Implementation Research Designs and Methods: Testing Implementation Strategies

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Objectives

• Learn the fundamentals of the Implementation Research Logic Model (IRLM)
• Understand the basic goals of research to scale up effective clinical and health interventions
• Explore using the IRLM for studies of scale up
  • Present a “scale up extension” of the IRLM
  • Hypothetical case example
The Delivery System Matters

“The use of effective interventions without [effective] implementation strategies is like a serum without a syringe; the cure is available, but the delivery system is not.”

Fixsen, Blase, Duda, Naom, Van Dyke, 2010
Hybrid Approaches

Effectiveness Research

Implementation Strategies to Support the Delivery System

Intervention Effectiveness
Symptoms, Functioning, Quality of Life, Infections, etc.

Clinical/Prevention/Health Promotion Intervention
Evidence-Based Clinical/Preventive/Health Interventions

• The 7 P’s
  o **Pill** (PrEP)
  o **Program** (PROMISE)
  o **Practice** (routine HIV screening in clinical settings)
  o **Principle** (HIV Treatment as Prevention)
  o **Product** (condom)
  o **Policy** (housing for people at high risk for HIV)
  o **Procedures** (male circumcision)

Brown et al., 2017
Implementation Strategies

• Implementation Strategies are an intervention on the system to increase adoption of evidence-based innovations into usual care
  o 9 categories derived from 75 discrete evidence-informed strategies
• Theory- or logic-driven connection between the implementation strategy and the barriers (that it will attempt to overcome) and the facilitators (that it will attempt to leverage) (CFIR → ERIC study)
• Rarely 1-to-1 (i.e., 1 strategy often is linked to multiple determinants; > 1 strategy to address 1 barrier; increasing 1 implementation outcome could be the result of ≥1 determinant and require ≥ strategy)

ERIC Study
Powell et al. 2015
Hybrid Approaches

Effectiveness Research

Implementation Strategies to Support the Delivery System

Clinical/Prevention/Health Promotion Intervention

Implementation Impact
Adoption, Cost, Fidelity, Reach, Sustainment

Implementation Research

Implementation Strategies to Support the Delivery System

Clinical/Prevention/Health Promotion Intervention

Hybrid Effectiveness–Implementation Approaches

Type 1

Type 2

Type 3

test the thing, observe/gather information on doing the thing
test the thing, test/study strategies to do the thing

test strategies to do the thing, observe/gather information on the thing

Intervention Effectiveness
Symptoms, Functioning, Quality of Life, Infections, etc.
Approach, NOT Design

• Changing the language from hybrid “design” to hybrid “approach”
  • Helps folks recall that this is an approach that can be used with a variety of research designs
<table>
<thead>
<tr>
<th>Study Characteristic</th>
<th>Hybrid Type I</th>
<th>Hybrid Type II</th>
<th>Hybrid Type III</th>
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| Research Aims        | **Primary Aim:** Determine effectiveness of an intervention  
|                      | **Secondary Aim:** Better understand context for implementation | **Primary Aim:** Determine effectiveness of an intervention  
|                      | | **Co-Primary* Aim:** Determine feasibility and/or (potential) impact of an implementation strategy | **Primary Aim:** Determine impact of an implementation strategy  
|                      | | | **Secondary Aim:** Assess clinical outcomes associated with implementation |

*or “secondary”…
Why should we consider hybrid designs?

• Maybe we can speed this up a little?
  • Sequential examination can be slow
  • Don’t wait for “perfect” intervention effectiveness data before moving to implementation research
  • We can “backfill” effectiveness data while we test/evaluate implementation strategies

• How do intervention/innovation outcomes relate to levels of adoption and fidelity?
  • How will we know this without data from “both sides”?
Characteristics and Challenges of Designing Implementation Trials

• External validity > internal validity
• Minimize disruptions to and burden on the systems
• Randomization occurs at “higher levels” of the service system (e.g., provider, clinic, county, etc.)
  • Small number of “units”
  • Nesting within multiple levels of the system(s)
  • Interactions between
• Experimental Designs: The implementation strategy/strategies are manipulated (serve as the IV)

Hwang, Birken, Melvin, Rowheder, & Smith, 2020, *J Clin Trans Sci*
Choosing a Design

• What design type is required to answer your implementation research question(s)?
  o Implementation preparation aim?
  o Consider at what level in the system the primary outcome is measured (aligned with the level the strategy is targeting)

• Do you have sufficient units to answer your implementation research question(s)?

