Applying the RE-AIM Framework to Intervention Planning and Evaluation

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Workshop 01 – SBM – April, 2014
What you Want to Know

- What are the best measures for each dimension?
  - Would like to learn more than the basics.
  - How do we evaluate prevention interventions using RE-AIM?

- Learn how to use RE-AIM when addressing multiple dimensions
  - How do you retrofit a community project to a RE-AIM evaluation?
  - How to apply to an organization/initiative with multiple interventions?

- Using RE-AIM for planning
  - Is it the same for small projects (R21/R03) as larger projects?

- Melding implementation and effectiveness research with RE-AIM
What you Want to Know

• Focus on the AIM
  ○ Actual versus implied implementation
  ○ Balancing Fidelity with Adaptation

• Understanding challenges with RE-AIM
  ○ How do you address reach when you don’t have access to all necessary information?
  ○ Is adoption always applicable?
  ○ How to best evaluate grant proposals?

• How to report components of the RE-AIM across a multi-year project?

• What are resources to use after the workshop?
RE-AIM History, Core Concepts, Common Challenges

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COLORADO HEALTH OUTCOMES PROGRAM

RE-AIM Workshop – SBM – April, 2014
Outline

- Fundamentals
- Tools and resources

- Full employment of the RE-AIM
- Considering Different Designs-Primer

- RE-AIM Activities
  - Refining a RE-AIM research question
  - Refining a RE-AIM study design

- Wrap—did you learn what you want to know!
• Traditional RCTs study the effectiveness of treatments delivered to carefully selected populations under ideal conditions.

• This makes it difficult to translate results to the real world.

• Even when we do implement a tested intervention into everyday clinical practice, we often see a “voltage drop”—a dramatic decrease in effectiveness.

“If we want more evidence-based practice, we need more practice-based evidence.”
Green LW. *Am J Pub Health* 2006

Bench to Bookshelf
Readiness for Translation? RE-AIM

- **Internal validity perspective**
  - The *magnitude of effect* as the key indicator of readiness for translation and adheres to the principles of *evidence rating* for determining efficacy

- **External validity perspective**
  - Attention to intervention features that can be *adopted* and delivered broadly, have the ability for *sustained* and consistent *implementation* at a reasonable cost, *reach* large numbers of people, especially those who can most benefit, and produce *replicable* and *long-lasting effects*

Original RE-AIM

• First published articles in 1999

• Originally intended to increase balance between internal and external validity

• First used to evaluate prevention and health behavior change programs

• RE-AIM Trivia: was going to be called ARIEM

Moral of the Story?

• Are multiple issues (steps) in successfully delivering a program

• All steps are important—and can impact other steps or RE-AIM dimensions

• Focus on the “denominator(s)”
Planned Parenthood Smoking Cessation Example

- Patient randomized study (n = 1154) in low income Planned Parenthood clinics
- Eligible and target population = women smokers coming into clinic for contraception, wellness, or non-pregnancy follow-up
- INT = 9-minute tailored video, clinician advice to quit, brief behavioral counseling, follow-up phone calls
- Control = Advice to Quit and Stop Smoking brochure

Glasgow R et al. A brief smoking cessation intervention. AJPH, 2000, 90: 786-789
Planned Parenthood Smoking Cessation Results

- **Reach:** 99% had smoking identified, 76% of smokers approached participated, no differences on demographics for participants vs. decliners

- **Effectiveness:** 10.2% quit INT vs. 6.9% CON at 6-week follow-up, p<.05

- **Adoption:** Approached 4 clinics in lowest SES neighborhoods in area (most below 125% poverty level), also most diverse clinics—all participated
Results (cont.)

• Implementation:
  - Excellent (>85%) on all components except phone calls, which were problematic—only 43% successfully contacted

• Maintenance:
  - Individual level: Higher, but NS different levels cessation (18.3 vs. 14.9%, p=.09) in INT condition at 6-month follow-up
  - Setting level: Not reported
Community Physical Activity Program

- Quasi-experimental trial (n = 5911) in statewide cooperative extension system

- Target population (eligibility) = Adults with no contraindications for moderate intensity physical activity

- Intervention = 8-week group dynamics program with group goals, self-monitoring, and feedback via 9 weekly newsletters.

- Control = Participants served as own control

Community Physical Activity Program Results

- **Reach**: 590,327 Adults in participating counties; 5911 participated (1% of eligible population); participants were more likely to be women, older, and more likely to be meeting physical activity recommendations when compared to the general population.

