Study design and measurement (Topic 2)

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Implementation research definition

• Implementation research is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and public health
• It includes the study of influences on healthcare professional and organizational behaviour.

(Eccles/Mittman, 2006)
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(Eccles/Mittman, 2006)
• What is the evidence gap?
• “Question is King”
• Examples of study types/approaches:
  – Pragmatic Trials
  – Effectiveness-Implementation Hybrid Designs
  – Quality Improvement Studies
  – Comparative Effectiveness Research
  – Participatory Action Research

Translational Research

T0: Define mechanisms underlying health or disease
Basic research & Studies in animals

T1: Test basic research findings for clinical effect
Translation to humans: Case studies (Phase 1 & 2 CTs)

T2: Test new interventions under controlled environments
Translation to patients: Efficacy studies

T3: Explore ways of applying guidelines in general practice
Translation to practice: Effectiveness studies

T4: Study influences on the health of populations
Translation to population health: Implementation research
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Traditional vs pragmatic trials?
Pragmatic randomized trials

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

Source: Krist et al, 2013
Effectiveness vs Implementation Trial?

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- “Question is King”
- Examples of study types/approaches:
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Research Pipeline

Adapted from Landsverk 2012 and Aarons 2011

Implementation pipeline - Mittman & Curran 2012

Hybrid Designs

Traditional Translation Pipeline

Hybrid – Type 1
Test intervention, gather information on implementation

Hybrid – Type 2
Test intervention, Test implementation strategy

Hybrid – Type 3
Test implementation strategy, gather effectiveness data
Differences between hybrid designs 1, 2 and 3

Clinical Effectiveness Research → Implementation Research

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?
Differences between hybrid designs 1, 2 and 3

- 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 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?
Example 1: Comprehensive intervention for HTN control in Argentina

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

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

Example 3: Educational Intervention to reduce LDL-chol in patients with high CV risk in low-resource settings in Argentina

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

Intervention → Outcome Measures → Intermediate outcomes → Final outcomes

Essential Components of the Evaluation

Implementation fidelity refers to the degree to which an intervention or programme is delivered as intended.

Context
Reach/Recruitment
Fidelity
Dose delivered
Dose received
Drop-out

Process Measures
Outcomes Measures
Intermediate outcomes
Final outcomes