

Study Planning & Design to Enhance Translation of Health Behavior Research



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<http://www.re-aim.org>

Learning Objectives

- 1. To understand the need to design health promotion studies to enhance their generalizability and potential for translation to practice-based settings**
- 2. To understand the elements of an evaluation and study planning framework**
- 3. To become familiar with methods to design health behavior change intervention studies to enhance their translation to practice settings**

Performance Objectives

- 1. Be able to identify elements of RE-AIM evaluation framework designed to enhance the translation of behavior change research to practice.**
- 2. Understand methods to design studies that enhances their translation from research to practice settings.**
- 3. Demonstrate ability to evaluate each dimension in a variety of situations.**

Who We Are

**Workgroup to Evaluate and Enhance the Reach &
Dissemination of Health Promotion Interventions
Behavior Change Consortium**

Members

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Mission Statement

To implement a framework to 1) evaluate intervention impact in its broadest sense (e.g., develop a policy relevant criterion for success, gauge evidence for prevention effectiveness, assess translatability); 2) aid the design of interventions that take fidelity, reach, adoption, and sustainability into consideration; and 3) emphasize elements of both internal and external validity

[\(http://www.re-aim.org/\)](http://www.re-aim.org/)

Problem with Research Translation

- Existing research evidence identifies numerous behavioral risk factors related to morbidity and mortality
- Behavioral interventions to modify lifestyle practices have been studied but few are translated to practice settings
- Need exists for generalizable, effective & sustainable behavioral interventions

Improving Translation of Research

- **Consider study designs and features to enhance the generalizability of research**
- **Reporting of the dissemination potential and generalizability of study results**
- **Conduct more effectiveness studies of successful behavioral interventions**
- **Address needs and questions of interest to practitioners and decision-makers**

Framework Needed to Guide Translation of Research

- Tool to evaluate both the internal & external validity of health behavior change research results
- Allow recommendations to enhance translation potential of behavior change studies in their design phase

RE-AIM Framework

Dimensions important to planning & translating behavioral change interventions

- Recruitment/Reach
- Efficacy/Effectiveness
- Adoption
- Implementation
- Maintenance

for more detailed definitions see

<http://www.re-aim.org/framework.html>

RE-AIM Dimensions

| | DIMENSION | DEFINITION |
|------------------|------------------------------------|--|
| Individual Level | <u>REACH</u> | <ol style="list-style-type: none">1. Participation rate among eligible individuals2. Representativeness of participants |
| | <u>EFFICACY/ EFFECTIVENESS</u> | <ol style="list-style-type: none">1. Effects on primary outcome of interest2. Impact on quality of life & negative outcomes |

RE-AIM Dimensions (cont.)

DIMENSION

DEFINITION

Setting Level

ADOPTION

1. Participation rate among possible settings
2. Representativeness of settings participating

Both

IMPLEMENTATION

1. Extent that intervention was delivered as intended
2. Time and costs of intervention

RE-AIM Dimensions (cont.)

DIMENSION

DEFINITION

Individual & Setting Level

MAINTENANCE

1. (Individual) Long-term intervention effects (≥ 6 mo)
 2. (Individual) Impact of attrition on outcomes
 3. (Setting) Continuation or modification of treatment
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Recruitment/Reach

- **Conduct population-based interventions and assessments or purposefully sample from diverse groups (e.g. low-income, older adults, racially-diverse) to enhance generalizability**
- **Use recruiting methods and intervention features that enhance the reach within underserved populations and settings**
- **Review your criteria for study eligibility - consider implications of exclusions on generalizability and translation of results**

Recruitment/Reach

- Plan to calculate the absolute number, proportion, and representativeness of individuals who are willing to participate in your research study
- Links to information and data sources for these estimations can be found at <http://www.re-aim.org/links.html>

Efficacy/Effectiveness

- **Include multiple outcome measures to triangulate intervention effects**
- **Specify a theoretical framework that might explain change in behavior**
- **Measure relevant theoretical constructs to assess mediational relationships between the intervention and outcomes**

Efficacy/Effectiveness

- **Record adverse outcomes & assess quality of life to judge unintended consequences of your intervention**
- **Conduct intent-to-treat analyses or use imputation to better estimate study effects for both individuals and settings**

Adoption

- **Prepare intervention and training materials to be easily replicated or disseminated to a practice setting**
- **Consider “modular” interventions that can be adapted or customized for various settings**
- **Based on available literature & formative evaluation, anticipate and reduce primary barriers to participation in your program for settings and for intervention agents**

Implementation

- **Conduct formative evaluation to assess how your intervention will interface with potential adopters of the program**
- **Record extent to which organizational settings complete or make use of components of your intervention**
- **Track costs of all aspects of intervention e.g., intervention materials, equipment, personnel, time, and space requirements**

Implementation

- Record the extent to which participants complete or make use of the different components of your intervention
- Measure the extent to which different agents deliver the intervention as stated in the protocol (e.g., % of scheduled visits made)

Maintenance

- **Plan long-term follow-up (≥ 6 mos to 1 yr) following your last intervention contact**
- **Plan continued contact with participating settings who wish to continue the intervention after your study has ended**
- **Debrief intervention agents & decision makers in organizations about continuing and modifying the intervention**

Goals of RE-AIM Planning

Design behavioral interventions to:

- Reach majority of target population
- Be widely adopted by different settings
- Be consistently implemented by program staff with moderate levels of training and content expertise
- Produce replicable and long-lasting effects (and minimal negative impacts) at reasonable cost

Summary

Achievement of goals will...

Lead to more comprehensive studies and an evidence base that gives attention to both internal and external validity, that is relevant to the translation of research to practice, and is helpful to researchers, practitioners, decision-makers, and society