Global Health Webinar: Applying RE-AIM in Low- and Middle-Income Country Settings

December 12, 2018

Russell E. Glasgow, PhD
University of Colorado School of Medicine

Meredith Fort, PhD, MPH
Colorado School of Public Health
Overview

Pragmatic research: rationale and characteristics

RE-AIM: ONE pragmatic framework for global health
- Early work: external validity and public health impact
- Recent past: policy, health equity, broad application
- Current and Future: context, replication, adaptation and costs

Global health issues in applying RE-AIM and example

Discussion; Resources; Q & A
Need for Pragmatic Research

Usual Research is Slow

- Traditional RCTs are slow and expensive
- Most common reason for non-adoption…research not seen as relevant
- Rarely produce findings that are easily put into practice

It takes an average of **17 years before 14% of research findings lead to widespread changes in care.**
Pragmatic Research: Fewer Exclusions Allow for a Broader Subset of Settings, Staff, and Participants

**Traditional Research**
- Eligible population
- Exclusions, non-response, etc.
- Efficacy, among a defined subset

**Pragmatic Research**
- Eligible population
- Exclusions, non-response, etc.
- Effectiveness, in a broad subset

Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research
Too often we have assumed, “If you build it…and *if you have evidence*”…
An Evidence-Based Cancer Prevention... or Hypertension Control... or (fill in blank) Story

**Even if 100% effective...** it’s only as good as how and whether:

- it is adopted - *and where it is not adopted*
- practitioners are trained to deliver it - *and who is not trained*
- trained practitioners consistently deliver it - *and who does not*
- eligible populations receive it - *and which do not*
- it can be sustained - *and where, why and when is it not*

If we **assume 50% success for each step** (even with perfect access/adherence/dosage/maintenance - *and equal benefit throughout*)

**Impact:** \(0.5 \times 0.5 \times 0.5 \times 0.5 \times 0.5 = 3\% \text{ benefit}\)


www.re-aim.org
RE-AIM Questions for Planning or Evaluation

- What percent and what types of patients or individuals are likely to Receive this program; *(Reach)*
- For whom among them is the intervention Effective; in improving what outcomes; what broader effects and potential negative consequences?
- What percent and what types of potential settings and delivery staff are likely to Adopt this program;
- How consistently are different parts of the program likely to be Implemented across settings, clinicians, and patient subgroups… at what cost, and how will/was the program adapted?
- And how well is the program or policy and its effects likely to be Maintained?
Purpose and History of RE-AIM Framework

- Intended to facilitate translation of research to practice
- Balance internal and external validity, and emphasize representativeness
- Individual and setting level factors - Public health impact depends on all elements (reach x effectiveness, etc.)

[www.re-aim.org](http://www.re-aim.org)
RE-AIM Current Use Summary Points

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

• RE-AIM is an evaluation/outcomes framework that can be used for planning and evaluation

• Each dimension is an opportunity for intervention

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

• RE-AIM can be used for observational, efficacy, effectiveness, and dissemination projects
Using RE-AIM for Planning

- Do initial ESTIMATES of results on different RE-AIM dimensions - with your stakeholders
- Include multiple perspectives on ongoing basis

- 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

http://www.re-aim.org/resources-and-tools/self-rating-quiz/
Ratings on RE-AIM Dimensions

Hospital-based Group Counseling

System-wide Health Policies

Reach  Efficacy  Adoption  Implementation  Maintenance

Hi     Med     Low
<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>
## 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 (was) it be <em>adapted</em>, <strong>HOW</strong> much will (did) it <em>cost</em>, and <strong>WHY</strong> will (did) the results come about?</td>
</tr>
<tr>
<td>Maintenance</td>
<td><strong>WHEN</strong> will (was) the initiative become operational; how long will (was) it be sustained (setting level); and how long are the results sustained (individual level)?</td>
</tr>
</tbody>
</table>

Resource Informative

- Need to know *implementation costs* (as conducted) and *replication costs* (under different conditions)

