Outcomes and Evaluation in Implementation Research: Key Issues and Examples from RE-AIM

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Russell E. Glasgow, PhD
Department of Family Medicine, University of Colorado School of Medicine
VA Eastern Colorado QUERI and Geriatric Research Centers, and
Dissemination and Implementation Science Program of Adult and Child
Consortium for Outcomes Research and Delivery Science
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• RE-AIM Colleagues

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UNLABELED/UNAPPROVED USES DISCLOSURE
None
Overview

• How Implementation Research (IR) outcomes are different from other types of health outcomes research

• Key issues in implementation outcomes (my view)

• Representativeness/equity; costs; adaptations; sustainability

• Evaluation frameworks in Implementation Research
  Example issues using RE-AIM
If an intervention works…

and nobody can use it…does it still make an impact?
Elements of an IR Logic Model

Implementation Outcomes
The effects of deliberate and purposive actions to implement new treatments, practices and services.

- indicators of implementation success
- proximal indicators of implementation processes
- key intermediate outcomes in relation to service or clinical outcomes

Interactions among IR outcomes

Proctor, et al. 2011
IR Outcomes are Distinct from Clinical Outcomes

<table>
<thead>
<tr>
<th>CHARACTERISTIC OF MEASURE &amp; OUTCOME</th>
<th>IMPLEMENTATION OUTCOMES &amp; MEASURES</th>
<th>HSR &amp; CLINICAL EFFECTIVENESS OUTCOMES &amp; MEASURES</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOCUS</td>
<td>Delivery and implementation issues (aka process: feasibility, fidelity, adoption, reach)</td>
<td>Clinical outcome or measure of control</td>
</tr>
<tr>
<td>BREADTH</td>
<td>Multiple levels, broad focus, systems perspective</td>
<td>Narrower focus; often a single primary outcome</td>
</tr>
<tr>
<td>PREFERRED MODALITY</td>
<td>Multiple - observation, interview, tracking forms</td>
<td>Biological (e.g., BP, A1c); more recently, data in the EHR</td>
</tr>
<tr>
<td>EXPENSE and INTENSIVENESS of ASSESSMENT</td>
<td>Brief, low burden, pragmatic</td>
<td>Often expensive, requires expert assessment, emphasis on blinding when possible</td>
</tr>
<tr>
<td>LEVEL and WHO IS ASSESSED</td>
<td>Setting, staff</td>
<td>Usually patients</td>
</tr>
</tbody>
</table>
## Types of Outcomes in Implementation Research

<table>
<thead>
<tr>
<th>Implementation Outcomes</th>
<th>Service Outcomes</th>
<th>Client Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability</td>
<td>Efficiency safety</td>
<td>Satisfaction</td>
</tr>
<tr>
<td>Adoption</td>
<td>Safety</td>
<td>Function</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Effectiveness</td>
<td>Symptoms</td>
</tr>
<tr>
<td>Costs</td>
<td>Equity</td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td>Patient-centeredness</td>
<td></td>
</tr>
<tr>
<td>Penetration</td>
<td>Timeliness</td>
<td></td>
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<tr>
<td>Sustainability</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D&amp;I Outcome</th>
<th>Level of Analysis</th>
<th>Theoretical Basis (RE-AIM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>Individual</td>
<td>RE-AIM</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Individual</td>
<td>RE-AIM: implicit; needed for Reach</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Individual, Organization, Policy</td>
<td></td>
</tr>
<tr>
<td>Feasibility</td>
<td>Individual, Organization, Policy</td>
<td></td>
</tr>
<tr>
<td>Adoption</td>
<td>Individual, Organization, Policy</td>
<td>RE-AIM</td>
</tr>
<tr>
<td>Fidelity</td>
<td>Individual</td>
<td>RE-AIM: part of implementation</td>
</tr>
<tr>
<td>Cost</td>
<td>Individual, Organization, Policy</td>
<td>RE-AIM: part of implementation</td>
</tr>
<tr>
<td>Penetration</td>
<td>Organization, Policy</td>
<td>RE-AIM: necessary for reach</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Organization, Policy</td>
<td>RE-AIM: maintenance</td>
</tr>
</tbody>
</table>

Evidence-Based… on what?
External Validity and Implementation (often Ignored)

- Participant representativeness
- Setting representativeness
- Context and setting
- Community/setting engagement
- Adaptation/change
- Sustainability
- Costs/feasibility of treatment
Widely Used Implementation Evaluation Models

