Suicide Prevention Outreach Trial

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SPOT Trial summary

- Pragmatic trial of two outreach interventions to reduce long-term risk of suicide attempt
- Automatically enroll health system patients who report frequent thoughts of death or self-harm (score of 2 or 3 on PHQ9 item 9)
- Randomly assign to continued usual care or to one of two outreach-based interventions
- Examine risk of suicide attempt over 12-18 months after randomization
- Planned sample size = 18,000 (6000 per group)

Automated weekly sampling:

- Inclusion:
  - Score of 2 or 3 on routinely administered PHQ9 item 9
  - Has sent or read portal message in last year
- Exclusion:
  - Age <18
  - Diagnosis of dementia or mental retardation
  - Identified as needing interpreter
- NO Exclusion:
  - Diagnosis
  - History of suicidal behavior
  - Engagement in care
  - Willingness to accept any intervention services

Randomization

- Automatically assigned to:
  - Usual care (no contact)
  - Usual Care plus Offer of Care Management intervention
  - Usual Care plus Offer of Skills Training intervention

Intervention programs

- Dialectical Behavior Therapy Skills Training
  - Specific emotion regulation skills found to reduce risk of repeat suicide attempt
  - Delivered via interactive online program
  - Supported by an online health coach

- Risk Assessment and Care Management
  - Systematic outreach to assess acute risk
  - Care management to facilitate/maintain appropriate contact with outpatient mental health care

Key points regarding both intervention programs

- These are “cold calls” - unexpected outreach from an new and unknown representative of the health system
- Cost matters – NNT of 100 means that we are looking for an intervention like statins, not like revascularization. Our target cost is <$100 per patient
- High volume – A coach or care manager caseload may exceed 500 and weekly tasks may exceed 150

Outcomes:

- Complete Intent-To-Treat Comparison
- Primary Outcome: Fatal or non-fatal suicide attempt over 18 mos
  - Nonfatal suicide attempts ascertained from diagnoses in EHR and claims data
  - Fatal suicide attempts ascertained from state death certificate data
  - Censored at time of disenrollment or death from other cause
- Secondary Outcomes:
  - Broader: All injury/poisoning diagnoses
  - Narrower: Suicide attempts requiring hospitalization

Informed consent for Modifed Zelen Design

- Waiver of consent to use records to identify eligible patients
- Waiver of consent to randomize to usual care or offer of intervention
- Abbreviated consent procedure at first offer of intervention:
  - Notification that this is research
  - Description of intervention goals and procedures
  - Acknowledge “risk” of being bothered
  - Right to refuse or withdraw
- Waiver of consent to use records to ascertain outcomes

Pilot study issues/questions:

- Collaboration with health system leaders to design/integrate intervention programs
- Testing and refinement of outreach procedures and messages
- Develop informatics tools to support outreach and intervention delivery
- Test abbreviated consent procedures and language

Easier than we expected: Collaboration with health systems

- Mental health leaders had already identified suicide prevention as a top priority
- Recent increases in suicide mortality rates
- National Zero Suicide Initiative created more momentum
- Broad agreement regarding parameters of care management program
- Strong interest in DBT (but traditional delivery models could not scale)

As difficult as we expected: Engagement in outreach programs

- Hopelessness and isolation are at the core of suicidal ideation
- Low “emotional bandwidth” of secure messaging communication
- Concerns about coercive or involuntary treatment
- Extensive consultation with people with lived experience
- After 3 rounds of pilot testing, engagement rates of approx. 45% in both programs (borne out in full-scale trial)

More difficult than we expected
Informatics tools for intervention delivery

- Portal messaging tools had very limited capacity for automation and customization
- Online content management system could not integrate with EHR
- Population-management tools did not travel well between different instances of the same EHR

Much more difficult than we expected: IRB review and DSMB oversight

- IRB
  - Fundamental disagreements regarding interpretation of “minimal risk” and “practicability”
  - Time-consuming debates over every word of invitation messages
- DSMB
  - Re-litigate issues of IRB review (sequentially, not simultaneously!)
  - Required additional clinical personnel continuously available at all sites
  - Traditional reporting of “adverse events” (round up the usual suspects)
  - Quarterly interim analyses (vs. one originally planned)