Study questions, study designs and types of evidence for implementation science

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• What is the evidence gap?
• “Question is King”
What is the best study design to use in IR?

- Research question
- Type of intervention
- Target population(s)
- Feasibility
- Logistics
- Setting
- Costs
- Funding opportunity
- Stakeholders
- Timeline
- Ethics
- Data
What is the best study design to use in IR?

• Observational: cohorts, cross-sectional, existing databases

• Experimental: RCT, cRCT, Pragmatic trials

• Quasi-experimental: Before-After w/o control; Before-after w/ control group; interrupted time series

• Hybrid designs

• Mixed Methods: Quantitative & Qualitative

• Health Economics: Cost-Effectiveness; Cost-Utility
# Pragmatic trials vs traditional trials

<table>
<thead>
<tr>
<th>Pragmatic trials</th>
<th>Traditional trials</th>
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<tbody>
<tr>
<td>Few exclusion criteria: higher external validity</td>
<td>More exclusion criteria: low external validity</td>
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<tr>
<td>Wide range of patients, providers and settings</td>
<td>Limited range of patients, providers and settings</td>
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<tr>
<td>Active comparators</td>
<td>Mostly placebo-controlled</td>
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<tr>
<td>Patient-centered outcome measures</td>
<td>Clinical or physiological outcome measures</td>
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<tr>
<td>Longer follow-up with less intensity</td>
<td>Shorter follow-up with more intensity</td>
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<tr>
<td>Often not blinded</td>
<td>Often double-blinded</td>
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<tr>
<td>Often cluster-randomized</td>
<td>Often individual-randomized</td>
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## Pragmatic trials vs traditional trials

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<td><strong>Stakeholder involvement</strong></td>
<td>Engaged in all study phases including study design, conducting the study, collecting data, interpreting results, disseminating findings</td>
<td>Limited engagement, often in response to investigator</td>
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<tr>
<td><strong>Research design</strong></td>
<td>Includes internal and external validity, design fidelity, local adaptation, real life settings and populations, contextual assessments</td>
<td>Focus on limiting threats to internal validity, typically uses RCT, participants and settings typically homogenous</td>
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<td><strong>Outcomes</strong></td>
<td>Reach, effectiveness, adoption, implementation, comparative effectiveness, sustainability</td>
<td>Efficacy, mechanism identification, component analysis</td>
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<td><strong>Measures</strong></td>
<td>Brief, valid, actionable with rapid clinical utility, feasible in real world and low-resource settings</td>
<td>Validated measures that minimize bias, focus on internal consistency and theory rather than clinical relevance</td>
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<tr>
<td><strong>Data Source</strong></td>
<td>May include existing data (health records, admin data) and patient reports</td>
<td>Data generation and collection part of clinical trial</td>
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<tr>
<td><strong>Availability of findings</strong></td>
<td>Rapid learning and implementation</td>
<td>Delay between trial completion and analytic availability</td>
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Source: Krist et al, 2013
Hybrid Designs
Research Pipeline

Adapted from Landsverk 2012 and Aarons 2011

Hybrid Designs

Scaling-up

Dissemination
Hybrid Designs

Hybrid Type 1
TEST CLINICAL INTERVENTION
Gather implementation data

Hybrid Type 2
TEST CLINICAL INTERVENTION & TEST IMPLEMENTATION STRATEGY

Hybrid Type 3
TEST IMPLEMENTATION STRATEGY
Gather data on clinical intervention effectiveness
Hybrid Trial Type 1

- Research Aim:
  - Primary Aim: Determine effectiveness of a clinical intervention
  - Secondary Aim: Better understand context for implementation

- Sample research question:
  - Primary question: Will a clinical treatment work in this setting/with these patients?
  - Secondary question: What are potential barriers/facilitators to a treatment’s widespread implementation?
Hybrid Trial Type 2

• Research Aims
  1. Determine effectiveness of a clinical intervention
  2. Determine feasibility and potential utility of an implementation intervention/strategy

• Sample research questions:
  1. Will a clinical treatment work in this setting/these patients?
  2. Does the implementation method show promise in facilitating implementation of a clinical treatment?
Hybrid Trial Type 3

- **Research Aim**
  - Primary: Determine utility of an implementation intervention/strategy
  - Secondary: Assess clinical outcomes associated with implementation trial

- **Sample research question:**
  - Primary question: Which method works better in facilitating implementation of a clinical treatment?
  - Secondary question: Are clinical outcomes acceptable?
WHO Guide – Framework Model

Relationship between implementation and the implementation research cycle

**STEP 1**
IDENTIFICATION OF APPROPRIATE POLICY OR INTERVENTION

- How will appropriate policies and interventions be selected?
- How will relevant evidence be identified and assessed?