• Can you randomize the units?

• Is “implementation as usual” an acceptable comparison to your community/clinical partners?
Different Types of Designs

• Formative/Developmental
  • Understanding context, selecting, tailoring, and adapting strategies for later testing

• Non-experimental
  • Observational studies (policy)

• Within-site designs:
  • Generally simpler, typically not randomized (compare to pre or to no implementation)

• Between-site designs:
  • Replication/aggregation, comparison of implementation strategies, randomization can reduce bias, produces generalized knowledge

• Within- and between-site designs:
  • Roll-out designs (e.g., stepped wedge)
  • Randomize timing (and potentially to implementation strategy)

Hwang, Birken, Melvin, Rowheder, & Smith, 2020, J Clin Trans Sci
Within-Site Designs

• Post Design
• Pre-Post Design
• Interrupted Time-Series
  • Rarely randomized
  • Single site can demonstrate feasibility and initial impact (more sites are needed for full evaluation)

• Any hybrid approach can be used
• Most commonly see either a Type I or a Type III as these designs lend themselves to a primary focus

Hwang, Birken, Melvin, Rowheder, & Smith, 2020, J Clin Trans Sci
Between-Site/Within- and Between-Site Designs

- Novel implementation strategy vs routine practice
- Comparative Implementation
  - Two novel implementation strategies for the same clinical/preventive intervention (7 Ps)

- Two/Three-arm cluster randomized trials
- Roll-out designs (Stepped-wedge)
- Factorial designs/SMART
  - Non-Randomized or Randomized

- Any hybrid approach can be used
  - If unit of randomization is patient > Type I (maybe a Type II)
  - If unit of randomization is clinician/clinic/CBO > Type II/Type III
  - Exceptions of course because Hybrid approaches are not dictated by trial/study design
  - Interesting design examples combining cluster and patient-level randomization (Raising Healthy Children, NU IMPACT)
Collaborative Care Model Trial

- Matched-pair randomized roll-out trial using a hybrid Type 2 effectiveness-implementation approach
- Comparing Collaborative Care Model (CoCM) for depression and anxiety with services as usual

- Implementation Strategies
  - In-person training
  - Ongoing booster trainings
  - EHR modifications (for ease of referral and tracking program status)
  - Audit and feedback from program status tracker
  - Financial/billing solutions (Wolk et al., 2021, *Medical Care*)
  - Illinois law for CoCM reimbursement

- Analysis Plan
  - **Effectiveness:** CoCM effects on reducing depression/anxiety symptoms (compared to non-enrolled and pre)
  - **Implementation:** Reach and adoption (closely examining health equity in outcomes) and sustainability (compared to pre and within and across the clinics)
  - Mixed methods to examine PCP and support staff acceptability, appropriateness and feasibility of CoCM and our implementation strategy

Smith, Fu et al. 2022, *Contemp Clin Trials Commun*
Figure 1. Prospective randomized roll-out schedule and study periods

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Notes. Light gray = Pre ‘go-live’ implementation period. Dark gray = Post ‘go-live’ implementation and sustainment periods. See text for changes to this prospective roll-out schedule. This figure is adapted from Figure 2 in Smith and Hasan (2020). Quantitative approaches for the evaluation of implementation research studies. *Psychiatry Research*, 283:112521–112529. doi: https://doi.org/10.1016/j.psychres.2019.1125

Smith, Fu et al. 2022, *Contemp Clin Trials Commun*
Example: Raising Healthy Children
Cluster non-randomized with embedded patient-level RCT hybrid Type 2

Non-Randomization of Clinics to Strategy Condition

Integrate/Co-Located Delivery in the Clinic

Services as Usual

Delivery System

FCU4Health

Implementation Strategy

Referral to Service Provider Outside the Clinic

Services as Usual

Delivery System

FCU4Health

Clinical Intervention

Smith et al 2018, *Implement Sci*
Comparison of Implementation Strategies

**Integrated/Co-Located Delivery**
- Existing BH staff deliver FCU4Health
- CHWs conduct assessments
- Delivery: home visiting > in-clinic

