SMART and Adaptive Designs for Testing Implementation Strategies to Improve Mental Health Outcomes

Amy M. Kilbourne, PhD, MPH
Department of Psychiatry, University of Michigan
VA Quality Enhancement Research Initiative (QUERI)
UCSD Child & Adolescent Services Research Center
August 3, 2018
amykilbo@umich.edu
Why Study Implementation Strategies?
Effective Practices are Not Routinely Implemented in Real-world Settings

80% of medical research dollars do not result in public health impact.


From Mark Bauer, MD,
VA Boston HSR&D Center
Harvard Medical School

© Can Stock Photo
Study Designs for Implementation

**Implementation strategies:** technical and interpersonal methods that help providers adapt/adopt, sustain, and scale effective practices into routine care

- Bottom-up (frontline engagement)
- Top-down (leadership engagement)
### Implementation Science Addresses the Research-to-Practice Gap

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Implementation Strategies to Consider</th>
<th>Design Barrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions not designed for real-world</td>
<td>Tools to adapt to local settings/populations</td>
<td>Sufficient numbers of sites</td>
</tr>
<tr>
<td>Interventions rolled out with limited planning</td>
<td>Provider training, facilitation, community engagement</td>
<td>Policy imperative, urgency to “do something”</td>
</tr>
<tr>
<td>Intervention reach hard to sustain</td>
<td>Policy incentives, leadership development, organizational change</td>
<td>Long-term data access/reliability</td>
</tr>
</tbody>
</table>
### QUERI Implementation Strategies to Support Scale-up and Spread of Effective Practices

<table>
<thead>
<tr>
<th>Relative Site Complexity/Need</th>
<th>Relative Intensity of Strategy</th>
</tr>
</thead>
</table>
Hybrid Effectiveness/Implementation Designs

• Compare implementation strategies

• Address limits of step-wise research (speed research → practice)

• Promote external validity

• Blend effectiveness, implementation stages

Types of Hybrid Designs

- Hybrid Type 1: test clinical intervention, observe/gather information on implementation
- Hybrid Type 2: test clinical intervention, test implementation strategy
- Hybrid Type 3: test implementation strategy, observe/gather information on clinical intervention outcomes
Hybrid Type III Example:
Enhanced Replicating Effective Programs (REP) Implementation Strategy

• REP was developed by the Centers for Disease Control to rapidly translate prevention programs to community-based settings (Social Learning Theory, Rogers’ Diffusion model) (Kegeles 2000; Kilbourne 2007)

• Enhanced REP added Facilitation (regular consultation by implementation expert) to support providers in implementation self-efficacy through identifying/mitigating barriers to adoption, building coalitions at sites, and enhancing communication

Pre-implementation
Identification of quality gaps/barriers
Customize best practices- local input
Package intervention
Manual core elements
Menu options (adapt)

Implementation
Orientation
Cross-functional team
Training
Technical assistance
Facilitation (Enhanced REP)
Provider strategic thinking, consultation

Dissemination
Further diffusion, spread
Sustainability
Budget impact
Re-Engage Program Implementation Trial
Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI
Re-Engage Program Implementation Trial
Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI
Culture & Climate Moderated Re-Engage Uptake

Attempted contact

Veterans at sites with higher entrepreneurial culture & task climate benefitted more from Enhanced REP
Sequential Multiple Assignment Trials (SMART) **Towards Precision Implementation**

- Multi-stage trials; same subjects throughout
- Each stage corresponds to a critical decision point
- Pre-specified measure of responsiveness
- Treatment options at randomization restricted depending on history of responsiveness
- Subjects randomized to set of treatment options

*The goal of a SMART is to inform development of adaptive intervention strategies*
When to Use SMART Designs for Implementation

Often insufficient evidence/theory to decide:

• Which implementation strategy(ies) should I start with?
• What should I do for sites that are non-responsive to first-line implementation strategy?
• What should I do for sites that are responsive to first-line implementation?

SMART designs can help to answer these questions.
Adaptive Implementation Interventions: Example: Adaptive Implementation of Effective Programs Trial (ADEPT) Study

The question:
What is the best way to implement a collaborative care model (Life Goals) in community-based practices to improve patient mental health outcomes?

