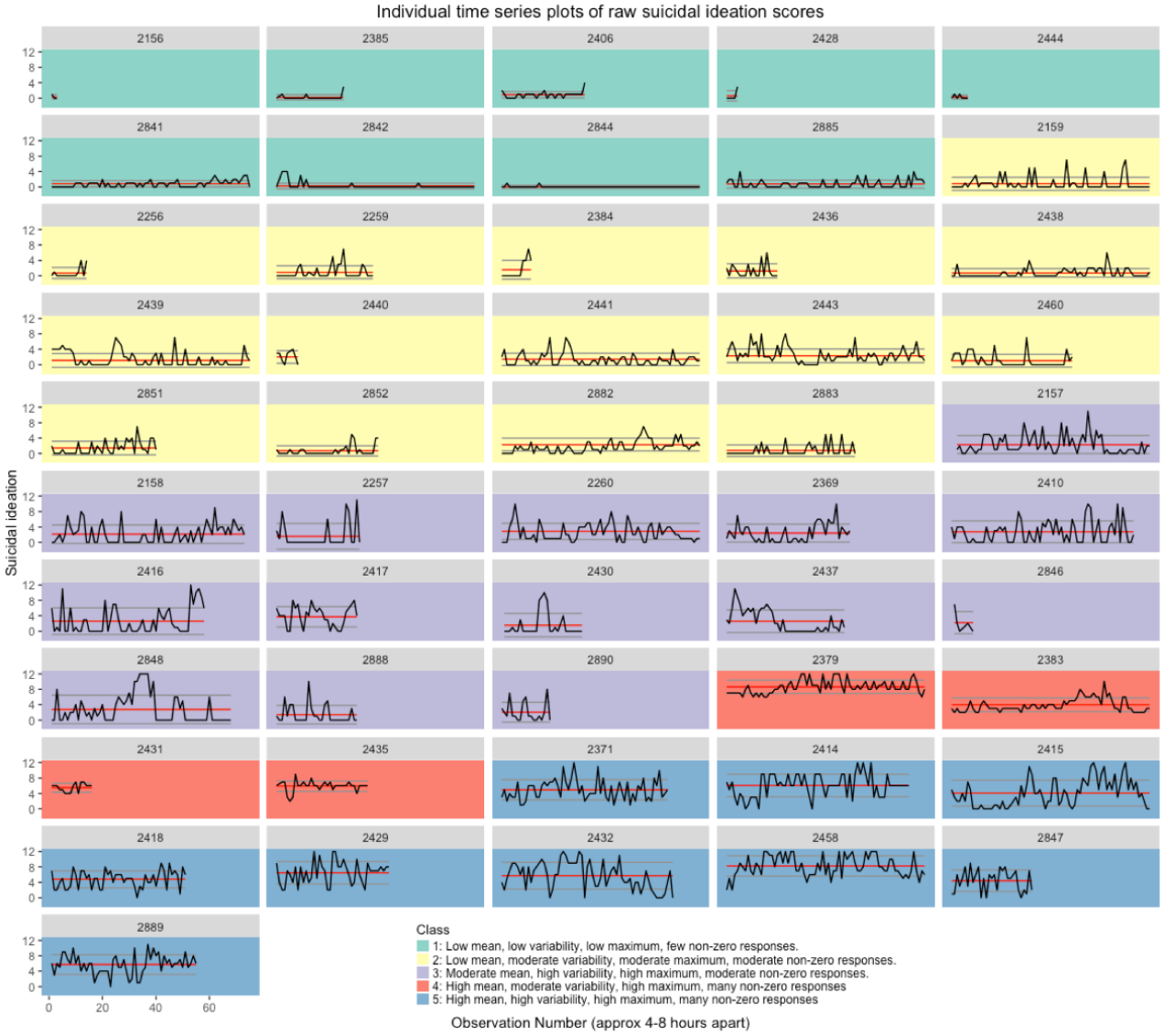


Variability of Suicidal Thoughts



Kleiman et al. (2017). J Abnormal Psychology.

Subtypes of Suicidal Thoughts(?)