- Need to report staff time, training, *recruitment*, supervision, delivery costs

- Do **NOT** need complete, comprehensive societal analyses of downstream consequences, etc.- unless for nationwide
Implementing complex interventions: “Adaptation happens”

- Complex interventions usually **can be, will be** and **should be** adapted
- Adaptation should be:
  - embraced, studied, and guided *rather than*
  - ignored, and/or
  - suppressed
Sources of Intervention Adaptation

- **INTRODUCTION**
  - 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**

Evolution of RE-AIM

- Applied to many different content areas - over 450 articles
- Setting level factors reported much less often (e.g., adoption)
- Guides for application and reporting; other resources at www.re-aim.org
- Focus on transparent reporting and replication

NEW AREAS

- Costs and resources
- Adaptations
- Patient centered outcomes research
- Qualitative RE-AIM assessments

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

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

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
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
Implementing a Multicomponent Intervention to Improve Hypertension Control in Central America

- Evidence-based program implemented in Argentina
- Adaptation to Guatemalan context
- Institutions: Institute of Nutrition of Central America and Panama (INCAP), Institute for Clinical Effectiveness and Health Policy (IECS), Tulane, U. of Colorado, Guatemalan Ministry of Health and Social Welfare
- Funded by NHLBI (HyTREC)
Double Burden of Disease

Source:
Multi-Component Intervention Program

1. Protocol-based treatment (stepped-care protocol using a standard-treatment algorithm)
2. Education for health care workers
3. Team-based collaborative care
4. BP audit and feedback
5. Home BP monitoring
6. Health coaching (auxiliary nurses)

Drawing on materials developed in a previous NHLBI-funded project implemented in Guatemala.
Setting and Design

- Hybrid Type 2 Effectiveness-Implementation
- Cluster Randomized Trial (beginning in 2019)
- 36 districts in Guatemala’s public primary health care system.
  - 5 departments/Health Areas
  - Health center, 2 health posts per district
  - About 10 languages spoken (24 in the country)

Health post within the primary care level of Guatemala’s public sector, staffed by 1-2 auxiliary nurses.
## Needs Assessment

<table>
<thead>
<tr>
<th>Building block</th>
<th>Long-term needs</th>
<th>Needs that may be addressed through the intervention</th>
</tr>
</thead>
</table>
| **Service delivery**    | • Insufficient coverage  
                          • Limited supplies and physical infrastructure  
                          • Limited emphasis on the primary level of care                                      | • Treatment guidelines are not available to all providers  
                          • Hypertension is detected by chance  
                          • Communication gaps between levels of care  |
| **Human resources**     | • Auxiliary nurses (key primary care providers) have basic training with an MCH emphasis  
                          • Contracts vs. budgeted positions increasingly common  
                          • Staff turnover                                                                 | • Limited training in NCDs |
| **Information system**  | • Lack of electronic infrastructure/connectivity  
                          • NCDs do not have indicators that are routinely tracked  
                          • Focus on service production                                                                                 | • Forms and processes used for clinic visits are not standardized  
                          • Undercounting  
                          • Providers do not have a list of patients with hypertension – controlled/uncontrolled |
| **Medications and technologies** | • Lack of laboratory capacity                                                                  | • Variability in the availability of medications (early/late in the year)  
                          • Limited administrative capacity to request needed quantity of medications |
| **Financing**           | • Low public investment in health  
                          • High out-of-pocket costs  
                          • No estimate of the cost of care for patients with hypertension                          |                                                                                      |
| **Leadership/governance** | • Lack of a national plan (changes with each administration)  
                          • Absence of high-level support for NCDs  
                          • Lack of investment in regulation/health promotion  
                          • Need to increase inter-sectoral collaboration                                              | • Patients with hypertension have not demanded treatment |

Adaptation Workshops (June-August)
RE-AIM Assessment

- Assessing Patient, Provider, and Systems Levels
- Mixed Methods

Data capture:
- Every 6 months
- 18-20 local data gatherers, central-level research team members (patient and provider levels), 2 Research Assistants (system level)
# RE-AIM Measures