**PRECEDE-PROCEED** (Green LW & Kreuter MW. *Health program planning*...(2005) www.lgreen.net)
- PRECEDE for planning and context- PROCEED for intervention and summative evaluation
- Social and epi/ecological assessment: predisposing, enabling, reinforcing factors
- Implementation, process, impact, and outcome assessment

- Pre-evaluation to assess likelihood that intervention, guidelines or policy could realistically be successful (e.g., feasible, affordable,
- Key to involve stakeholders

Medical Research Council Guidance for **Complex Interventions** (UK)
- Process evaluation
- Implementation; mechanisms; and context
- Steps involve planning; design and conduct; analysis; and reporting

**RE-AIM** www.re-aim.org; Gaglio and Glasgow. Ch.19 in Brownson et al. *DIRH in health*
Evaluation & Reporting in Implementation Research

Context and Representativeness (Expanded CONSORT)*
Implementation - including fidelity, adaptation, and variability
Costs - stakeholder perspective, replication costs, feasibility
Standards for Reporting Implementation Studies (StaRI)**

DOI: https://doi.org/10.1016/j.amepre.2018.04.044

Too often we have assume, “If you build it…”
An Evidence-Based Obesity Intervention (or HIV prevention, or depression Tx) Story

Even if 100% effective...it’s only as good as how and whether:
- it is adopted widely and in low-resource settings
- practitioners choose to deliver it
- trained practitioners deliver it well
- eligible populations, including those at highest risk, receive it
- it can be sustained

If we assume 50% threshold for each step...(even with perfect access/adherence/dosage/maintenance)

Impact: \[0.5 \times 0.5 \times 0.5 \times 0.5 \times 0.5 = 3\% \text{ population based benefit}\]

Pragmatic Models- RE-AIM
Purpose and History of RE-AIM Framework

- Intended to facilitate translation of research to practice
- Internal and external validity, and emphasizes representativeness
- Multi-level: Individual and organizational factors - experimental and observational
- Public health impact depends on all elements (reach x effectiveness, etc.)
Pragmatic Use of RE-AIM- What is Feasible?

<table>
<thead>
<tr>
<th>RE-AIM Dimension</th>
<th>Key Pragmatic Priorities to Consider and Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td><strong>WHO</strong> is/was intended to benefit and who actually participates or is exposed to the intervention?</td>
</tr>
<tr>
<td>Effectiveness</td>
<td><strong>WHAT</strong> is/was the most important benefit you are trying to achieve and what is/was the likelihood of negative outcomes?</td>
</tr>
<tr>
<td>Adoption</td>
<td><strong>WHERE</strong> is/was the program or policy applied and <strong>WHO</strong> applied it?</td>
</tr>
<tr>
<td>Implementation</td>
<td><strong>HOW</strong> consistently is/was the program or policy delivered, <strong>HOW</strong> will it be/was it adapted, <strong>HOW</strong> much will/did it cost, and <strong>WHY</strong> will/did the results come about?</td>
</tr>
<tr>
<td>Maintenance</td>
<td><strong>WHEN</strong> will/did the initiative become operational; how long will it be/was it sustained (setting level); and how long are the results sustained (individual level)?</td>
</tr>
</tbody>
</table>

Glasgow R and Estabrooks P. *Preventing Chronic Disease (2018)* 15, E02.
RE-AIM Summary Points

• RE-AIM is not a theory- but it tells you where to look; where things often break down

• RE-AIM is an outcomes framework that can be used for planning and evaluation; and with other frameworks

• Each dimension is an opportunity for intervention

• All dimensions can be addressed within a given study (though likely not all intervened upon)

• RE-AIM and Implementation Outcomes are complex, dynamic, interrelated (often cannot have it all)
Ratings on RE-AIM Dimensions

- **Hospital-based Group Counseling**
- **System-wide Health Policies**

Dimensions: Reach, Efficacy, Adoption, Implementation, Maintenance
Evolution of RE-AIM

- Applicability to many different content areas- over 430 articles
- Used for both planning and evaluation
- Underreporting of key components
- Setting level factors reported much less often (e.g., adoption)
- Increasing use of qualitative measures*

FIT among:
- Intervention
- Implementation strategy
- Context
- You can’t have it all-interactions

Crosscutting issues
- Proportion who benefit
- Representatives of the who benefit
- Reasons: how and why they benefit
- Adaptations made
- Costs incurred

Changing Outer Context
PRISM External Environment (e.g., policy, guidelines, incentives)

Changing Internal Context
PRISM factors of
- Organizational & Patient Characteristics
- Organizational & Patient Perspectives (values)
- Implementation & Sustainability Infrastructure

Evidence-based intervention (components)
Implementation strategies
All models (and methods) are wrong…
Some are useful

“To every complex question, there is a simple answer… and it is wrong.”