Kleiman et al. (2018). Depression & Anxiety.

Some Key Concerns

- How to respond to “high risk”

  (What exactly is “high risk”? What should our response be? Likely varies based on context [inpt vs. outpt…chronic vs increased SI])

- Should data be monitored in real-time?

- What should we share with participants, parents, clinicians, others?

- Are there iatrogenic effects of repeatedly asking about suicidal thoughts?

What Precautions are We Using Now?

- Systematic review of EMA (66 studies, 5,918 participants):
  - 60% of studies actively monitor data (40% do not)
  - 47% before 2017, vs 65% since
  - 95% of studies that monitored reached out to participant if above some threshold of perceived risk (varied across studies)
  - Larger (n>100) and longer (>28 days) studies more likely to monitor & respond

Bentley et al. (2021). Clinical Psychology Review.

What Should we Strive to Do?

Consensus Statement on Ethical & Safety Practices for Conducting Digital Monitoring Studies with People at Risk of Suicide and Related Behaviors

Matthew K. Nock, Ph.D., Evan M. Kleiman, Ph.D., Melissa Abraham, Ph.D., Kate H. Bentley, Ph.D., David A. Brent, M.D., Ralph J. Buonopane, Ph.D., Franckie Castro-Ramirez, A.M., Christine B. Cha, Ph.D., Walter Dempsey, Ph.D., John Draper, Ph.D., Catherine R. Glenn, Ph.D., Jill Harkavy-Friedman, Ph.D., Michael R. Hollander, Ph.D., Jeffrey C. Huffman, M.D., Hye In S. Lee, B.S., Alexander J. Millner, Ph.D., David Mou, M.D., Jukka-Pekka Onnela, Ph.D., Rosalind W. Picard, Ph.D., Heather M. Quay, J.D., Osiris Rankin, A.M., Shannon Sewards, M.A., John Torous, M.D., Joan Wheelis, M.D., Ursula Whiteside, Ph.D., Galia Siegel, Ph.D., Anna E. Ordóñez, M.D., Jane L. Pearson, Ph.D.

- Consensus meeting of diverse panel of 24 experts
- Psychiatrists, psychologists, funders (AFSP, NIMH), statisticians, industry, university legal office, IRB, research/practice, trainees
- Delphi process: survey, in-person meeting, survey

Nock et al. (2021). Psychiatric Research and Clinical Practice.

Ethical & Safety Practices

- Some clear consensus (may be helpful for study planning/IRB):
  - 90% said don't exclude participants because of high risk
  - 90-100% agreement on including key points in informed consent
  - 95-100% agree that P contact info (cell) should be required
  - 95-100% agreement on need to test safety procedures BEFORE study
  - 100% agree on need to develop safety triggering protocol (provide emergency contact info, set threshold for triggering, train staff in responding)
  - 100% agree no one should be removed from the study due to risk
  - 90% agree data on suicide should be reviewed at least daily
  - 94% agree suicide intent and plan should determine risk level
  - 94% agree high risk responses should be responded to in 24hrs

Nock et al. (2021). Psychiatric Research and Clinical Practice.

Is frequent assessment of SI iatrogenic?