- **Effectiveness**: Previously inactive and insufficiently active participants increased moderate physical activity by 177 and 107 minutes per week, respectively.

- **Adoption**: 48 of 105 counties adopted in first year of delivery, 41 additional counties adopted by year 5 of delivery. In initial year, counties with extension agents who were not meeting PA recommendations were less likely to adopt.
• **Implementation** - No data reported but refers to consistent delivery across counties.

• **Maintenance Individual Level** - Previously inactive and insufficiently active participants sustained an increase of moderate physical activity of 134 and 101 minutes per week 6 months after the program was completed, respectively.

• **Maintenance Setting Level** - All counties that initiated the program in the initial year sustained delivery for the subsequent 4 years. Each adopting county in years 2-4, delivered the program in subsequent years.
RE-AIM Evolution

- Used to conduct reviews of the literature—many different content areas, consistent results
  - Setting level factors reported much less often
  - Maintenance (sustainability) reported least often
- More recently used for diverse areas ranging from education to health policy to community/environmental interventions
RE-AIM Precision (Personalized) Medicine Questions

Determine

• What percent and types of patients are **Reached**;
• For whom among them is the intervention **Effective**, in improving what outcomes, with what unanticipated consequences;
• In what percent and 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**?

Challenges and Complexities

- Combining Dimensions—no overall summary score
- Confusing Reach and Adoption
- Is a framework, not a theory—tells you what to attend to, not HOW or WHAT to do
- When used to evaluate multi-component programs, how to treat components in terms of denominators and overlap
Your Questions and Issues
Tools, Research, and Application: the RE-AIM Website

- Samantha M. Harden, PhD
- University of British Columbia

What’s available?  Website Statistics  How can I contribute?
1. Monthly search for ‘RE-AIM’
2. Email correspondence
3. Presentations
4. Blog posts
5. RE-AIM workgroup meetings

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Samantha Harden, PhD, University of British Columbia, Postdoctoral Fellow
Welcome to RE-AIM.org!

The use of the RE-AIM model across different research domains and countries has been growing almost exponentially.

Last August the Guide to Useful Interventions for Activity (GUIA) completed a systematic review of physical activity interventions in Brazil and Latin American and developed an external validity evaluation tool based on the RE-AIM framework.
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<thead>
<tr>
<th>Country / Territory</th>
<th>Sessions</th>
<th>% Sessions</th>
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<tbody>
<tr>
<td>United States</td>
<td>6,569</td>
<td>59.83%</td>
</tr>
<tr>
<td>Canada</td>
<td>863</td>
<td>7.86%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>800</td>
<td>7.29%</td>
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<tr>
<td>Australia</td>
<td>451</td>
<td>4.11%</td>
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<td>Germany</td>
<td>146</td>
<td>1.33%</td>
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<tr>
<td>Brazil</td>
<td>119</td>
<td>1.08%</td>
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<tr>
<td>Singapore</td>
<td>116</td>
<td>1.06%</td>
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<tr>
<td>Ireland</td>
<td>104</td>
<td>0.95%</td>
</tr>
<tr>
<td>Belgium</td>
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<td>0.86%</td>
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# Statistics - Users

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<th>January - April 21, 2014</th>
<th>March 1 - March 31</th>
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<td>Visitors</td>
<td>7,552</td>
<td>2,320</td>
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<tr>
<td>New Visitor</td>
<td>7,289 (66%)</td>
<td>2,125 (71%)</td>
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<td>Average Session Duration</td>
<td>00:03:41</td>
<td>00:03:17</td>
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<td>Pages/Session</td>
<td>3.31</td>
<td>3.10</td>
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<td>Most visited page</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>1. About RE-AIM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Presentations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. What is efficacy?</td>
<td></td>
</tr>
</tbody>
</table>
Statistics - Keywords

RE-AIM or variation of

Each dimension

Planning, implementation, dissemination, evaluation

Community, education, lifestyle, practitioners, pediatric, garden, school
Seeking Contributions!

- Presentations
- Blog Post Ideas
- Publications
- Events
- Resources
What Does It Mean to Plan for and Employ RE-AIM?