Kilbourne AM et al. (2014). Implementation Science, 9(1), 132; R01 MH 099898
Background

Collaborative care models work

Practice guidelines: Best practice tx, metabolic syndrome for mental health conditions

Care management:
- Registry tracking (Symptoms, QOL, functioning)
- General Medical Provider Liaison

Decision Support

Self-management

Access/Continuity

Life Goals sessions:
- CVD Risk, symptoms, healthy behaviors, provider engagement

Kilbourne et al. Psych Serv 2008; 2013
Community-based Practices in Michigan & Colorado

ADEF Setting:
Overview

But CCMs face barriers to implementation in community-based practices

• Consumers/Families
• Providers
• Systems
ADEPT Background

Implementation strategies can help to address barriers

Replicating Effective Programs (REP): Strategy combining manualized intervention protocol, didactic training, technical support

- Low-level, easily scalable
- Will work for some sites, probably not for most

ADEPT Background

Implementation strategies can help to address barriers

Facilitation: Multi-faceted implementation strategy that focuses on “helping rather than telling”; PARiHS framework

- Assessing barriers to uptake
- Guiding problem-solving in context of need for improvement
- Ensuring communication and priority alignment with site leadership

Rycroft-Malone et al., 2002, 2004; Kirchner et al., 2014
Flavors of facilitation

**External facilitator (EF):**
- **Location:** Off-site, research team member
- **Topical focus:** Benchmarking, coaching
- **Role:** Confidante, outside observer

**Internal facilitator (IF):**
- **Location:** On-site, direct report to leadership
- **Topical focus:** Leveraging, rapport-building, internal recognition, sustainability
- **Role:** Inside expert, champion

Implementation strategy options

REP
(Replicating Effective Programs)
Provides intervention manualization, didactic training and technical assistance.

EF
(External facilitation)
Help identifying & addressing barriers from an outside ‘expert.’

IF
(Internal facilitation)
Inside expert who works with site leaders to address barriers & champion cause.

Less intensive  More intensive
Research question

What is the best way to use External and Internal Facilitation to improve patient mental health outcomes through implementation of the Life Goals CCM for sites non-responsive to REP?

- Is it better to provide EF or EF+IF first?
- If sites don’t respond to EF after six months, should we continue EF or augment with IF?
Research design

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

**Non-Responders**
- REP (S ≤ 10 patients receiving LG OR ≤ 50% of patients receiving ≥ 3 LG sessions)
- Add Internal & External Facilitation REP+EF/IF

**Responders**
- Continue REP
- Continue REP+EF/IF

**Month 6 Assessment**
- Add External Facilitation REP+EF
- Continue REP
- Continue REP+EF

**Month 12 Assessment**
- Continue REP
- Add IF
- Continue REP
- Continue REP+EF

**Month 18 Assessment**
- Continue REP
- Continue REP+EF

**Follow Up**

*Kilbourne et al., 2014; Funding: NIMH R01 MH99899*
Primary Aim

Determine among patients in sites that do not exhibit response to REP alone, the effect of adding an External and Internal Facilitator (REP + EF/IF) versus REP + EF on patient-level changes in mental health-related quality of life (MH-QOL), mood symptoms, and receipt of Life Goals month 6 to month 18.
Kilbourne et al., 2014; Funding: NIMH R01 MH99899
Methods

**Change in MH-QOL & PHQ-9 at 12 months**

Three-level linear mixed model

- **Fixed effects:** Time pre-randomization, time post-randomization, treatment, and treatment post-randomization
- **Random effects:** Site- and patient-level random intercepts
- **Controls:** State, urban vs. rural, baseline site-aggregated MH-QOL

**Receipt of Life Goals between months 6 and 18**

Two-level binary mixed model

- **Fixed effects:** Treatment
- **Random effects:** Site-level random intercept
- **Controls:** State, urban vs. rural, baseline site-aggregated MH-QOL

All models run with and without multiple imputation.
Results: Number of sites/consumers

**Study Start**
- **Run-In Phase**
  - All sites offered REP to implement EBP; Patients start EBP by **Month 3**
  - **REP**
    - **k=43 sites**
  - **Non-Responders**
    - S (<10 patients receiving LG OR <50% of patients receiving ≥3 LG sessions) **k=27 sites (N=169)**
  - **Responders**
    - **k=16 sites**

**Month 6 Assessment**
- **Add External Facilitation**
  - **REP+EF**
    - **k=13 sites**
    - **(N=77)**
- **Responder**s
  - **k=2 sites**
- **Non-responders**
  - **Add Internal & External Facilitation**
    - **REP+EF/IF**
      - **k=14 sites**
      - **(N=92)**

**Month 12 Assessment**
- **Continue REP**
  - **k=2 sites**
- **Cont REP+EF**
  - **k=6 sites**
  - **Add IF**
  - **k=5 sites**
  - **Continue REP+EF/IF**
  - **k=1 site**
  - **Cont REP+EF/IF**
  - **k=13 sites**

