Using RE-AIM to Address Health Impact Evaluation Issues

Cynthia A. Vinson, MPA
Implementation Science Team
Division of Cancer Control and Population Sciences
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Outline of Talk

- Background and Definitions
- Comprehensive use of RE-AIM framework
- Adaptation of RE-AIM for rating evidence-based interventions
- Creation of new RE-AIM tool for practitioners
Definitions

• **Internal Validity** – identifies causal relationships … in this study, the intervention made a difference in the outcome.

• **External Validity** – findings are true beyond the controlled limits of the study. “To what populations, settings, treatment variables and measurement variables can this effect be generalized?” (Campbell & Stanley, 1963)

Internal vs. External Validity

- What are the trade-offs of in maximizing internal or external validity?
Gold Standard≠ Translation

“Where did the field get the idea that evidence of an intervention’s efficacy from carefully controlled trials could be generalized as THE best practice for widely varied populations and settings?”

L.W. Green

Green LW. From research to "best practices" in other settings and populations
Am J Health Behav 2001; 25:165-78
External Validity

- A framework for closing the gap between research and practice/policy
Purposes of RE-AIM

- To broaden the criteria used to evaluate programs to include elements of external validity
- To evaluate issues relevant to program adoption, implementation, and sustainability
- To help close the gap between research studies and practice by:
  - Suggesting standard reporting criteria
  - Informing design of interventions
  - Providing guides for program planners and potential adopters

www.re-aim.org
Goal of RE-AIM Evaluation

Determine characteristics of interventions that can:

- **Reach** large numbers of people, especially those who can most benefit
- Be widely **adopted** by different settings
- Be consistently **implemented** by staff members with moderate levels of training and expertise
- Produce **replicable and long-lasting effects** (and minimal negative impacts) at reasonable cost

## Example of Applying RE-AIM

### Ultimate Impact of ‘The Magic Pill’

<table>
<thead>
<tr>
<th>Dissemination</th>
<th>Concept</th>
<th>% Impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>50% of Federally Qualified Health Centers Use</td>
<td>Adoption</td>
<td>50%</td>
</tr>
<tr>
<td>50% of Clinicians Prescribe</td>
<td>Adoption</td>
<td>25%</td>
</tr>
<tr>
<td>50% of Patients Accept Medication</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% of Those Taking Correctly Benefit</td>
<td>Effectiveness</td>
<td>3.1%</td>
</tr>
<tr>
<td>50% Continue to Benefit After 6 Months</td>
<td>Maintenance</td>
<td>1.6%</td>
</tr>
</tbody>
</table>
The Moral of the Story?

1. “Focus on the Denominator” (not just the numerator)

2. Each step of the dissemination sequence, or each “RE-AIM” dimension is important
RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact

<table>
<thead>
<tr>
<th>RE-AIM ELEMENT</th>
<th>GUIDELINES AND QUESTIONS TO ASK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>REACH</strong></td>
<td>Can the program attract large and representative percent of target population?</td>
</tr>
<tr>
<td>Percent and</td>
<td>Can the program reach those most in need and most often left out (i.e., the poor, low literacy</td>
</tr>
<tr>
<td>representativeness</td>
<td>and numeracy, complex patients)?</td>
</tr>
<tr>
<td>of participants</td>
<td></td>
</tr>
<tr>
<td><strong>EFFECTIVENESS</strong></td>
<td>Does the program produce robust effects across sub-populations?</td>
</tr>
<tr>
<td>Impact on key</td>
<td>Does the program produce minimal negative side effects and increase quality of life or broader</td>
</tr>
<tr>
<td>outcomes, quality</td>
<td>outcomes (i.e., social capital)?</td>
</tr>
<tr>
<td>of life, unanticipated</td>
<td></td>
</tr>
<tr>
<td>outcomes and subgroups</td>
<td></td>
</tr>
</tbody>
</table>
## RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact (Cont)

<table>
<thead>
<tr>
<th>RE-AIM ELEMENT</th>
<th>GUIDELINES AND QUESTIONS TO ASK</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADOPTION</strong></td>
<td>Is the program feasible for majority of real-world settings (costs, expertise, time, resources, etc.)?</td>
</tr>
<tr>
<td>Percent and representativeness of settings and staff that participate</td>
<td>Can it be adopted by low resource settings and typical staff serving high-risk populations?</td>
</tr>
<tr>
<td><strong>IMPLEMENTATION</strong></td>
<td>Can the program be consistently implemented across program elements, different staff, time, etc.?</td>
</tr>
<tr>
<td>Consistency and cost of delivering program and adaptations made</td>
<td>Are the costs—personnel, up front, marginal, scale up, equipment costs—reasonable to match effectiveness?</td>
</tr>
</tbody>
</table>
RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact (Cont)