**Referral to External Provider**
- Hired BH staff (study employees)
- Undergraduates conduct assessments
- Delivery: home visiting > community
Results

- Failure of Integrated/Co-Located Care model
- Switched to all participating clinics participating in referral-based model
  - 5 FQHCs
  - Children’s hospital outpatient clinic
  - Military Health Clinic
  - Private Peds Practices
- FCU4Health effective (Smith et al. 2021; Berkel et al. 2021a)
- High fidelity to the model (Berkel et al. 2021b)
Using the IRLM for Different Purposes and Stages of Research

Planning, Executing, Reporting, Synthesizing
• **Planning**
  - Work with community partners and/or organization stakeholders to fill in the implementation strategies
  - Often begins with the known parameter(s) of the study

• **Executing**
  - Completed IRLM can serve as ”protocol” and can form the basis for ongoing tracking of what occurs, what is altered, deviations, etc.

• **Reporting**
  - Show what happened during the study; reporting of the hypothesized relationships that were observed; facilitates communication of findings

• **Synthesizing**
  - Draw conclusions for the implementation of an EBP/similar EBPs in a particular context (or across contexts) that are shared and generalizable to provide a guide for future research and implementation
Standard Implementation Research Logic Model (IRLM)

Determinants

Implementation Strategies

Mechanisms

Outcomes

- Inner Setting
- Outer Setting
- Characteristics of Individuals
- Process

- Intervention Characteristics

- Implementation
- Service
- Clinical/Patient

- Determinants
- Implementation Strategies
- Mechanisms
- Outcomes
IRLM for Comparative Implementation

**Determinants**
- Intervention Characteristics
  - Inner Setting
  - Outer Setting
  - Characteristics of Individuals

**Implementation Strategies**
- Strategy Condition #1
- Strategy Condition #2

**Mechanisms**

**Outcomes**
- Implementation
  - Service
  - Clinical/Patient
IRLM with Clinical Intervention

Determinants

Inner Setting

Intervention Characteristics

Outer Setting

Characteristics of Individuals

Process

Clinical Intervention

Implementation Strategies

Mechanisms

Outcomes

Implementation Service

Clinical/Patient
IRLM for a Multilevel Intervention

An intervention at two or more levels of individuals, clinical teams, institutions and/or community settings that measures outcomes at three or more of these levels.

**Determinants**

**Inner Setting**

**Outer Setting**

**Characteristics of Individuals**

**Process**

**Implementation Strategies**

- All Clinics
  - Training (in-person and asynchronous)
  - EHR modifications
  - Workflow analysis

- Experimental Condition
  - Practice Facilitation

- Control Condition
  - Implementation as Usual

**Multilevel Intervention – Kaiser BP Control “Bundle”**

- A health system-wide HTN registry
- Distribution of an evidence-based BP control guideline
- BP control reports generated at least quarterly for clinic directors
- Medical assistant follow-up visits for BP measurement and management

**Strategy Mechanisms**

- Clinical/Preventive/Health Intervention Components
  - Guidelines from the International Society of Hypertension
  - Single Pill Combination Therapy

**Outcomes**

**Implementation**

**Service**

**Clinical/Patient**
IRLM Principles of Use

1. Strive for Comprehensiveness
2. Indicate Key Conceptual Relationships
3. Specify Critical Study Design Elements

More detail in Smith, Liu, & Rafferty, 2020, *Implementation Science*
## IRLM for Pediatric HTN Guideline Implementation in Primary Care