SBM 2014

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University of Vermont College of Medicine
Director, Collaborative Care Research Network, National Research Network
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Clinical Associate Professor,
Nicholas A. Cummings Doctoral Program in Behavioral Health
Arizona State University
Variable implementation of the RE-AIM model across the five key dimensions

- Applications all proposed measures of effectiveness (100%) and many (86%) proposed use of multiple measures of effectiveness, although few measured broader outcomes such as unintended consequences or quality of life.
- Estimates of the percent of target settings that were excluded were frequently proposed (75%).
- Elements of reach were also addressed more frequently than in earlier literature reviews and in published behavioral intervention applications (Glasgow et al., 2004; Klesges et al., 2012; Klesges et al., 2005; Klesges et al. 2008).
- Applications frequently proposed to collect measures of representativeness of participants (67%).
Variable Implementation continued

- Plans to assess adoption at the delivery staff level were reported less frequently (45%), with the assessments of percentage of potential staff participating (31%) being substantially lower.

Most applications had measures of implementation fidelity (85%) but far fewer proposed collecting measures of intervention adaptation (49%) or costs (59%).

- Slightly more than half (59%) of the grant proposals claiming to use RE-AIM specified plans to assess items of long-term maintenance ($\geq 6$ months follow-up) at the individual level.

- More proposals included measures of maintenance at the setting (73%) than at the individual level (59%).
Their appears to be confusion between reach- which deals with participation and representativeness at the *individual* citizen, consumer or patient level- and adoption- which addresses participation and representativeness at multiple *setting and staff levels*.

Guidance on properly calculating reach: divide the number of participants (persons beginning or coming to the first session of a program) by the eligible participants in target populations (all the potential participants in the target population minus the number excluded by researcher or those lost or indeterminant cases) to determine Percent Participation or Reach.

Another common error was use of an ‘incorrect denominator' in calculating percentages of individual and setting level participation by using only respondents rather than one’s target population as the denominator.
Example

- If an email was sent to 200 County health departments about a new CQI program and how they could adopt this program and 50 participated in an informational phone call to get more information, and 20 actually begin participation in the program, the Adoption calculation would be 20/200, not 20/50.
Key Issues

- The key issues for both errors is that the denominator should reflect all who were approached and considered for participation, at both the individual (Reach) and setting (Adoption) levels.

- Additionally, it is important to also determine the representativeness of participants (Reach) and the adopters (Adoption) by comparing demographic characteristics and other relevant variables between participants and nonparticipants and to report the most common reasons for declining participation.
Emerging issues related to more sophisticated or advanced uses of RE-AIM

- Collection of data on representativeness and reasons for participation/nonparticipation at both the individual (reach) and setting (adoption) levels.
- Use of mixed methods to more fully understand implementation issues and combining scores or results on multiple dimensions to provide estimates of overall impact.
- Increased study of relationships among outcomes on different RE-AIM dimensions.
- More transparent reporting on all items, especially adaptations made during or following evaluation, and unintended consequences.
What does it mean to use the RE-AIM framework?

- Increased standardized reporting on multiple RE-AIM dimension and items
- Not all grant questions may be appropriate for inclusion of all RE-AIM dimensions.
- If a proposal claims to employ the (full) RE-AIM model the items and criteria we have proposed are reasonable expectations.
- It is reasonable to only decide to employ two or three RE-AIM dimensions.
- If so it should state this clearly and provide justification, rather than claiming to employ the entire model.
- Researchers may consider use of a brief table that summarizes the specific definitions of each of the key components of RE-AIM for their particular question or study and associated measures, for purposes of clarity and communication to both grant and manuscript reviewers.
If RE-AIM is to be regarded as a meaningful yardstick for evaluating interventions, then a standard definition of meaningful use of the framework is required.

- If “anything” it loses meaning, but if “you have done everything to have a practical account as RE-AIM” then the framework loses application and local adaptation. For example, some studies or interventions are more amenable to the use of some RE-AIM dimensions and items than others, which is why “fully developed” typically is defined by choices (e.g., 3 out of 4 criteria), not having to include every single item.
An evolving idea to use RE-AIM at earlier stages of program and policy planning

PRE-AIM

- The earliest applications of RE-AIM were retrospective evaluations and reports on intervention outcomes, and initial RE-AIM reviews focused on its use for literature review and synthesis (Gaglio & Glasgow, 2012 (in press); Glasgow et al., 1999; Glasgow, Bull, Gillette, Klesges, & Dzewaltowski, 2002)

- More recent applications have emphasized use of RE-AIM for planning and for comparing different intervention and policy alternatives (e.g., (Jilcott et al., 2007; King et al., 2010; Klesges et al., 2005)
Example: Does rigorously implementing CBT for at risk cardiac patients impact on mood and cardiac event outcomes in on the ground practices?