~H. L. Mencken
Key Issues in Implementation Outcomes (my view)

— Representativeness/equity
— Costs
— Adaptations
— Sustainability
### Health Equity Example from RE-AIM Perspective

<table>
<thead>
<tr>
<th>RE-AIM Issue</th>
<th>Disparity</th>
<th>Overall Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>30%</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>0 (equal)</td>
<td>70% of benefit</td>
</tr>
<tr>
<td>Adoption</td>
<td>30%</td>
<td>49% of benefit</td>
</tr>
<tr>
<td>Implementation</td>
<td>30%</td>
<td>34% of benefit</td>
</tr>
<tr>
<td>Maintenance</td>
<td>30%</td>
<td>24% of benefit</td>
</tr>
</tbody>
</table>
Costs: Reporting Resources Required

• Understand *from perspective of stakeholders*, including patients and decision makers
• Simple is fine – sophisticated economic analyses are not needed for most D&I purposes
  – Report costs of conducting or *replicating interventions*
  – Beyond money, costs can include clinician and staff time, training, infrastructure, startup costs, opportunity costs

Key Issues Regarding Adaptation

• Adaptations to evidence-based interventions or implementation strategies are common and inevitable. They should be assessed and reported - rather than this information being suppressed (PCORI guidelines).

• Adaptation of programs often occurs to improve the fit (or compatibility) of a program to a new setting, or to increase the cultural appropriateness of a program.

• Adaptations might lessen the effectiveness of the program if they compromise the core elements and underlying program functions.
# Types of Adaptations

<table>
<thead>
<tr>
<th>Focus of Adaptation</th>
<th>Timing of Adaptation (point in the study)</th>
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<tbody>
<tr>
<td></td>
<td>Planning</td>
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<tr>
<td>Intervention</td>
<td></td>
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<tr>
<td>Implementation</td>
<td></td>
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<tr>
<td>Strategy</td>
<td></td>
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<tr>
<td>Setting</td>
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</table>
Key Evaluation Questions- IR vs General HSR

• **Traditional science** and evidence question: *(necessary but not sufficient): What intervention produces the largest average effect in tightly controlled trials on the major (clinical) outcome?*

• **Implementation Research** question: *(contextual)*
  What program/policy components are most effective for producing what implementation outcomes for which populations/recipient when implemented by what type of persons using what strategies under what conditions, with how many resources and how/why do these results occur?
Key Take Home Points

• Implementation Outcomes are different than usual HSR outcomes...they are multi-level, contextual and inter-related

• There are several good IR outcomes and evaluation models: Which is best depends...and may need to be adapted for your project or integrated with others

• Key issues are transparent reporting, equity/representativeness, costs, and sustainability
Questions?

‘I am all ears!’
Pragmatic RE-AIM “Precision Implementation” and Health Questions

Determine:

• What percentage and what types of patients are Reached;
• For whom is the intervention Effective in improving what outcomes (including health equity), with what unanticipated consequences;
• In what percentage and in what types of settings and staff is this approach Adopted;
• How consistently are different parts of it Implemented and at what cost to different parties;
• And how well are the intervention components and their effects Maintained?
Sources of Intervention Adaptation

- **INTERVENTION**
  - Adaptation Examples
    - Who delivers the intervention; fit with other interventions; financing source
  - Service Setting Adaptations
    - Age-appropriateness; health literacy; responsive to individual needs; comorbid conditions
  - Target Audience Adaptations
    - Number of sessions; dose; technological format; session length
  - Mode of Delivery Adaptations
    - Cultural sensitivity; imagery used; consistency with belief system
  - Cultural Adaptations
    - Core components of intervention identified through testing; mechanisms of action
  - Core Components
Planning and ‘Evaluability’

- Do initial estimates of RE-AIM dimensions when no data exists (evaluability) - with stakeholders
- Often helpful to compare two or more program or policy options (create RE-AIM profiles)
- Expect different programs or interventions to do well on different RE–AIM dimensions
- Include multiple perspectives on ongoing basis

http://www.re-aim.org/resources-and-tools/self-rating-quiz/
Pragmatic Measures

Required Criteria
• Important to stakeholders
• Burden is low to moderate
• Broadly applicable, has norms to interpret
• Sensitive to change

Additional Criteria
• Actionable
• Low probability of harm
• Addresses public health goal(s)
• Related to theory or model
• Maps to “gold standard” metric or measure