Planning an Implementation Research Study

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1. Helps develop effective strategies for implementing evidence-based practices, of which improve health-related processes & outcomes.

2. Produces generalizable knowledge regarding selected strategies by understanding the different processes, barriers, and facilitators that can influence either success or failure.

3. Aids in the development, testing and refining of relevant theories, conceptual frameworks, as well as measures to advance implementation science.

Reference:
### Distinguishing Clinical/Public Health Research from Implementation Research

<table>
<thead>
<tr>
<th>Study feature</th>
<th>Clinical / Public Health research</th>
<th>Implementation research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim: evaluate a / an …</strong></td>
<td>clinical intervention, health promotion intervention, policy</td>
<td>implementation strategy</td>
</tr>
<tr>
<td><strong>Typical intervention</strong></td>
<td>drug, procedure, therapy, prevention program</td>
<td>organizational practice change, training</td>
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<tr>
<td><strong>Typical outcomes</strong></td>
<td>symptoms, health outcomes, patient behavior</td>
<td>adoption, adherence, fidelity, level of implementation</td>
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<tr>
<td><strong>Typical unit of analysis, randomization</strong></td>
<td>Patient, community member</td>
<td>clinic, team, facility, community, school</td>
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Implementation Research Has a Different Emphasis

Effectiveness vs. Implementation

- System to Support Adoption and Delivery with Fidelity
- Implementation Strategies
- Implementation Outcomes
- Health Outcomes

Smith & Hasan, 2020, Psychiatry Research
Step by Step Guide

1. Frame/Identify your research question
2. Create an implementation logic model
3. Pick an implementation science theory, model, or framework
4. Identify implementation strategies
5. Select research method
6. Select study design
7. Choose measures and evaluation approach
8. Secure Funding
9. Conduct Study
10. Disseminate Results
Frame the Research Question
Locating yourself on the “subway line” of translational research

Yes

No

Efficacy Research

(Design for implementation)

Effectiveness Research

Has the intervention or practice of interest shown efficacy?

Has the intervention or practice of interest shown effectiveness?

No / Partial*

No

Yes

Yes

Hybrid effectiveness-implementation trials

Mixed methods studies to understand context

Testing implementation strategies

Designing implementation strategies

Effectiveness Research

Implementation Research


*In some cases it may be appropriate to move forward with a hybrid Type I trial in the absence of effectiveness evidence (e.g. very strong efficacy, indirect evidence supportive of potential effectiveness in context of interest, and/or strong momentum supporting implementation in a health care context).
Identifying the Problem

- Thorough understanding of the context
- Identify stakeholders
  - Implementers, clinicians, researchers, community workers, NGOs, health ministry
- Identify the evidence-based intervention*
- Conduct a focused literature review
- Formulate the research question and research objectives

Frame your question

Questions relating to the objective of:
- Exploring
- Describing
- Influencing
- Explaining
- Predicting

Questions relating to the challenge of:
- Scaling up
- Sustainability
- Replication
- Program Integration
- Equitability
- Real-world effectiveness

https://impsciuw.org/implementation-science/research/frame-your-question/
Characteristics of a “good’ implementation research question

- Relevant
- Appropriate
- Problem-driven
- Actionable
- Specific
- Innovative
- Generalizable
Characteristics of a “good’ implementation research question

Example: What are the most effective strategies to improve the use of evidence-based smoking cessation counseling services among patients at risk for heart disease?

- Relevant – to individuals, health systems, and policy makers
- Appropriate – answerable with a thoughtfully planned approach
- Problem-driven – addresses a known gap or challenge
- Actionable – identifying effective strategies can help implement them
- Specific – precise focus in a well-defined population
- Innovative – should add information and improve knowledge
- Generalizable – strive for application of findings across contexts
Step 2

Create an Implementation Logic Model
Implementation Research Logic Model

Planning
Executing
Reporting
Synthesizing

**Intervention Mapping (2016)**

**Steps**

- **Step 1**
  Logic model of the problem

- **Step 2**
  Logic model of change

- **Step 3**
  Program Design

- **Step 4**
  Program Production

- **Step 5**
  Plan for Implementation

- **Step 6**
  Program Evaluation

**Evaluation**

**Implementation Mapping Process (2019)**

**Tasks**

1. **Task 1.** Conduct a needs and assets assessment and identify adopters and implementers.

2. **Task 2.** Identify adoption and implementation outcomes, performance objectives, and determinants; create matrices of change.