<table>
<thead>
<tr>
<th>Planning Q</th>
<th>Evaluation Q</th>
</tr>
</thead>
<tbody>
<tr>
<td>• How do we optimize reach?</td>
<td>• Who participated- patients and practices?</td>
</tr>
<tr>
<td>• What will demonstrate effectiveness patient/pract?</td>
<td>• Were there mood and cardiac changes?</td>
</tr>
<tr>
<td>• Can we use a QI implementation process?</td>
<td>• Are outcomes different in QI/ regular care settings?</td>
</tr>
<tr>
<td>• How can we observe implementation differences?</td>
<td>• What were differences?</td>
</tr>
<tr>
<td>• What do we need to do to generate sustainability?</td>
<td>• Did intervention maintain?</td>
</tr>
</tbody>
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Applying the RE-AIM Framework to Effectiveness, Implementation, and Hybrid Effectiveness-Implementation Trials

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VIRGINIA TECH
CARILION CLINIC

RE-AIM Workshop – SBM – April, 2014
Targeting Different RE-AIM Outcomes

- Each RE-AIM dimension:
  - Provides a target for intervention
  - Is influenced by the study design
  - Is influenced by the target population
  - Is influenced by the characteristics of the intervention
<table>
<thead>
<tr>
<th>REACH</th>
<th>EFFECTIVENESS</th>
<th>ADOPTION</th>
<th>IMPLEMENTATION</th>
<th>MAINTENANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention: Incentives tied to a weight loss program</td>
<td>Intervention: ATSM; GMV</td>
<td>Intervention: Integrated research practice partnership.</td>
<td>Intervention: Multicomponent intervention to improve delivery of clinical services</td>
<td>Intervention: Sustainability action planning with technical training and assistance</td>
</tr>
<tr>
<td>Proposed Indicators Outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>Number of participants Proportion Representativeness</td>
<td>Number of participants Proportion Representativeness</td>
<td>Number of participants Proportion Representativeness BY Setting</td>
<td>Number of participants Proportion Representativeness over time</td>
</tr>
<tr>
<td>E</td>
<td>Operationalized as changes in reach as a result of the intervention and cost per participant recruited</td>
<td>Degree to which DSM is improved. Changes in QOL. Potential negative consequences</td>
<td>Operationalized as changes in adoption and cost of intervention start-up</td>
<td>Operationalized as continued institutional delivery of intervention and cost of sustainability</td>
</tr>
<tr>
<td>A</td>
<td>Number, proportion and representativeness of clinics that agree to participate in incentive study</td>
<td>Number, proportion and rep. of clinics that agree to participate in incentive study</td>
<td>Number, proportion and representativeness of agents that agree to participate</td>
<td>Number, proportion, &amp; representativeness, of clinics that agree to the implementation intervention</td>
</tr>
<tr>
<td>I</td>
<td>Degree to which incentives are offered as intended and cost of implementation</td>
<td>Degree to which physician/staff counseling is completed. Cost of implementation</td>
<td>Degree to which the protocol to engage organizational leadership is completed as intended and the costs of implementation.</td>
<td>Degree to which sustainability action planning steps are completed as intended.</td>
</tr>
<tr>
<td>M</td>
<td>Organizational: Degree to which the incentives intervention can be sustained at the clinical level and cost of continued delivery</td>
<td>Organizational: Degree to which the intervention can be sustained and cost of continued delivery</td>
<td>Organizational: Degree to which the involvement of organizational leadership is sustained and the cost</td>
<td>Organizational: Degree to which the intervention can be sustained at the clinical level and cost of continued delivery</td>
</tr>
</tbody>
</table>
A more Pragmatic Approach

- All dimensions are considered in the design, but some are intervention targets while others are only assessed and described.

- Intervene or describe…
  - **Reach**
  - **Effectiveness**
  - **Adoption**
  - **Implementation**
  - **Maintenance_i**
  - **Maintenance_o**
Identifying Trial Type

• **WHAT IS AN EFFECTIVENESS TRIAL?**
  ○ To date the majority of RE-AIM studies have focused determining the efficacy or effectiveness of individual-level interventions

• **WHAT IS AN IMPLEMENTATION TRIAL?**
  ○ Emerging literature with Implementation as the focus

• **WHAT A HYBRID IMPLEMENTATION/EFFECTIVNESS TRIAL?**
  ○ New models of hybrid effectiveness/implementation designs.
Type 1 - Focus on Effectiveness
- Test a clinical/community intervention
- Descriptive data on implementation
- Individual is the unit of analysis
- Primary outcome—Change in individual behavior/health

