Improving Mental Health Outcomes: Building an Adaptive Implementation Strategy Using a Cluster-randomized SMART

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Outline

- Overview of implementation strategies
- 2-arm adaptive implementation strategy design
- SMART design - implementation strategies
- Implications
Implementation and the 3T’s Road Map

Basic Biomedical Science

Efficacy Studies
What works

Clinical Efficacy Knowledge

Effectiveness Studies
Who benefits

Clinical Effectiveness Knowledge

Implementation
How

Improved Population Health

Modified from Dougherty and Conway, JAMA 2008;299:2319-2321
Why Implementation Research?
## Gaps in Treatment Quality

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage of Recommended Care Received</th>
</tr>
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<tbody>
<tr>
<td>Breast Cancer</td>
<td>75.5%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>64.7%</td>
</tr>
<tr>
<td>Depression</td>
<td>57.7%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>45.4%</td>
</tr>
<tr>
<td>Alcohol Dependence</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

Delays in Research Adoption

1871  First recorded medical use
1949  First publication showing efficacy
1970  FDA approval

*Lithium for mania*
The Need for Implementation Research

- New treatments take too long to get adopted
- Providers lack tools to implement effective treatments
- Large-scale treatment initiatives rolled out without adequate planning to sustain effects
Implementation - General Definition

“A deliberately initiated process, in which agents intend to bring into operation new or modified practices that are institutionally sanctioned, and are performed by themselves and other agents”

Key terms:
Process
Agents
Institutionally sanctioned practices

General Theory of Implementation

- **Capacity**
  (Social-structural resources available to agents)

- **Potential**
  (Social-cognitive resources available to agents)

- **Contribution**
  (What agents do to implement a complex intervention)

- **Capability**
  (Possibilities presented by the complex intervention)

May C. Towards a general theory of implementation. Implement Sci. 2013
Implementation Strategies

*Highly-specified, systematic processes used to implement treatments/practices into usual care settings*

- Guideline dissemination insufficient
- Need buy-in from providers, healthcare leaders
- Understanding barriers, facilitators to adoption
Implementation Strategies
Some Examples

- Evidence-based Quality Improvement (EBQI)
- Promoting Action on Research Implementation in Health Services (PARiHS)
- Getting to Outcomes (GTO)
- Replicating Effective Programs (REP)
Replicating Effective Programs

Implementation Intervention Strategy

Pre-implementation
- Identify need & program
- Identify settings
- Adapt & develop package - community working group input

Implementation
- Disseminate package
- Training
- Technical assistance (brief)
- Evaluation

Dissemination
- Outcomes
- Further diffusion, spread

REP was developed by the Centers for Disease Control to rapidly translate HIV prevention programs to community-based settings

Based on Social Learning Theory, Rogers’ Diffusion model

Emphasis on treatment fidelity and roll-out

REP and Uptake of HIV Prevention Interventions in AIDS Service Organizations

Kelly J, et al. AJPH 2000
Is REP Sufficient for Complex Programs?

- Collaboration across multiple providers
- Start-up logistics
- Leadership buy-in
- Need for sustainability plan (after study is completed)

REP can be augmented using other implementation strategies
Study #1: Enhanced vs. std. REP
(ROCC Study; R01 MH79994)

- Clustered RCT comparing Enhanced versus standard REP to promote provider use of a collaborative care model for bipolar disorder
- Enhanced REP → provider coaching (“Facilitation”)
- 384 patients w/bipolar disorder, 7 outpatient clinics
- Primary outcomes: Fidelity (# collaborative care sessions), mood disorder remission, quality of life

Enhanced REP Implementation Strategy

**Pre-Implementation**
- Identify need & program
- Identify settings
- Adapt & develop package-community working group input

**REP Implementation**
- Disseminate package
- Training
- Evaluation
- Monitor response

**Facilitation (external)**
- Barriers assessment
- Provider coaching and problem-solving- weekly calls
- Promote success