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<tr>
<td>MAINTENANCE</td>
<td>Does the program include principles to enhance long-term improvements (i.e., follow-up contact, community resources, peer support, ongoing feedback)?</td>
</tr>
<tr>
<td></td>
<td>Can the settings sustain the program over time without added resources and leadership?</td>
</tr>
</tbody>
</table>
What Evidence is Needed?
EXTENDED CONSORT DIAGRAM

**RE-AIM Issue**

- **ADOPTION**
  - Total number potential settings
  - Settings Eligible n and %
  - Excluded by Investigator n, %, and reasons
  - Setting and Agents Who Participate n and %
  - Setting and Agents Who Decline n, %, and reasons
  - Other n and %

- **REACH**
  - Total Potential Participants, n
  - Individuals Eligible n and %
  - Excluded by Investigator N, %, and reasons
  - Individuals Enroll N and %
  - Not Contacted/Other N and %
  - Individuals Decline N, %, and reasons

- **IMPLEMENTATION**
  - Extent Tx Delivered By Different Agents as in Protocol
  - Component A = XX%
  - Component B = YY%
  - Etc.
  - Complete Tx (n and %) and Amount of Change (By Condition)
  - Drop out of TX N, %, and Reasons; And Amount of change (By Condition)

- **EFFECTIVENESS**
  - Present at Follow-up (n and %) and Amount of Change or Relapse (By Condition)
  - Lost to Follow-up N, %, and Reasons Amount of change or Relapse (By Condition)

- **MAINTENANCE**
  - a) Individual Level
  - Settings in which Program is Continued And/or Modified after Research is Over (n, %, and reasons)
  - Settings in which Program not Maintained (n, %, and reasons)
  - b) Setting Level

**Critical Considerations**

- Characteristics Of Adopters vs Non
- Characteristics Of Enrolles vs. Decliners
- Extent Tx Delivered as Intended
- Characteristics of Drop-outs vs Completers
- Characteristics of Drop-outs vs Completers
- Characteristics of Settings that Continue vs Do Not

*At each step, record qualitative and quantitative information and factors affecting each RE-AIM dimension and step in flowchart*
External Validity
Checklist for Researchers
(from meeting of 13 journal editors)

1. _____ Record recruitment and/or selection procedures, participation rate, and representativeness at each of the following levels:
   a. Individuals, patients, citizens, or clients
   b. Intervention staff, or program delivery agents
   c. Delivery settings, work sites, health care clinics, schools

2. _____ Take note of any differences in delivery across:
   a. Settings, populations, and/or staff
   b. Program components
   c. Time, taking special care to note any modifications over time

3. _____ Record all impacts of intervention, including:
   a. Quality of life, or unintended adverse consequences
   b. Costs of implementation and/or program replication
   c. Moderator variables, especially those related to health disparities

4. _____ When conducting long-term follow-up report, pay attention to:
   a. Long-term effects on item #3 above
   b. Attrition at all levels in #1 above
   c. Institutionalization, modification, or discontinuance of the program

Reporting External Validity
Future Directions

• Document reliability of EV coding criteria
• Consider *summary metrics*, composite or overall EV quality scores
• Report on impact on health equity for all RE-AIM levels
• Assistance to practitioners on how to combine with theory and local experience
• Evaluate which criteria most strongly related to long-term dissemination success
• Revise criteria based on lessons learned
Assistance to practitioners on how to combine with theory and local experience

- NCI has revised the Research-tested Interventions Program (RTIPs) review process and website to incorporate RE-AIM
- April 2012 began scoring new RTIPs programs on RE-AIM criteria
- October 2012 launched “RE-AIM notes” on all program summary pages

http://rtips.cancer.gov/rtips/index.do
Research-tested Intervention Programs (RTIPs)

Use the link below to select a number of criteria, and see a list that contains programs from several topics.

Select from 128 Intervention Programs

RTIPs is a searchable database of cancer control interventions and program materials and is designed to provide program planners and public health practitioners easy and immediate access to research-tested materials.

Register your program now and be part of the RTIPs Community.