**STEP 2**
ADAPTATION AND PILOTING OF POLICY OR INTERVENTION

- How will a policy or intervention for a new setting be refined and translated?
- How acceptable is the policy or intervention?

**STEP 3**
FULL IMPLEMENTATION OF POLICY OR INTERVENTION

- What is the reach of the policy or intervention?
- What is the adoption?
- How well is it implemented?
- What are the moderators of implementation?
- How effective is implementation?

**STEP 4**
SCALE-UP OF POLICY OR INTERVENTION

- Is the policy or intervention appropriate for new contexts?
- What resources need to be mobilized for scale up and how will these be mobilized?
- How will knowledge be translated and exchanged effectively?
Example 1: Comprehensive intervention for HTN control in Argentina

Step 1: Identification of appropriate policy or intervention

- Is the policy or intervention appropriate for new contexts?
- What resources need to be mobilized for scale up and how will these be mobilized?
- How will knowledge be translated and exchanged effectively?

Step 2: Adaptation and piloting of policy or intervention

- CHWs
- Complex intervention
- Physician's training
- SMS

Step 3: Full implementation of policy or intervention

- 18 Eligible Public Primary Care Clinics Selected
- 18 Clinics Randomized (1,954 eligible participants)
- 9 Clinics randomized to intervention (970 participants)
- 9 Clinics randomized to usual care (984 participants)

Step 4: Scale-up of policy or intervention

How to improve HTN control rate at the primary care level in the public health care system?
Example 2: Comprehensive intervention for HTN control in Guatemala

**STEP 1**
IDENTIFICATION OF APPROPRIATE POLICY OR INTERVENTION

**STEP 2**
ADAPTATION AND PILOTING OF POLICY OR INTERVENTION

**STEP 3**
FULL IMPLEMENTATION OF POLICY OR INTERVENTION

**STEP 4**
SCALE-UP OF POLICY OR INTERVENTION

Is the policy or intervention appropriate for new contexts?
What resources need to be mobilized for scale up and how will these be mobilized?
How will knowledge be translated and exchanged effectively?

What is the reach of the policy or intervention?
What is the adoption?
How well is it implemented?
What are the moderators of implementation?
How effective is implementation?

Successful comprehensive intervention to improve HTN control in vulnerable population in Argentina

- Nurses
  - Auxillary nurses
- Complex Intervention
  - Physician's training
  - SMS
Example 3: Educational Intervention to reduce LDL-chol in patients with high CV risk in low-resource settings in Argentina

**Step 1:** Identification of appropriate policy or intervention

**Step 2:** Adaptation and piloting of policy or intervention

**Step 3:** Full implementation of policy or intervention

**Step 4:** Scale-up of policy or intervention

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Is the policy or intervention appropriate for new contexts? What resources need to be mobilized for scale up and how will these be mobilized? How will knowledge be translated and exchanged effectively?

How to improve detection, treatment and control of hypercholesterolemia at the primary care level in the public health care system?

10 Public Primary Care Clinics

- Comprehensive Intervention 5 Clinics (175 participants)
  - 12 Month Intervention Assessment & follow up
- Usual Care 5 Clinics (175 participants)

Net Change in cholesterol levels and secondary outcomes

Multifaceted educational intervention delivered to physicians

- Educational intervention delivered to pharmacy assistants
- SMS messages to patients
Indicadores de Proceso y Resultado

Intervention

Process & Implementation Outcome measures

How does the intervention work?
Intermediate measures

How is the intervention being implemented?
Implementation effectiveness
Context - Reach - Adoption - Fidelity - Sustainability

Clinical Outcome Measures

Clinical Effectiveness

Intervention/Program Evaluation
Further readings


Thank you!

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