<table>
<thead>
<tr>
<th>RE-AIM</th>
<th>Patient</th>
<th>Provider</th>
<th>System</th>
</tr>
</thead>
</table>
| R      | • # participants/total eligible  
• **Representativeness**: age, M/F, language, literacy, SES, distance (home to health post) | | |
| E      | • BP control  
• Increased knowledge about heart healthy behavior  
• Quality of life  
• Stage of change  
• Adherence to medications  
• Heterogeneity of effects | • % of patients who achieve BP control  
• Provider’s increased knowledge about heart healthy behavior/guidelines  
• % patients who achieve adequate adherence to medications | |
## RE-AIM Measures

<table>
<thead>
<tr>
<th>RE-AIM</th>
<th>Patient</th>
<th>Provider</th>
<th>System</th>
</tr>
</thead>
</table>
| **A**  |         | • # aux. nurses participating/trained  
         |         | • Provider age & years of experience  
         |         | • Provider characteristics: non-, early, & late adopters  
         |         | • Composition of teams  
         |         | • Distance: health posts to health center  
         |         | • Setting characteristics: non-, early, & late adopters  
| **I**  | • # home BP monitor readings/patient  
         | • Defined health goal  
         | • # & location coaching sessions  
         | • Family member participation  
         | • # of coaching sessions provided/ aux. nurse  
         | • Delivery location of coaching sessions  
         | • Referrals to support & supervision team  
         | • Adaptations by providers  
         |         | • Availability of medications, supplies  
         |         | • Process to coordinate w/district  
         |         | • Adaptations by district  
| **M**  | • Sustained adherence to medications over time (12 and 18 months)  
         | • Sustained BP control over time (12 and 18 months)  
         | • Intention to continue implementation beyond the project period.  
         |         | • Intention to continue implementation beyond the project period.  
         |         | • Cost-effectiveness  

Current Study Considerations

Recruiting with **equity** in mind

**Data collection instruments:**
- Auxiliary nurses and district team vs. research study team
- Qualitative and quantitative data capture

**Adaptations**: up-front and during the intervention

Defined opportunities for review and feedback by authorities, health staff and patients
- Community Advisory Board, local level feedback sessions

**Sustainability:**
- Integrate the intervention into primary health care teams’ workflow
  - Contribute to a virtuous cycle of health system strengthening/ increased focus on NCDs
- Consider ways to address long-term system level needs
IF AN INTERVENTION WORKS

AND NOBODY CAN USE IT.....

DOES IT STILL MAKE AN IMPACT?
Future Evidence Needs and Opportunities—Keys to Advance Translation

- Health equity impacts
- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice
THE FUTURE OF RE-AIM?

Application to Comparative Effectiveness Research (CER-T)

Transparency focus (‘Expanded CONSORT figure*)

What it means to “Use RE-AIM”

Possible Directions:

Merge with PRECIS-2 model*?

Your IDEAS WELCOMED!

Kessler RS, et al. What Does It Mean to "Employ" the RE-AIM Model? Eval Health Prof., 2012 Mar;36, 44-46
General Resources

- re-aim.org
- www.ucdenver.edu/accords/implementaton
- www.Dissemination-Implementation.org
EVIDENCE-BASED PROGRAM AND RE-AIM RESOURCES

Purpose:
- Designed to increase breast cancer screening among low-income Korean-American women (2010)

Program Focus:
- Awareness building, Behavior Modification and Self-efficacy

Population Focus:
- Medically Underserved

Screening:
- 49-60:文章未提供具体信息
- Older Adults (65+ years)

http://re-aim.org/resources_and_tools/index.html

http://rtips.cancer.gov/rtips/index.do
Practical, Robust Implementation and Sustainability Model