RTIPs and Research Reviews

The Guide to Community Preventive Services evaluates the effectiveness of types of interventions (as opposed to individual programs) by conducting systematic reviews of all available research in collaboration with partners. The Task Force on Community Preventive Services then uses the systematic review findings as the basis for their recommendations for practice, policy and future research. The symbol to the right links to Community Guide findings. Many Research-tested Intervention Programs (RTIPs) are directly linked to associated Community Guide findings.

Tools Available:

- Using What Works: a train-the-trainer course that teaches users how to adapt a research-tested intervention program to the local community context

We welcome your feedback on the Research-tested Intervention Programs Web site. To submit feedback, please contact us. Thank you for helping to improve this site for the cancer control community.
# Healthy-Steps

## Highlights

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Designed to enhance the quality of life for breast cancer survivors. (2005)</td>
</tr>
<tr>
<td><strong>Program Focus</strong></td>
<td>Psychosocial - Coping</td>
</tr>
<tr>
<td><strong>Population Focus</strong></td>
<td>Cancer Survivors</td>
</tr>
<tr>
<td><strong>Topic</strong></td>
<td>Survivorship</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>Adults (40-65 years), Older Adults (65+ years), Young Adults (19-39 years)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>Female</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td>Black, not of Hispanic or Latino origin, Hispanic or Latino, White, not of Hispanic or Latino origin</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Clinical, Suburban, Urban/Inner City</td>
</tr>
<tr>
<td><strong>Origination</strong></td>
<td>United States</td>
</tr>
<tr>
<td><strong>Funded by</strong></td>
<td>This information is not available.</td>
</tr>
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## RTIPs Scores

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Integrity</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>Intervention Impact</td>
<td>3.0</td>
<td></td>
</tr>
<tr>
<td>Dissemination Capability</td>
<td>5.0</td>
<td></td>
</tr>
</tbody>
</table>

1.0 = low 5.0 = high

## RE-AIM Scores

<table>
<thead>
<tr>
<th>Category</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>50.0%</td>
<td></td>
</tr>
<tr>
<td>Effectiveness</td>
<td>66.7%</td>
<td></td>
</tr>
<tr>
<td>Adoption</td>
<td>80.0%</td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>71.4%</td>
<td></td>
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</tbody>
</table>
The Need
An increasing number of women are living with breast cancer and adjusting to the changes that accompany survivorship. Many factors can profoundly affect quality of life for survivors, such as disturbances in body image, reduced range of motion in the shoulder hindering full engagement in everyday activities, and changes in psychological well-being. Women with breast cancer report distress, depression, and anxiety at greater rates, and these symptoms may persist for years following treatment.

The Program
Description
Healthy-Steps is a dance and movement program based on The Lebed Method, Focus on Healing Through Movement and Dance developed by Lebed-Davis, which was designed to restore shoulder range of motion, reduce lymphedema, and bring a renewed sense of body symmetry, femininity, sexuality, and grace through dance and arm movements. For the Healthy-Steps program, the Lebed Method is designed to help improve quality of life, body image, and shoulder function in breast cancer survivors.

Implementation Guide
The Implementation Guide is a resource for implementing this program. It provides important information about the staffing and functions necessary for administering this program in the user's setting. Additionally, the steps needed to carry out the research-tested program, relevant program materials, and information for evaluating the program are included. The Implementation Guide can be viewed and downloaded in the Products page.

Time Required
The Healthy-Steps program includes 3 days of training for instructors who administer the program to breast cancer survivors. The program is 12 weeks in duration, with two sessions per week for the initial 6 weeks and one session per week for an additional 6 weeks, for a total of 18 sessions. Each session consists of 10-15 minutes of warm-ups, 10 minutes of core exercises, 25-30 minutes of dance movements, 5-7 minutes for water breaks, and 10 minutes for the wrap-up.

Intended Audience
Healthy-Steps is designed for adult women who have undergone diagnosis and surgical treatment for breast cancer.

Suitable Settings
Healthy-Steps was evaluated in an out-patient and community setting. It has also been implemented in health centers, and churches.
Take Home Points

• Failure to focus on external validity is a major contributor to the disconnect between research and practice
• Need a broader approach to evaluating interventions that places appropriate focus on dimensions of external validity
• Reporting on external validity issues is needed to facilitate moving research into practice
• RE-AIM is continuing to evolve and welcomes your input
Resources

- www.re-aim.org
Questions?