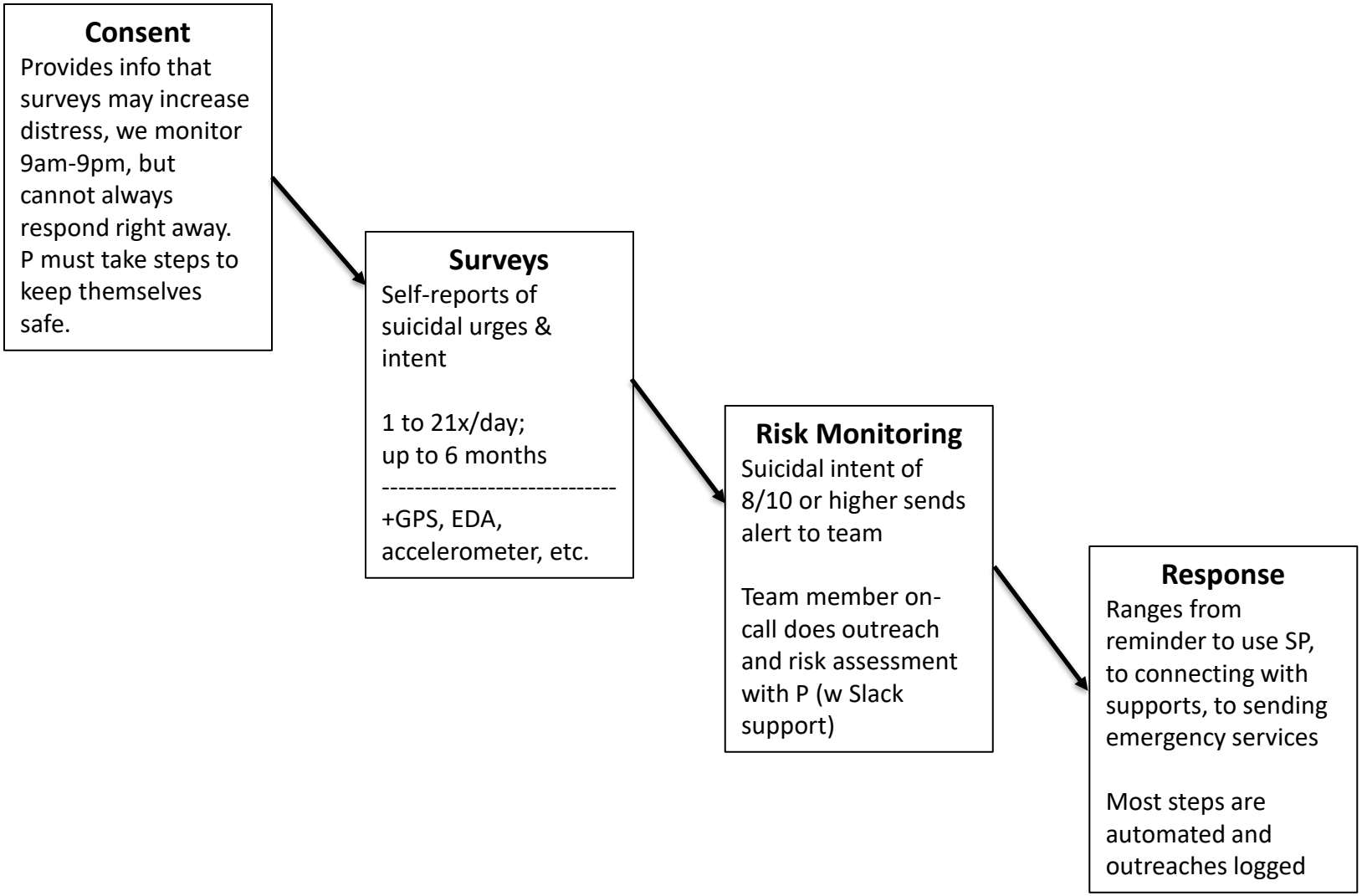
- No.
- Frequent assessment of SI (even up to 6x/hr) does not increase severity of SI
- However, some individual participants do report increased distress due to repeated questions about suicide, depression, etc.

Coppersmith et al. (2021). British Journal of Psychiatry

Steps to Take Now

- Thorough consent that provides clear info about study procedures
- Review survey responses as quickly as possible
- Have a clear, detailed plan for responding to elevated SI
- Use safety plans, on-call clinician, and outreach as needed
- Store data in de-identified form, in secure servers, following HIPAA guidelines
- Consider using ISM or DSMB when possible

Sample Study Set-up



Conclusions

- EMA is safe and ethical (and not iatrogenic)
- Researchers should take precautions to minimize risk of harm and maximize benefits to participants
- Recommend monitoring data and responding to elevated SI using clear and detailed procedures
- Need research on most effective responses at varying levels of SI/risk (JITAIs, MRTs)

Funding & Collaborators

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Nock Lab

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Azure Reid-Russell
Taylore McGuire…& many others!

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