**Evaluation**
- Outcomes
- Further diffusion, spread
- Process Evaluation
- Build business case: sustainability

*Kilbourne AM et al. 2012; Waxmonsky J et al. 2013*
## Study Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Overall N=384</th>
<th>Enhanced REP (n=221)</th>
<th>Standard REP (n=163)</th>
<th>F (p)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td>Mean(SD)</td>
<td></td>
</tr>
<tr>
<td>Age, years</td>
<td>42.0 (11.3)</td>
<td>42.2 (11.4)</td>
<td>41.8 (11.3)</td>
<td>.36 (.72)</td>
</tr>
<tr>
<td>N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>256 (66.7)</td>
<td>146 (66.1)</td>
<td>110 (67.5)</td>
<td>.09 (.77)</td>
</tr>
<tr>
<td>Non-White</td>
<td>108 (29.3)</td>
<td>54 (25.2)</td>
<td>54 (34.8)</td>
<td>4.01 (.04)</td>
</tr>
<tr>
<td>College Education</td>
<td>71 (18.8)</td>
<td>59 (27.1)</td>
<td>12 (7.5)</td>
<td>23.2 (&lt;.001)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>279 (72.7)</td>
<td>149 (67.4)</td>
<td>130 (79.8)</td>
<td>7.2 (.007)</td>
</tr>
<tr>
<td>Alcohol misuse</td>
<td>40 (10.7)</td>
<td>24 (11.2)</td>
<td>16 (10.0)</td>
<td>.13 (.71)</td>
</tr>
<tr>
<td>Illicit drug use</td>
<td>123 (32.0)</td>
<td>70 (31.7)</td>
<td>53 (32.5)</td>
<td>.03 (.86)</td>
</tr>
</tbody>
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## REP and Patient-level Fidelity

<table>
<thead>
<tr>
<th>Treatment Fidelity Measure</th>
<th>REP package, training, TA</th>
<th>REP package, training only</th>
</tr>
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<tbody>
<tr>
<td>% completing self-management sessions</td>
<td>64%</td>
<td>22%</td>
</tr>
<tr>
<td>Total # contacts (self-management, care management)</td>
<td>8.1 (3.0)</td>
<td>5.5 (2.1)</td>
</tr>
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</table>
### 12-Month Patient Outcomes

<table>
<thead>
<tr>
<th></th>
<th>REP package, training, TA</th>
<th>REP package, training only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood disorder remission (PHQ-9 &lt;5)</td>
<td>30.6%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Mental health quality of Life (SF-12) score</td>
<td>33.9</td>
<td>34.0</td>
</tr>
</tbody>
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Secondary analyses adjusting for patient differences across sites revealed null findings comparing Enhanced, standard REP.

Small number of sites precluded sufficient power to detect differences in Enhanced versus standard REP.
Is Enhanced REP Enough?
Need for an Adaptive Implementation Study

♦ REP may not be sufficient for improving patient outcomes across sites
♦ Facilitation is time-consuming and costs more
♦ Can sites solve barriers to treatment uptake on their own?
Study #2: Enhanced REP Adaptive Implementation Strategy

♦ Compare effectiveness of 2 adaptive implementation strategies enhance program uptake: Enhanced REP (+External Facilitation) for non-responsive sites immediately or later

♦ Two-arm cluster randomized trial taking advantage of a natural experiment of national program rollout

♦ REP initially used to implement program in 158 sites

♦ 88 non-responding sites randomized to receive added External Facilitation or continue standard REP

BMC CCT ISRCTN21059161; Davis et al AJPH 2012; Kilbourne et al. 2013
Primary Outcomes
Core Components of Outreach Program

1. Site-level updated documentation of patient clinical status using electronic registry
2. Attempted contact by phone or mail
3. Patient scheduled appointment

Non-response defined as site with <80% of patients with updated clinical status documentation within 6 months (#1)
Re-Engage Adaptive Implementation Trial

National Implementation
March 2012 - August 2012

Phase I
6 months
September 2012
- Enhanced REP (N=39)

Phase 2
6 months
February 2013
- Standard REP (N=53)

Follow-up
12 months
September 2013

Standard REP 158 Sites
Non-response (N=88)

Standard REP (N=49)
Response (N=14)

