Implementation Science, Context, and Health Equity: RE-AIM Applications and Ideas for Feedback

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Acknowledgments and Conflicts of Interest

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- Amy Huebschmann, Borsika Rabin
- University of Colorado SOM - ACCORDS D&I Science Program
- RE-AIM Colleagues

FINANCIAL DISCLOSURE

National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Robert Wood Johnson Foundation (RWJF) funding on various projects

UNLABELED/UNAPPROVED USES DISCLOSURE

None
Health Equity and How Pragmatic RE-AIM Research Might Help....need your feedback

- Considering context - PRISM extension of RE-AIM
- Planning programs - estimating RE-AIM impacts
- Adaptations - types and implications
- Representativeness and transparent reporting
  - Be Fit Be Well example
- Your feedback and opportunities for D&I research
carrying coals to Newcastle?
Using Systematic Reviews to Select Evidence-Based Programs that Are Pragmatic (using PRECIS-2 and RE-AIM)

<table>
<thead>
<tr>
<th>Level of Effectiveness</th>
<th>Level of Pragmatism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>High</td>
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<tr>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>Pragmatic</td>
</tr>
<tr>
<td>Traditional Efficacy</td>
<td>Traditional Effective</td>
</tr>
<tr>
<td></td>
<td>Pragmatic and Effective</td>
</tr>
</tbody>
</table>

Pragmatic Models- RE-AIM
Other Models

Consolidated Framework for Implementation Research

Many commonalities across models and theories
“D&I theories are kind of like toothbrushes: Everybody has one and no one wants to use somebody else’s”

Cara Lewis via Anne Sales via ????
Purpose and History of RE-AIM Framework

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

www.re-aim.org
## 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 <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>? <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>

## RE-AIM—Health Equity Implications

<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% benefit</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>0 (equal)</td>
<td>70% benefit</td>
</tr>
<tr>
<td>Adoption</td>
<td>30%</td>
<td>49% benefit</td>
</tr>
<tr>
<td>Implementation</td>
<td>30%</td>
<td>34% benefit</td>
</tr>
<tr>
<td>Maintenance</td>
<td>30%</td>
<td>24% benefit</td>
</tr>
</tbody>
</table>
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 (maybe?) iteratively

• 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 implementation science projects
Evolution of RE-AIM

- Applicability to many different content areas…more than 420 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*

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

Crosscutting issues
- Proportion who benefit
- Representativeness of who benefits
- Reasons: how and why they benefit
- Adaptations made
- Costs incurred
PRISM = Pragmatic Robust Implementation and Sustainability Model

Context Issues from RE-AIM Perspective

- People exist in the context of culture and places in which they work, live, study and play
- Context is multi-level and dynamic
- Challenges of studying and understanding context:
  - So many factors…which are most important for which issues, for which settings, for which populations?
  - Need for brief, validated and quantitative pragmatic measures

Practical, Robust Implementation & Sustainability Model

Addresses contextual factors impacting RE-AIM outcomes

Key Aspects for Context in PRISM:
Practical Robust Implementation & Sustainability Model

External Context- Multi-level and dynamic
• Polices/guidelines
• Incentives/reimbursement
• Resources
• History (and trust)

Internal Context- consider fit
• Multi-level organization characteristics and perspectives
• Multi-level citizen/patient/end-user characteristics & perspectives
• Implementation and sustainability infrastructure
Roadmap for Whirlwind RE-AIM & Equity Journey

- Considering Context - PRISM extension of RE-AIM
- **Planning programs- Estimating RE-AIM impact**
- Adaptations - types and implications
- Representativeness and transparent reporting
  - Be Fit Be Well example
- Your feedback and opportunities for D&I research
Applying RE-AIM to Planning Interventions
Planning and ‘Evaluability’*

- Do initial **estimates** of RE-AIM dimensions where you don’t have data (evaluability)* - with stakeholders
- Include multiple **perspectives** on an ongoing basis
- Expect different programs or interventions to do well on different RE–AIM dimensions
- Often helpful to compare two or more program or policy options (create RE-AIM ‘profiles’)

Similar to P.S. Hovmand. Community-based system dynamics (2014)?