### Barriers & Facilitators

<table>
<thead>
<tr>
<th>Intervention Characteristics</th>
<th>Process</th>
<th>Characteristics of Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor adherence to CPG for pediatric HTN -1</td>
<td>A,B,C,D,F,K,M,O</td>
<td>Providers have limited time -2</td>
</tr>
<tr>
<td>BP measurement technique -1</td>
<td>A,B,C,D,F,K,M,O</td>
<td>Limited knowledge of elevated BP values -1</td>
</tr>
<tr>
<td>Poor follow-up for elevated BP -1</td>
<td>A,B,C,D,G,J,K,L,M,N,O,P</td>
<td>Providers are in pediatric BP +1</td>
</tr>
<tr>
<td>Time needed for population health tool -1</td>
<td>B,D,K,L,M</td>
<td>QI teams and processes in place +1</td>
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<tr>
<td>Inconsistent use of diagnosis code -1</td>
<td>B,C,D,L,P</td>
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<tr>
<td>Equipment and clinic structure/layout -2</td>
<td>D,E,O</td>
<td>Coordination and consults for specialty care 0</td>
</tr>
<tr>
<td>Limited time for BP measurement -2</td>
<td>D,E,O,M</td>
<td>Patient/family not invested in health 0</td>
</tr>
<tr>
<td>Buy-in from organization/leadership -1</td>
<td>A,B,E,I,N,O,P,Q</td>
<td>External sources of grant support 0*</td>
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<tr>
<td>Staff availability for managing population health tool -1</td>
<td>E,K,M,O</td>
<td>External quality benchmarks (e.g., UDS/HEDIS metrics) +1</td>
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<tr>
<td>Limited continuity of care with same PCP -1</td>
<td>B,C,D,L</td>
<td>Cosmopolitanism (Alliance Chicago Network) +2</td>
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<td>Availability of internal funding sources +1*</td>
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### Implementation Strategies

- Training
  - Training of clinic staff A
  - Training of providers B
- EHR reminders/features C
- Workflow changes D
- Leadership support E
- Visual reminders/materials F
- For clinic staff F
- For patients/families H
- Population health tool
  - Provider use of tool G
  - Stages of tool
    - Day-to-day patient care I
    - Identify at-risk patients J
  - Bundling with UDS/HEDIS-related activities J
- Staffing changes
  - New BP Champion position K
  - Task shifting M
- Financial support
  - Provider incentives N
  - Accessing funding O
- Audit and feedback P
- Build on existing QI structure for adult HTN O

### CPG for Pediatric HTN

- Annual BP measurements for children/adolescents ≥3 years.
- BP checks at every encounter for high-risk children/adolescents (e.g., obesity).
- Diagnosis HTN in children/adolescents who have at least 2 BP readings >95th percentile, based on sex, age, and height tables, at 3 different visits.
- Record a detailed history and physical examination for EBP to identify potential secondary causes of HTN.
- Children/adolescents diagnosed with HTN should be prescribed pharmacologic therapy.
- Treatment goals are BP <90th percentile or <130/80 (≥13 years).
- Children/adolescents who fail lifestyle changes should be referred to the PCP for potential pharmacologic therapy.

### Mechanisms

- Improved knowledge of pHTN CPG among clinic staff
- Increased skill set of clinic staff and pediatric providers on pHTN CPG roles and responsibilities
- Improved self-efficacy of clinic staff and pediatric providers
- Increased awareness of pHTN
- Greater organizational support for pHTN diagnosis and management
- Bundling pediatric HTN strategies with other health priorities (routinization)
- Accountability (via BP Champion, audit and feedback, and incentives)

### Outcomes

- Reach: Individuals willing to participate
- Effectiveness: impact of intervention on important outcomes
- Adoption: settings and agents willing to initiate the program
- Implementation
  - Acceptability
  - Appropriateness
  - Cost
  - Feasibility
  - Fidelity
- Maintenance/Sustainability: extent to which a program is part of routine organizational practice

- Guideline-adherent diagnosis of pediatric HTN
- Guideline-adherent management of pediatric HTN
- Appropriate follow-up scheduled/completed
- Lifestyle counseling or pharmacologic therapy
- Cost effectiveness
- Population health tool usage
- (Distal: better HTN management, lifestyle management)

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**Notes.** *Significant variation between clinics. Tier 1 = High priority, high effectiveness, higher feasibility; Tier 2 = Moderate priority, moderate effectiveness, moderate feasibility; Tier 3 = Lower priority, moderate effectiveness, low feasibility. IRLM is incomplete per the guidelines of Smith, Li, & Rafferty (2020); depiction is accurate to the progress made with the Stakeholder Advisory Panel (SAP) to this stage of the project, as described in this article.**

Knapp et al. 2022 Implementation Science Communications
Thank you!

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