3. **Task 3.** Choose theoretical methods; Select or create implementation strategies.

4. **Task 4.** Produce implementation protocols and materials.

5. **Task 5.** Evaluate implementation outcomes.

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Implementation Mapping Logic Model

EBI

Implementation

Outcomes

Evidence-Based Intervention (EBI) Program, Guideline or other Health Innovation

Multilevel Implementation Context
Setting characteristics, policy climate, culture, readiness, resources

Implementation Strategies
Contain methods (techniques) and practical applications...
to change determinants

Determinants of Program Use

Determinants of Adoption

Determinants of Implementation

Determinants of Maintenance

Program Use Tasks (Performance Objectives)

Adoption Performance Objectives

Implementation Performance Objectives

Maintenance Performance Objectives

Program Use Outcomes

Adoption

Implementation

Maintenance

Health and Quality of Life Outcomes


Planning process
Step 3

Pick an Implementation Science Theory, Model, or Framework
Use of Theory – Cornerstone of Implementation Science

- Use of theories and frameworks:
  - Provide systematic structure for the development, management, and evaluation of studies.
  - May help to enhance the effectiveness of interventions.
  - Ensures the inclusion of essential IS strategies.
  - Enhances the interpretability of findings; explain why an intervention works (or doesn’t).
  - Helps to link aims, research designs, measures and analytic strategies.
  - Provides an opportunity to advance theories in the field.
  - May be a source of innovation (e.g., use of models from outside of health).

https://impsciuw.org/implementation-science/research/frameworks/
Implementation Science Models and Frameworks

Research Question:
What are the practice, organizational, and contextual factors associated with meeting ABCS performance goals/targets among smaller primary care practices?

Step 4

Identify Implementation Strategies
Implementation Strategies Are…

Methods or techniques used to enhance the adoption, implementation, and/or sustainability of a clinical or public health program or practice

OR

The ‘how to’ component of changing healthcare or public health practice.

Adapted from Proctor, Powell, & McMillen, 2013
## Implementation Strategies

<table>
<thead>
<tr>
<th>Types of Strategies</th>
<th>Examples</th>
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<tr>
<td><strong>Discrete</strong> - often involve one action or process such as an educational session.</td>
<td>Education or training sessions</td>
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</table>
| **Multifaceted** - often combine two or more discrete strategies in a package of implementation strategies. | Providing interactive assistance  
- Facilitation  
- Technical assistance |
| **Blended** - composed of multiple discrete strategies that have been packaged and/or protocolized. | Population-based registry + new clinical workflow + facilitation |
Practice Facilitation approach to supporting improvement in clinics focusing on building organizational capacity for continuous improvement

Facilitator
- Engage leadership; identify care gaps; provide team education; set data-driven goals; monitor/encourage progress

Practice/change team

Monthly for up to 12 months

One in-person contact per month for 12 months; 60-90 mins each

Adoption, Penetration

Lack of capacity due to competing time and resource constraints

Developing and Selecting Strategies

- Group Model Building
- Conjoint Analysis
- Concept Mapping
- Implementation Mapping – Dr. Fernandez is the developer
Step 5

Select Research Method
Types of methods

- Quantitative - QUAN
  - Surveys
  - Clinical quality measures
  - Healthcare Utilization

- Qualitative – QUAL
  - Interviews
  - Direct Observation
  - Focus Groups

- Mixed methods – “integrate” QUAL and QUAN
  - Sequential
  - Convergent

Aim 1: Conduct a hybrid type III Effectiveness-Implementation Cluster-Randomized Trial

Randomize 30 primary care clinics to Basic Support (control) or Enhanced, In-Person Support (implementation strategy), receiving Basic Support plus QI facilitation (up to 4 hours/month for 15 months) and assistance from expert consultants

Hypotheses: Adult patients with DMII in practices randomized to In-Person Support will demonstrate significantly greater decrease (improvement) in PHQ-9 and HbA1c scores at 15 months post-baseline as compared to Basic Support - QUAN

Aim 2: Conduct Mixed Method Evaluation of Implementation

We will select 12 clinics (6 higher-change; 6 lower-change) and observe and interview clinic staff, then use comparative analysis to identify factors that influenced implementation, outcomes, and sustainability - QUAL

Primary Research Question: What patient, organizational, intervention and external factors explain why some practices implement and sustain changes aligned with ADA recommendations, while others do not? – QUAL and QUAN
Step 6

