Designs for Dissemination and Implementation Research for Small Populations

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Outline

Implementation and dissemination science overview

Intervention study designs for implementation research, e.g.,
  Hybrid designs
  Stepped-wedge
  Sequential Multiple Assignment Trial (SMART) designs
Setting the Stage

• *Dissemination research* is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based health interventions.

• *Implementation research* is the scientific study of the use of strategies to promote the uptake of evidence-based health interventions in clinical and community settings in order to improve patient/population outcomes.

From: NIH PAR 16-238: Dissemination and Implementation Research in Health (R01)
Designs for Implementation & Dissemination Intervention Research

- Randomized controlled trial (RCT)
- Pragmatic clinical trials (PCT)
- Interrupted time series (ITS)
- Dynamic wait list design (DWLD)
- Regression point displacement design (RPDD)
- Stepped-wedge designs
- Hybrid Effectiveness/Implementation Designs
- Sequential Multiple Assignment Randomized Trial/adaptive designs
Study Designs for Implementation Strategies

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)
Why Research on Implementation Strategies?
Effective Practices are Not Routinely Implemented for Small Populations

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

—Chalmers & Glasziou, Lancet 2009

From Mark Bauer, MD, VA Boston HSR&D Center Harvard Medical School
### Implementation Science Addresses the Research-to-Practice Gap

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Implementation Strategies to Consider</th>
<th>Design Barrier</th>
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<tbody>
<tr>
<td>Interventions not designed for small populations</td>
<td>Tools to adapt to local settings/populations</td>
<td>Sufficient numbers of sites</td>
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<td>Interventions rolled out with limited planning</td>
<td>Provider training, facilitation, community engagement</td>
<td>Policy imperative, urgency to “do something”</td>
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<tr>
<td>Intervention reach hard to sustain</td>
<td>Policy incentives, organizational change</td>
<td>Data access/reliability</td>
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Hybrid Effectiveness/Implementation Designs

- Compare implementation strategies
- Address limits of step-wise research (speed research $\rightarrow$ 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 Effectiveness/Implementation Designs

<table>
<thead>
<tr>
<th>Design Characteristic</th>
<th>Type I</th>
<th>Type II</th>
<th>Type III</th>
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<tbody>
<tr>
<td>Design</td>
<td>Test clinical intervention</td>
<td>Test clinical &amp; implementation strategies</td>
<td>Test implementation strategy</td>
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<tr>
<td>Question</td>
<td>Is treatment effective versus usual care (UC)?</td>
<td>Is treatment delivered through tailored provider coaching effective vs UC?</td>
<td>Does provider coaching vs. training alone improve treatment uptake?</td>
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<tr>
<td>Unit of analyses</td>
<td>Patient</td>
<td>Providers/clinics</td>
<td>Providers/clinics</td>
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<td>Primary outcomes</td>
<td>Health outcomes</td>
<td>Process measures</td>
<td>Provider Uptake, Sustainability</td>
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<td>Key Advantage</td>
<td>“Cleanest” in determining intervention effectiveness</td>
<td>Ideal when there is time-sensitive need to roll out intervention</td>
<td>All participants get intervention, focus on what will it take to sustain</td>
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Hybrid Type I Example:
National Implementation of Collaborative Care Model (CCM) for Aetna Enrollees with Mood Disorders from Small Group Practices

Kilbourne AM et al, BMC Psychol, 2014
Hybrid Type II Example:
Implementing Doctor-Office Collaborative Care to Improve Pediatric Behavioral Health Outcomes

KOllko DJ et al, Pediatrics 2014
Hybrid Type III Examples: Enhanced Replicating Effective Programs (REP) Implementation Strategy

**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 mentoring

**Dissemination**
- Further diffusion, spread
- Sustainability
- Budget impact

- 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 coaching by implementation expert) to support providers in implementation self-efficacy through identifying/mitigating barriers to adoption, building coalitions at sites, and enhancing communication with leaders (Kilbourne et al Implementation Science 2014)
Hybrid Type III Example #1:
Implementation Strategies and Uptake of HIV Prevention Interventions in AIDS Service Organizations