**Follow Up**
- **Month 18 Assessment**
  - **Continue REP**
    - **(A)**
  - **Continue REP+EF**
    - **(B)**
  - **Continue REP+EF/IF**
    - **(C)**
  - **Continue REP**
    - **(D)**
  - **Continue REP+EF/IF**
    - **(E)**

**Kilbourne et al, 2014; Funding: NIMH R01 MH99899**
## Results: Baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>REP+EF (N=77)</th>
<th>REP+EF/IF (N=92)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Michigan</strong></td>
<td>52 (68%)</td>
<td>56 (61%)</td>
</tr>
<tr>
<td><strong>Rural site</strong></td>
<td>58 (75%)</td>
<td>71 (77%)</td>
</tr>
<tr>
<td><strong>Age: Mean (SD)</strong></td>
<td>48.18 (11.14)</td>
<td>43.01 (11.19)</td>
</tr>
<tr>
<td><strong>White race</strong></td>
<td>61 (79%)</td>
<td>73 (79%)</td>
</tr>
<tr>
<td><strong>Female?</strong></td>
<td>54 (70%)</td>
<td>70 (77%)</td>
</tr>
<tr>
<td><strong>College graduate</strong></td>
<td>10 (13%)</td>
<td>10 (11%)</td>
</tr>
<tr>
<td><strong>Employed</strong></td>
<td>10 (13%)</td>
<td>11 (12%)</td>
</tr>
<tr>
<td><strong>Retired</strong></td>
<td>14 (18%)</td>
<td>4 (4%)</td>
</tr>
<tr>
<td><strong>Live alone?</strong></td>
<td>25 (32%)</td>
<td>28 (30%)</td>
</tr>
<tr>
<td><strong>Ever homeless?</strong></td>
<td>50 (65%)</td>
<td>51 (55%)</td>
</tr>
<tr>
<td><strong>Mental health quality of life: Mean (SD)</strong></td>
<td>39.75 (12.92)</td>
<td>36.66 (13.10)</td>
</tr>
<tr>
<td><strong>Physical health quality of life: Mean (SD)</strong></td>
<td>35.25 (11.18)</td>
<td>37.85 (12.85)</td>
</tr>
<tr>
<td><strong>PHQ-9: Mean (SD)</strong></td>
<td>11.45 (6.46)</td>
<td>12.61 (6.94)</td>
</tr>
</tbody>
</table>

**Note:** Bold numbers indicate significant differences.
Results: MH-QOL

\[ \text{BEF} = 0.57 \]
\[ \text{BEF+IF} = 0.02 \]

*Difference in slopes: \( t = -2.70, p < 0.01 \)

(Higher numbers better)
Results: PHQ-9

BEF = -0.14
BEF + IF = -0.05

Difference in slopes: $t = 1.09, p = 0.28$

(Lower numbers better)
Results: Receipt of Life Goals

Odds ratios for reporting receipt, months 6-18
Implications

In spite of its added expense and intensity, augmenting EF with IF did not lead to better downstream patient outcomes than offering EF alone.

Why? We conjecture...

- EF more easily scalable
- Potential EF dose response
- Heterogeneity in quality/activity of IFs
- Burden of EF+IF at initial assignment
Limitations

• Fewer sites than anticipated failed to provide patient names, and thus are not included in analyses.

• Self-report data for certain outcomes (e.g., receipt of Life Goals).

• Limited fidelity data for LG delivery when it occurred.

• Self-report data for IF activities limits understanding of what tasks they performed.
Next Steps

- **Secondary analyses**: cost effectiveness, second randomization for EF sites (though note power limitations)
- **Mechanisms**: what (else) can the EF & IF log data reveal?
- **Moderators**: for which sites did EF+IF seem to work well? How did organizational and leadership factors (ICS, ILS) influence implementation?
Adaptive School-based Implementation of CBT (ASIC)

- 1 in 5 students affected by mood disorders, 20% receive any treatment
- EBTs such as CBT are effective, school professionals not adequately trained
- Organizational barriers to EBT uptake in schools
- ASIC will compare the effectiveness of a statewide, school-level adaptive implementation intervention involving REP, provider-CBT Coaching, and school-based Facilitation versus REP alone on:
  - Frequency of CBT delivered to students by SPs
  - Student mental health outcomes
Adaptive School-based Implementation of CBT (ASIC)
THANK YOU!

Contributors:
Shawna Smith, PhD, UM Dept. of Psychiatry, Institute for Social Research
Daniel Almirall, PhD, UM Institute for Social Research
Mark Bauer, MD, VA Boston and Harvard Medical School

Funding: NIMH R01 MH099898, R01 MH114203, VA HSRD 11-232

Disclosure: The views expressed are those of the authors and do not necessarily represent the views of the U.S. Dept. of Veterans Affairs