Select Study Design
# Traditional Study Designs

<table>
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<tr>
<th>Experimental Designs</th>
<th>Randomized-controlled trial</th>
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<tr>
<td></td>
<td>Cluster-randomized trial</td>
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<td>Stepped-wedge cluster-randomized trial</td>
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<td>SMART Adaptive designs</td>
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<td>Quasi-Experimental Designs</td>
<td>Pre-post study</td>
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<td></td>
<td>Regression-discontinuity designs</td>
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<tr>
<td></td>
<td>Interrupted time-series</td>
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<tr>
<td>Observational</td>
<td>Cross-sectional</td>
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<td></td>
<td>Prospective cohort</td>
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<td>Positive Deviance</td>
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Hybrid Implementation-Effectiveness Designs

Hybrid Type 1: test clinical/prevention intervention, observe/gather information on implementation

Hybrid Type 2: test clinical/prevention intervention, test/study implementation strategy

Hybrid Type 3: test implementation strategies, observe/gather information on clinical/prevention outcomes

From Curran, G. et al. (2012); Medical Care, 50(3), 217-226
**Example**

**Aim 1: Conduct a hybrid type III Effectiveness-Implementation Cluster-Randomized Trial**

Randomize 30 primary care clinics to Basic Support (control) or Enhanced, In-Person Support (implementation strategy), receiving Basic Support plus QI facilitation (up to 4 hours/month for 15 months) and assistance from expert consultants.

Hypothesis: Adult patients with DMII in practices randomized to In-Person Support will demonstrate significantly greater decrease (improvement) in PHQ-9 and HbA1c scores at 15 months post-baseline as compared to Basic Support.

**Aim 2: Conduct Mixed Method Positive-Deviance Evaluation of Implementation**

We will select 12 clinics (6 higher-; 6 lower-change) and observe and interview clinic staff, then use comparative analysis to identify factors that influenced implementation, outcomes, and sustainability.

Primary Research Question: What patient, organizational, intervention and external factors explain why some practices implement and sustain the strategies, while others do not?
Step 7

Choose measures and evaluation approach
The RE-AIM Framework

• RE-AIM is an acronym that consists of five elements:
  • Reach the target population
  • Efficacy or effectiveness
  • Adoption by target settings or institutions
  • Implementation - consistency of delivery of intervention
  • Maintenance of intervention effects in individuals and populations over time

Step 8-10

Secure Funding
Conduct Study
Disseminate Results
Implementation Science in Simple Terms

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether **THE THING** works
- D&I research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the *stuff we do* to try to help people/places **DO THE THING**
- Implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

*Curran, 2020, Implementation Science Communications*

*THE THING = HPV vaccine or Care Coordination*
Training Opportunities

Training Institute for Dissemination and Implementation Research in Cancer (TIDIRC)

• 8 free, self-paced modules intended to be an introduction to implementation science methods and approaches regardless of disease area

https://cancercontrol.cancer.gov/is/training-education/training-in-cancer/TIDIRC-open-access

University of Washington

• 11-week, online course covering the fundamentals of Implementation Science (estimated 6-9 hours per week)

• Individuals or site groups can register

https://impsciuw.org/implementation-science/learn/uw-opportunities/
Training Opportunities

Special Programme for Research and Training in Tropical Diseases

- Massive open online course (MOOC) on implementation research
- 5 modules, 6 weeks, multiple languages

https://tdr.who.int/home/our-work/strengthening-research-capacity/massive-open-online-course-(mooc)-on-implementation-research

Cancer Prevention and Control Research Network

- Self-paced, all materials available online

https://cpcrn.org/training
Training Opportunities

UNC at Chapel Hill
• No cost, self-paced tutorials with a particular focus on research methods applied in dissemination & implementation research
  https://impsci.tracs.unc.edu/get-informed/tutorials/

Columbia University
• Mini, video-based course introducing implementation science to researchers
  https://www.cancer.columbia.edu/research/researchers/community-based-research/implementaition-science-mini-course
Training Opportunities

Washington University in St. Louis

• The Institute for Implementation Science Scholars (IS-2) is a mentored training program for investigators interested in applying dissemination and implementation (D&I) methods and strategies to reduce the burden of chronic disease and address health inequities.

  https://is2.wustl.edu/apply/

Additional conferences, workshops, and other trainings can be found at:

• https://societyforimplementationresearchcollaboration.org/dissemination-and-implementation-training-opportunities/
• https://impsci.tracs.unc.edu/get-informed/trainings/
Summary
Thank You!

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