Kelly J, et al. AJPH 2000
Hybrid Type III Example #2: Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI
Hybrid Type III Example #2: Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI

Phase I

Phase II

- Immed. Enhanced REP-% Attempted contact
- Delayed Enhanced REP-% Attempted contact

Month/Year (2012-2013)
Stepped-Wedge Designs Overview

- All participants receive uniform intervention
- Start-time is randomized
- Ideal when resources are too limited to intervene at same time
Stepped-Wedge Design Advantages

**Budgetary:**
- Resources too limited to intervene at the same time at all participants/sites

**Policy:**
- Policy imperative to have all participants receive intervention

**Pragmatic:**
- Advantageous for recruiting & retention to have all participants receive intervention

**Ethical:**
- Intervention clearly causes more good than harm for participants, rather than equipoise
Stepped-Wedge Design Example:
Provider Facilitation - Collaborative Care in Mental Health Clinics

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Facilitator 1
Facilitator 2
Facilitator 3
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
ADEPT Setting:
Small Practices in Michigan & Colorado
Example: Adaptive Implementation of Effective Programs Trial (ADEPT)

Implementation strategy options:
• Replicating Effective Programs (REP)
• External Facilitation (EF)
• External + Internal Facilitation (EF/IF)
Adaptive Implementation Interventions: Rationale for ADEPT

Prior evidence says:

• **REP** will work for some sites, but likely not most
  • But we don’t really know which…
• Most sites will need more support than **REP**

But we don’t know:

• What do we do when **REP doesn’t work**?
  • Step up directly to **EF/IF** or to **EF**? (Aim 1)
  • What if we step up to **EF** but sites still don’t respond? (Aim 2)
ADEPT Study Design

**Start of study**

- REP

**6 month assessment**

- Responders
- Non-Responders

**12 month assessment**

- REP + EF
- REP + EF/IF

**18 month assessment**

- Follow-up assessments
- Continue REP + EF
- Step up to REP + EF/IF

**Experimental condition**

- A
- B
- C
- D
- E

**Response:** <50% of patients receiving ≥3 LG sessions

**Implementation strategies:**
- REP = Replicating Effective Programs
- EF = External facilitation
- IF = Internal facilitation

ADEPT Study Design: Aim 1

Is EF+IF better than EF alone for non-responding sites?

- **REP** = Replicating Effective Programs
- **EF** = External facilitation
- **IF** = Internal facilitation

**Phase 1**
- Start of study
- 6 month assessment
- **RESPONDERS**
- **NON-RESPONDERS**

**Phase 2**
- 12 month assessment
- **RESPONDERS**
- **NON-RESPONDERS**
- Follow-up assessments

**Phase 3**
- 18 month assessment
- **RESPONDERS**
- **NON-RESPONDERS**
- Follow-up assessments
- **A**
- **B**
- **C**
- **D**
- **E**

**Experimental condition**

**Response:**
- <50% of patients receiving ≥3 LG sessions

**Implementation strategies:**
- REP = Replicating Effective Programs
- EF = External facilitation
- IF = Internal facilitation
ADEPT Study Design: Aim 2
Is continuing EF+IF or EF alone better for non-responding sites?

Response: <50% of patients receiving ≥3 LG sessions
Implementation strategies:
REP=Replicating Effective Programs
EF=External facilitation
IF=Internal facilitation

Phase 1
Start of study
REP
Non-Responders
Follow-up assessments
6 month assessment
Responders
REP+EF

Phase 2
Follow-up assessments
12 month assessment
Responders
REP+EF/IF
Non-Responders

Phase 3
Follow-up assessments
18 month assessment
Responders
Continue REP+EF/IF
Non-Responders
Continue REP+EF/IF

Experimental condition
A
B
C
D
E

Response: <50% of patients receiving ≥3 LG sessions
Implementation strategies:
REP=Replicating Effective Programs
EF=External facilitation
IF=Internal facilitation
Future Directions

• Enhancing reach: community organizations, schools, etc.
• Implementation strategies: everyone gets something
• Randomization: stakeholder timelines
• Data capture strategies
Thank you!

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