Addresses Contextual Factors Impacting RE-AIM Outcomes
Over 91 D&I Frameworks: [http://dissemination-implementation.org/index.aspx](http://dissemination-implementation.org/index.aspx)

Most Commonly used models in NIH grants: RE-AIM and DOI (now also CFIR)

**Many commonalities across models and theories**
In Summary, D & I Science is about:

- Multi-level, *contextual* issues and external validity
- Relevant, *pragmatic* models, research methods and measures
- Real-world implementation and *adaptation*
- Reducing, or at least not exacerbating *health inequities*
- *Designing* for dissemination, sustainability and equity
- *Normal science (T1– T2)* is necessary but not sufficient
## Types of Adaptations

<table>
<thead>
<tr>
<th>Focus of Adaptation</th>
<th>Timing of Adaptation (point in the study)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Planning</td>
</tr>
<tr>
<td>Intervention</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td></td>
</tr>
<tr>
<td>Strategy</td>
<td></td>
</tr>
<tr>
<td>Setting</td>
<td></td>
</tr>
</tbody>
</table>
Adaptation, Fidelity, and Tailoring Interest Group

• Began January 2016 as part of the IRG
• 61 members currently .... **YOU ARE INVITED TO JOIN**
• Representation from many VA QUERI research programs
• Co-chaired by Borsika Rabin, MPH, PhD, PharmD and Russell Glasgow, PhD; Facilitated by Christine P. Kowalski, MPH
• Meet monthly to discuss topics related to adaptation, tailoring and fidelity with attention to clinical application. Discussions include how to define interventions and implementation strategies, as well as how to describe and document adaptations.

For information or to join contact: Christine.Kowalski@va.gov
Key Differences Between Traditional Efficacy RCTs and Pragmatic Controlled Trials (PCTs)

<table>
<thead>
<tr>
<th></th>
<th>A traditional RCT tests a hypothesis under ideal conditions</th>
<th>A PCT compares treatments under everyday clinical conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GOALS</strong></td>
<td>To determine causes and effects of treatment</td>
<td>To improve practice and inform clinical and policy decisions</td>
</tr>
<tr>
<td><strong>DESIGN</strong></td>
<td>Tests the intervention against placebo, using rigid study protocols and minimal variation</td>
<td>Tests two or more real-world using flexible protocols &amp; local customization</td>
</tr>
<tr>
<td></td>
<td>A traditional RCT tests a hypothesis under ideal conditions</td>
<td>A PCT compares treatments under everyday clinical conditions</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>PARTICIPANTS</strong></td>
<td>Highly defined and carefully selected</td>
<td>More representative because eligibility criteria are less strict</td>
</tr>
<tr>
<td><strong>MEASURES</strong></td>
<td>Require data collection outside routine clinical care</td>
<td>Brief and designed so data can be easily collected in clinical settings</td>
</tr>
<tr>
<td><strong>RESULTS</strong></td>
<td>Rarely relevant to everyday practice</td>
<td>Useful in everyday practice, especially clinical decision-making</td>
</tr>
</tbody>
</table>
Effectiveness-Implementation Hybrid Designs

Clinical Effectiveness Research

Implementation Research

Hybrid Type 1
Test clinical intervention, observe/gather information on implementation

Hybrid Type 2
Test clinical intervention, test implementation intervention

Hybrid Type 3
Test implementation intervention, observe/gather information on clinical intervention and outcomes

Evidence-Based...on what?
External Validity/ Pragmatic Criteria (often Ignored)

- Participant representativeness
- **Setting** representativeness
- **Context** and setting
- Community/setting engagement
- **Adaptation**/change
- Sustainability
- **Costs/feasibility** of treatment
- Comparison conditions
Pragmatic D&I Bottom Line Question

“What program/policy components are most effective for producing what outcomes for which populations/recipients when implemented by what type of persons using what strategies under what conditions, with how many resources and how/why do these results come about?”

NOT possible to address all these issues in any one study.... BUT should consider each or them pragmatically and transparently; then select and report those most relevant.