RE-AIM assessment?
- R-#, %, representativeness of participants—Descriptive
- E-Δ in outcome, QOL, negative outcomes—Intervene
- A-#, %, representativeness of settings/staff—Descriptive
- I-proportion delivered as intended, cost, adaptation—Descriptive
- M-Degree to which program and outcomes are sustained—Descriptive/Intervene

Hybrid Effectiveness/Implementation Designs
Hybrid Effectiveness/Implementation Designs

- **Type 2—Focus on Effectiveness and Implementation**
  - Test a clinical/community intervention and implementation strategies
  - Individual and staff/setting is the unit of analysis
  - Primary outcome—implementation fidelity; I X E

- **RE-AIM assessment?**
  - R-#, %, representativeness of participants—Descriptive
  - E-Δ in outcome, QOL, negative outcomes—Intervene
  - A-#, %, representativeness of settings/staff—Descriptive/Intervene
  - I—proportion delivered as intended, cost, adaptation—Descriptive/Intervene
  - M—Degree to which program and outcomes are sustained—Descriptive
Hybrid Effectiveness/Implementation Designs

- **Type 3-Focus on implementation**
  - Test implementation strategies
  - Descriptive information on clinical adoption
  - Staff/setting is the unit of analysis
  - Primary outcome—implementation uptake

- **RE-AIM assessment?**
  - R-#, %, representativeness of participants—Descriptive
  - E-Δ in outcome, QOL, negative outcomes—Descriptive
  - A-#, %, representativeness of settings/staff—Descriptive/Intervene
  - I-proportion delivered as intended, cost, adaptation—Intervene
  - M-Degree to which program and outcomes are sustained—Descriptive/Intervene
339 patients with poor diabetes control were randomly assigned to one of three conditions:

- Practical controlled trial of UC, GVM, & ATSM
- Outcomes measured at baseline and 12 months
  - Behavioral Self-Management
  - Quality of Life
  - Patient reports of process of care
Primary Outcome - Effectiveness

- Days of self management at baseline and 12 mo.
  - UC: 3.9 to 3.8
  - ATSM: 3.7 to 4.4
  - GMV: 3.9 to 4.1

- Quality of Life
  - SF-12 ATSM improved mental health responses compared to GMV

- Potential negative outcomes
Descriptive Data

- Adoption: 4 out of 6 clinics participated. One only interested in ATSM and one uncomfortable with randomization.

- Implementation: 4106 calls delivered as intended; 112 GMVs delivered as intended. Patient completion of ATSM intervention sessions higher than in GMV. Cost analysis is planned.

- Maintenance: 12-month outcomes were reported. Organizational maintenance not reported.
Primary outcomes: implementation of wellness visits, recall and reminder systems, and standing orders

One clinician/nurse team from each of 24 practices participated

Mold, Aspy & Nagykaldi, 2008
Primary Outcome-Implementation

- Significant differences on recall & reminders; Standing orders
- Other improvement opportunities 52% completion for intervention to 17% for control
- Cost of intervention was approximately $7,500 per clinic
Descriptive Information

- Adoption-24 of 93 contacted clinics participated. No description of differences between those that agreed and those that declined
- Maintenance- Not assessed—but could followed with existing data
- Reach—increased reach of preventive services for mammography 33 to 60 percent and CRC screen 28 to 44%
- Effectiveness—may not be relevant, why?
Type 2

Integrated Research-Practice Model

Efficacy to Effectiveness to Demonstration to Dissemination Model

Fit Extension

Active Living Everyday
Primary Outcome-Adoption, Implementation, Effectiveness

*\(\chi^2(1)=7.2, \ p<.01\)
Implementation

- Degree delivered as intended
  - ALED ~90%
  - Fit Ex ~ 80%

- Adaptation
  - ALED None reported
  - Fit Ex Numerous small changes in feedback timing and structure

Cost assessed as implementation hours

![Bar chart showing hours for Fit Ex and ALED]
Effectiveness

- Baseline
- End Program
- 3 mo. Post

ALED
Fit Ex
Descriptive Information

- **Reach**
  - Fit Ex-75 participants per program
  - ALED 15 participants per program
  - Both underrepresented by men

- **Maintenance** - Delivered for 3 years post initial evaluation
RE-AIM Summary Points

- RE-AIM is an outcomes framework that can be used for evaluation of multiple trial types
- Each dimension is an opportunity for intervention
- All dimensions can be addressed within a given study (though likely not all intervened upon)