



Suicide Prevention Outreach Trial

April 2015 Update

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Timeline:



- March 2015 – Start enrollment at Group Health
- May 2015 – Start enrollment at HealthPartners and KPCO
- Nov 2017 – Complete enrollment
- Nov 2018 – Outcome data available



Recruitment projections



Group Health	70/week
HealthPartners	40/week
KP Colorado	55/week
TOTAL	165/week

30 months to reach planned sample size of 19,500



Report card

Barrier	Level of Difficulty				
	1	2	3	4	5
Engagement of clinicians and Health Systems					
Regulatory issues (IRBs and consent)					
Data collection and merging datasets					
Enrollment and engagement of patients/participants					
Stability of control intervention					



Report card

Barrier	Level of Difficulty				
	1	2	3	4	5
Engagement of clinicians and Health Systems		X			
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Data collection and merging datasets					
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Stability of control intervention					



Engagement of health systems and clinicians – Easy

- Establishing suicide prevention as a safety and quality priority
- Defining appropriate care pathways and standards for follow-up care
- Agreeing on standardized assessments



Engagement of health systems and clinicians – Not so easy

- Defining appropriate level of engagement with primary care clinicians
- Finding urgent appointments in supply-limited mental health systems



Report card

Barrier	Level of Difficulty				
	1	2	3	4	5
Engagement of clinicians and Health Systems		X			
Regulatory issues (IRBs and consent)					X
Data collection and merging datasets					
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Stability of control intervention					



Regulatory and ethical issues – Easy

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Regulatory and ethical issues – Not so easy

IRB

- Clarifying “minimal risk” – absolute vs. incremental risk
- Appropriate level of outreach – a classic autonomy vs. beneficence conflict
- Partial waiver of consent for delivery of interventions – clarifying the “practicability” criterion
- Waiver of consent to use records data to ascertain outcomes – re-litigating the “practicability” criterion



Regulatory and ethical issues – Not so easy

DSMB

- Defining “Serious Adverse Events”
- Timing of outcome ascertainment
- Limited access to records data
- Defining “Protocol Violations”
- Review of individual “adverse events”
- Interim analyses - purpose and procedure



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Data collection and merging datasets			X		
Enrollment and engagement of patients/participants					
Stability of control intervention					



Data and Informatics - Easy

- Implementing and testing sampling specifications across sites
- Implementing and validating outcome specifications across sites
- Simulations for power and sample size calculations



Data and Informatics – Not So Easy



- Translating EHR-based tools across Epic instances
- Re-validating outcome definitions during/after transition to ICD-10
- Defining denominator populations in non-member patients (i.e. predicting capture of suicide attempt data)



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Data collection and merging datasets			X		
Enrollment and engagement of patients/participants				X	
Stability of control intervention					



Enrollment and engagement of patients/participants

- Enrollment is automatic, the core challenge is engagement
- Finding the right balance between assertive and intrusive
- Several rounds of pilot-testing at Group Health
- We'll soon know if engagement rates are similar at other sites
- BUT – we won't know until we're finished:
 - What level of engagement is necessary
 - If we were able to engage the right people



Reducing the chances of getting it all wrong

- Partnering with people with lived experience of suicidal ideation and self-harm
- Careful choice of language (borrowing extensively from Motivational Interviewing)
- (For DBT skills program) Extensive use of first-person content



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Data collection and merging datasets			X		
Enrollment and engagement of patients/participants				X	
Stability of control intervention		X			



Stability of usual care in suicide prevention

- The vector of equipoise has a direction and a magnitude
- We can't (and shouldn't) control attempts to improve within-visit processes
- We are now in equipoise regarding outreach interventions, but that may change