Health Equity and How Pragmatic RE-AIM Research Might Help

- Considering Context - PRISM extension of RE-AIM
- Planning programs - estimating RE-AIM impacts
- Adaptations - types, implications and guidance
- Representativeness and transparent reporting
  - Be Fit Be Well example
- Your Feedback and opportunities for D&I research
Evaluating complex interventions: Confronting and guiding (vs. ignoring and suppressing) heterogeneity and adaptation

October 9, 2018

Brian S. Mittman, PhD
Department of Research and Evaluation, Kaiser Permanente Southern California
Quality Enhancement Research Initiative (QUERI), U.S. Department of Veterans Affairs
Clinical and Translational Science Institute, University of California at Los Angeles
Implementing EBP and Implementation Strategies

• Complex interventions usually can be, will be and should be adapted*

• Adaptation should be:
  – embraced, studied and guided, rather than
  – ignored and/or
  – suppressed

Casbassa, LJ. & Bauman, AA. A two-way street: Bridging IS and cultural adaptations.... Imp Sci 2013: 8: 90
PCORI Methodology Guideline SCI-3:
Specify how adaptations to the form of the intervention and comparator will be allowed and recorded

- Researchers should specify:
  - allowable adaptations in form and/or function
  - a description of how planned and unplanned adaptations will be managed, measured and reported over time
- Any planned adaptations should:
  - have a clear rationale
  - ideally be supported by theory, evidence or experience
  - maintain fidelity to the core functions of the intervention
- Upon study conclusion, researchers should provide guidance on:
  - allowable adaptations, or
  - unproductive adaptations
## Types of Adaptations - Cultural, Resources, Local

<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>
Adapting the Stirman, et al. Framework Using the RE-AIM Model and Clinical Experience

**WHY: What was the purpose of the adaptation?**
- Increase reach, participation, access
- Increase effectiveness
- Increase adoption by more clinics/settings or make intervention more aligned with organizational goals
- Increase implementation/ability of staff to deliver intervention successfully

**WHEN: When during the project the adaptation was made?**
- During planning stages, before intervention began
- Early, during first few weeks of intervention
- During the middle stages
- At or close to the end of project

**HOW: How or on what BASIS was this change made?**
- Based on our vision or values
- Based on a framework (for example, PCMH)
- Based on our knowledge or experience of working with patients
- Based on QI data, summary information or results
- Based on pragmatic/practical considerations (for example, “this is the only way it would work”)
- Based on financial incentives/payment
- Based on feedback or suggestions (Practice Facilitator/coach or other)
- Other

**IMPACT: What are (subjective) short-term results of the adaptation?**
- Are they positive, negative, no real impact?
- Did the changes impact:
  - Reach/participation/access
  - Effectiveness
  - Adoption
  - Implementation/ability of staff to deliver intervention successfully
  - Maintenance

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![Diagram showing the RE-AIM Model and Clinical Experience](image-url)
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
Health Equity and How Pragmatic RE-AIM Research Might Help

- Considering context - PRISM extension of RE-AIM
- Planning programs - estimating RE-AIM impact
- Adaptations - types and implications
- **Representativeness and transparent reporting**
  - Be Fit Be Well example
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Equity Issues in Evidence-Based Research: Evidence on What?

External Validity/Pragmatic Criteria, Often Ignored

- Participant representativeness
- Setting and staff representativeness
- Multi-level context
- Adaptation/change in intervention and implementation strategies
- What outcomes and over what time period
- Reasons for participation and drop out
Replicability (and Generalizability)

Important to report conditions under which the program was delivered

- To what extent is the program replicable:
  - In similar settings?
  - In different settings?

Bottom Line and **ULTIMATE USE 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 implementation strategies under what conditions, with how many resources and how/why do these results come about?”
An Evidence-Based Cancer Prevention... or Depression Reduction... or Care Transition.....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 it is not*

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

**Impact:** \[0.5 \times 0.5 \times 0.5 \times 0.5 \times 0.5 = 3\%\] benefit

www.re-aim.org
IF AN INTERVENTION WORKS

AND NOBODY CAN USE IT.....

DOES IT STILL MAKE AN IMPACT?
Adoption: Setting and Staff Issues

• Setting Level Adoption Factor Settings
  – What Sites are invited/excluded
  – Participation rate
  – Which participate
  – How representative are they
  – Reasons for participating/declining

• Staff Level Adoption Factors
  – Who is invited/excluded
  – Participation rate
  – Who participates
  – Reasons for participating/declining
Critical Considerations:
- Characteristics of Adopting Settings vs. Non
- Characteristics of Adopting Staff vs. Non
Expanded CONSORT Figure: With Mapping for RE-AIM Domains

- **Adoption**
- **Reach**
- **Maintenance**
“Original” CONSORT criteria are found here in the interior of the expanded CONSORT diagram.
Why is it Important to Use the Expanded CONSORT? (or similar reporting approach*)

- To understand and estimate health equity impact
- To enhance transparency and indicate generalizability factors
- To increase the frequency and quality of external validity reporting
- To address the replication failure crisis
- To align with evolving D&I reporting criteria (StaRI*)

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!

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
Be Fit Be Well: 24-month randomized weight loss and hypertension self-management intervention trial among low-income urban clinics.

