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

T₁

Clinical Efficacy Knowledge

Efficacy Studies
What works

Clinical Effectiveness Knowledge

T₂

Effectiveness Studies
Who benefits

T₃

Implementation
How

Improved Population Health

Modified from Dougherty and Conway, JAMA 2008;299:2319-2321
Why Implementation Research?
Delays in Research Adoption

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

*Lithium for mania*
Implementation Research

NIH definition: “The use of strategies to adopt and integrate evidence-based practices (EBPs) and change practice patterns within specific settings”

Synonyms include:
  Knowledge Translation
  Technology Transfer

So how is this different from Madison Avenue?
Implementation Strategies

1. Guidelines insufficient
2. Adoption takes too long
3. Providers lack tools to sustain
4. Relationships matter: top-down AND bottom-up strategies

Don Draper ➔
Dale Carnegie
Implementation Strategies

Highly-specified, systematic processes used to implement treatments/practices, often at the clinic or provider level, into usual care settings

- Guideline dissemination insufficient
- Need buy-in from providers, healthcare leaders
- Understanding barriers, facilitators to adoption
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 Health Services Practices?

- 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_
# 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>
</thead>
<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>
</tbody>
</table>
Is Enhanced REP Enough?
Need for Large-scale Adaptive Implementation Study

♦ External Facilitation used in this study may not be sufficient to address local barriers to adoption
♦ Enhanced REP may not be sufficient for improving patient outcomes across sites
♦ Can sites solve barriers to treatment uptake on their own?
Study #2: Enhanced REP National 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

Standard REP 158 Sites
Non-response (N=88)
Enhanced REP (N=39)
Response (N=14)
Low Response (N=35)

Phase 2
6 months
February 2013

Standard REP (N=53)
Enhanced REP 35 Sites

Follow-up
12 months
September 2013

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)

- Enhanced REP-% Attempted contact
- Standard REP-% Attempted contact

Month/Year (2012-2013)
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)
SMART REP (cont.)

- 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

**Run-In Phase**
- All sites offered REP to implement EBP;
- Patients start EBP by Month 3

**Month 6 Assessment**
- Add External Facilitation
  - REP+EF
    - k=30 sites
    - N=600 patients
- Non-Responders
  - k=60 sites

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

**Follow Up**
- Month 18 and 24 Assessments
- Responders
- Non-Responders
- Add IF
  - (REP+EF/IF)
- Responders
- Non-Responders

**Responders**
- k=40 sites
- 6 Month follow-up assessment
- Continue follow-up assessments

**Non-Responders**
- k=100 sites
- (<10 out of 20 enrolled patients receiving EBP or <75% sessions completed)
- k=60 sites
- Continue REP+EF
- Continue REP+EF/IF
- Add IF (REP+EF/IF)
- Continue REP+EF
- Continue REP+EF/IF
- Add IF (REP+EF/IF)
- Continue follow-up assessments (A)
- Continue REP+EF (B)
- Continue REP+EF/IF (C)
- Continue follow-up assessments (D)
- Continue REP+EF/IF (E)
- Continue follow-up assessments (F)
SMART REP Design

**Study Start**

**Run-In Phase**
All sites offered REP to implement EBP; Patients start EBP by Month 3

**Month 6 Assessment**
- **REP**
  - k=100 sites
  - 100 patients
- **Non-Responders**
  - (<10 out of 20 enrolled patients receiving EBP or <75% sessions completed)
  - k=60 sites

**Month 12 Assessment**
- **REP**
  - k=40 sites
  - 600 patients
- **Non-Responders**
  - k=30 sites
  - 600 patients
- **Add External Facilitation**
  - REP+EF
  - k=30 sites
  - 600 patients
- **Add Internal & External Facilitation**
  - REP+EF/IF
  - k=30 sites
  - 600 patients

**Follow Up**

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

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