Low Response (N=35)
Enhanced REP 35 Sites

Standard REP All Sites
Re-Engage 12 Month Results

*Preliminary*: Updated documentation (N=88 sites)
Re-Engage 12 Month Results

*Preliminary:* Attempted patient contact (N=88 sites)
Is External Facilitation Enough?
Building an Adaptive Implementation Strategy- SMART

- <50% patients with attempted contact
- One “dose” of 6-month Facilitation took on average 7.5 hours per site
- Site time commitment: 1-6 hours
- Leadership buy-in: Need additional internal agent to address local barriers to treatment adoption? (Kirchner, et al. 2011)
Study #3: Designing SMART Trial on Facilitation

- External Facilitator (EF): coaching in technical aspects of clinical treatment or intervention
- Internal Facilitator (IF): on-site clinical manager
  - Direct reporting line to leadership
  - Some protected time
  - Address unobservable organizational barriers
  - Develop sustainability plan with leadership
Enhanced REP
Adding Facilitation based on PARiHS Framework

**Pre-Implementation**
- Identify need & program
- Identify settings
- Adapt & develop package-community working group input

**REP Implementation**
- Disseminate package
- Training
- Evaluation
- Monitor response

**Facilitation** (Aim 1: Adaptive Implementation)
- External Facilitation
  - Technical assistance
- Internal Facilitation
  - Relationship-building/rapport

**Evaluation**
- Outcomes
- Further diffusion, spread
- EF/IF Process Evaluation
- Build business case: sustainability

External facilitator (EF): off-site, research team, technical assistance

Internal facilitator (IF): on-site provider with direct reporting line to leadership, protected time to build relationships, address unobservable organizational barriers, develop sustainability plan

*Kilbourne AM et al. 2013; Goodrich et al. 2012*
SMART REP Primary Aims

Among sites not initially responding to REP to implement collaborative care program, sites receiving External and Internal Facilitator (REP+EF/IF) vs External Facilitator alone (REP+EF):

1. Improved 12-month patient outcomes (QOL, sx)
2. Improved uptake (# collaborative care visits)
80 community clinics (1600 patients) from Michigan, Arkansas, and Colorado

Sequential Multiple Assignment Randomized Trial (SMART) design

Non-response, within 6 months:
- <50% patients enrolled by provider in collaborative care program AND
- Enrolled patients completing <75% collaborative care sessions
SMART REP Secondary Aims

- Effect of continuing REP+EF versus adding IF
- Effect of continuing with REP+ EF/IF for a longer period of time
SMART REP Design

Figure 3: SMART Trial Design of REP Combined with External (EF; REP+EF) and Internal Facilitation (IF, REP+EF/IF)

- **Start of Study**
  - Run-In Phase: All sites offered REP to implement LG; Patients start LG by Month 3

- **Month 6 Assessment**
  - Non-Response (<10 out of 20 enrolled patients receiving LG or <75% sessions completed) k=60 sites

- **Month 12 Assessment**
  - Add External Facilitation REP+EF k=30 sites N=600 patients
  - Responders
  - Add Internal & External Facilitation REP+EF/IF k=30 sites N=600 patients
  - Responders
  - Non-responders

- **Month 18 Assessment**
  - Continue follow-up assessments
  - Add IF (REP+EF/IF)
  - Responders
  - Continue REP+EF
  - Non-responders
  - Continue REP+EF/IF

- **Month 24 Assessment**
  - Cont. follow-up assessments (A)
  - Continue REP+EF (B)
  - Continue REP+EF/IF (C)
  - Cont. follow-up assessments (D)
  - Continue REP+EF (E)
SMART REP Implications

- Internal Facilitators (IFs) are costly for sites since they require additional time to recruit and administrative effort.
- Can off-site External Facilitation (EF) alone improve patient outcomes?
- Delayed effect of adding IF or EF/IF among non-responsive sites, especially in smaller practices.
Key Lessons

- Natural experiments
  - Operational partner buy-in re: study design
  - National data sources (patient, provider) key
- Testing implementation intervention strategies
  - Evidence base vs. time-sensitive opportunity
  - Cost and value of implementation interventions