- RE-AIM used to plan for and assess reduction in disparities, as well as report outcomes

# Baseline Characteristics of Be Fit Be Well Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care (n=185)</th>
<th>Intervention (n=180)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>122 (66%)</td>
<td>128 (71%)</td>
</tr>
<tr>
<td>Non-Hispanic Black/African-American</td>
<td>131 (71%)</td>
<td>129 (71%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>23 (12%)</td>
<td>25 (14%)</td>
</tr>
<tr>
<td>Language n(%) Spanish</td>
<td>22 (12%)</td>
<td>23 (13%)</td>
</tr>
<tr>
<td>&lt; High School Education</td>
<td>73 (40%)</td>
<td>47 (26%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>87 (47%)</td>
<td>86 (47%)</td>
</tr>
<tr>
<td>Medicare or Medicaid</td>
<td>99 (54%)</td>
<td>99 (55%)</td>
</tr>
</tbody>
</table>
One in-person visit, introduction to website with follow-up phone calls

Self-monitoring and feedback via CHOICE of
- Web,
- IVR and print
Results

REACH
60% of eligible population was invited to participate (604). Of those, 365 (60%) completed baseline and were randomized. Those who participated vs. those who did not, were younger and had a higher mean BMI. No other differences were found on demographics.

EFFECTIVENESS*

• At 24 months, intervention participants had greater weight losses compared with those receiving usual care (difference, −1.03 kg; 95% CI, −2.03 to −0.03 kg)

• Mean systolic blood pressure was significantly lower in the Ix arm compared with usual care

* No differential patterns in outcomes observed for minority vs. non-minority or disparity-related sub-groups.

Bennett et al. Obesity Treatment for Socioeconomically Disadvantaged Patients…Arch Intern Med. 2012;172(7):565-574
Results (cont.)

ADOPTION

• All three centers invited, participated. Four centers were excluded for lack of EHR system
• 19 of 20 primary care physicians (95%) referred their patients to the program

IMPLEMENTATION

• 71% completion rate for counseling calls; 63% of participants completing >70% of their calls
• English speakers were more likely to have goals, barriers and strategies documented (P<0.0001), as were participants making more than $10,000 (P<0.001)

MAINTENANCE

Strong individual-level maintenance with no sub-group differences, but at the setting-level none of the centers maintained the program components.
Health Equity and How Pragmatic RE-AIM Research Might Help

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• Your feedback and opportunities for D&I research
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, at what cost, to different parties?
• And how well are the intervention components and their effects Maintained?
This interactive website was designed to help researchers and practitioners to select the D&I Model that best fits their research question or practice problem, adapt the model to the study or practice context, fully integrate the model into the research or practice process, and find existing measurement instruments for the model constructs. The term 'Models' is used to refer to both theories and frameworks that enhance dissemination and implementation of evidence-based interventions more likely.

- **Select**
  - Search, view, and select D&I Models

- **Adapt**
  - Read strategies for adapting D&I Models to research or practice context

- **Integrate**
  - Read strategies for incorporating D&I Models into the full spectrum of your project

- **Measure constructs**
  - Find a list of constructs and links to measurement tools associated with the D&I Models

http://www.dissemination-implementation.org/
The 5 Rs to Enhance Pragmatism, D&I Science and Likelihood of Translation

Research that is:

- Relevant
- Rapid and recursive
- Redefines rigor
- Reports resources required
- Replicable


### Why Is This Important? Consider Impact of Loss at Each RE-AIM ‘Stage’

#### Example of Translation of Interventions into Practice

<table>
<thead>
<tr>
<th>Dissemination Step</th>
<th>RE-AIM Concept</th>
<th>% Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of settings use intervention</td>
<td>Adoption</td>
<td>50.0</td>
</tr>
<tr>
<td>50% of staff take part</td>
<td>Adoption</td>
<td>25.0</td>
</tr>
<tr>
<td>50% of patients identified, accept</td>
<td>Reach</td>
<td>12.5</td>
</tr>
<tr>
<td>50% follow regimen correctly</td>
<td>Implementation</td>
<td>6.2</td>
</tr>
<tr>
<td>50% benefit from the intervention</td>
<td>Effectiveness</td>
<td>3.2</td>
</tr>
<tr>
<td>50% continue to benefit after six months</td>
<td>Maintenance</td>
<td>1.6</td>
</tr>
</tbody>
</table>
PCTs: Fewer Exclusions Allow for a Broader Subset of Settings, Staff and Participants

<table>
<thead>
<tr>
<th>Traditional RCT</th>
<th>PCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Eligible population</td>
<td>● Eligible population</td>
</tr>
<tr>
<td>● Exclusions, non-response, etc.</td>
<td>● Exclusions, non-response, etc.</td>
</tr>
<tr>
<td>● Efficacy, among a defined subset</td>
<td>● Effectiveness, in a broad subset</td>
</tr>
</tbody>
</table>

Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research
### 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</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-</td>
<td></td>
</tr>
<tr>
<td>Penetration</td>
<td>centeredness</td>
<td></td>
</tr>
<tr>
<td>Sustainability</td>
<td>Timeliness</td>
<td></td>
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