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# External Validity: Why it Matters

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# OUTLINE OF TALK

- Background & Definitions
- Approaches to maximizing external validity
- Reporting external validity findings



# 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)*

Campbell DT, Stanley JC. Experimental and quasi-experimental designs for Research. Chicago, IL: Rand McNally. 1966.



# 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***



# Maximizing External Validity



# Top Down Approach

Chen HT. The Bottom-up approach to integrative validity: A new perspective for program evaluation *Evaluation and Program Planning* 2010; 33:205-14



# An Alternative: Integrative Validity Model and “Bottom-Up” Approach

**Integrative validity model:** “intervention . . . must be scientifically credible as well as relevant and useful in practice”

- Internal validity: extent to which evaluation provides objective evidence that intervention causally affects outcome
- External validity: Credible evidence that findings of effectiveness can be transferable from research setting to real-world setting
- Viable validity: credible evidence on the intervention’s real-world viability (e.g., whether it is practical, affordable, acceptable, etc.)

Chen HT. The Bottom-up approach to integrative validity: A new perspective for program evaluation *Evaluation and Program Planning* 2010; 33:205-14



# Bottom-Up Approach

Chen HT. The Bottom-up approach to integrative validity: A new perspective for program evaluation *Evaluation and Program Planning* 2010; 33:205-14



# Closing the Gap Between Research and Practice

- Bottom-Up Approach increases focus on external validity
  - Addresses how to make research relevant/generalizable/applicable in real medical and public health practice settings and policies
  - Addresses feasibility and cost-effectiveness when delivered in actual practice settings and with diverse populations



# Evaluability Assessment

Leviton, L.C., Khan, L.K., Rog,  
D., Dawkins, N., Cotton, D.  
Evaluability assessment to  
improve public health  
policies, programs and  
practices. *Annu. Rev. Public  
Health* 2010; 31:213-23

# Question

- How might you use these approaches in developing your own studies?

# External Validity

- A framework for closing the gap between research and practice



# 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*

# 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

Glasgow, Vogt, Boles, *Am J Public Health*, 89, 1999

Glasgow RE, Linnan L. Evaluation of theory-based interventions.

In: *Health Education: Theory, Research, and Practice*, 4<sup>th</sup> Ed., 2007.



# Example of Applying RE-AIM

## Ultimate Impact of 'The Magic Pill'

Dissemination	Concept	% Impacted
50% of Clinics Use	Adoption	50%
50% of Clinicians Prescribe	Adoption	25%
50% of Patients Accept Medication	Reach	12.5%
50% Follow Regimen Correctly	Implementation	6.2 %
<b>50% of Those Taking Correctly Benefit</b>	<b>Effectiveness</b>	<b>3.1%</b>
50% Continue to Benefit After 6 Months	Maintenance	1.6%

# 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

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
<p><b>REACH</b></p> <p>Percent and representativeness of participants</p>	<p>Can the program attract large and representative percent of target population?</p> <p>Can the program reach those most in need and most often left out (i.e., the poor, low literacy and numeracy, complex patients)?</p>
<p><b>EFFECTIVENESS</b></p> <p>Impact on key outcomes, quality of life, unanticipated outcomes and subgroups</p>	<p>Does the program produce robust effects across sub-populations?</p> <p>Does the program produce minimal negative side effects and increase quality of life or broader outcomes (i.e., social capital)?</p>

[www.re-aim.org](http://www.re-aim.org) ; Gaglio B and Glasgow RE. In Handbook of Dissemination and Implementation Research. Editors: R Brownson, E. Proctor, G Colditz. Oxford Univ. Press. 2011. In press.



# RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact (Cont)

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
<p><b>ADOPTION</b></p> <p>Percent and representativeness of settings and staff that participate</p>	<p>Is the program feasible for majority of real-world settings (costs, expertise, time, resources, etc.)?</p> <p>Can it be adopted by low resource settings and typical staff serving high-risk populations?</p>
<p><b>IMPLEMENTATION</b></p> <p>Consistency and cost of delivering program and adaptations made</p>	<p>Can the program be consistently implemented across program elements, different staff, time, etc.?</p> <p>Are the costs—personnel, up front, marginal, scale up, equipment costs—reasonable to match effectiveness?</p>

[www.re-aim.org](http://www.re-aim.org) ; Gaglio B and Glasgow RE. In Handbook of Dissemination and Implementation Research. Editors: R Brownson, E. Proctor, G Colditz. Oxford Univ. Press. 2011. In press.



# RE-AIM Guidelines for Developing, Selecting, and Evaluating Programs and Policies Intended to Have a Public Health Impact (Cont)

RE-AIM ELEMENT	GUIDELINES AND QUESTIONS TO ASK
<p><b>MAINTENANCE</b></p> <p>Long-term effects at individual and setting levels, modifications made</p>	<p>Does the program include principles to enhance long-term improvements (i.e., follow-up contact, community resources, peer support, ongoing feedback)?</p> <p>Can the settings sustain the program over time without added resources and leadership?</p>

[www.re-aim.org](http://www.re-aim.org) ; Gaglio B and Glasgow RE. In Handbook of Dissemination and Implementation Research. Editors: R Brownson, E. Proctor, G Colditz. Oxford Univ. Press. 2011. In press.





# What Evidence is Needed?

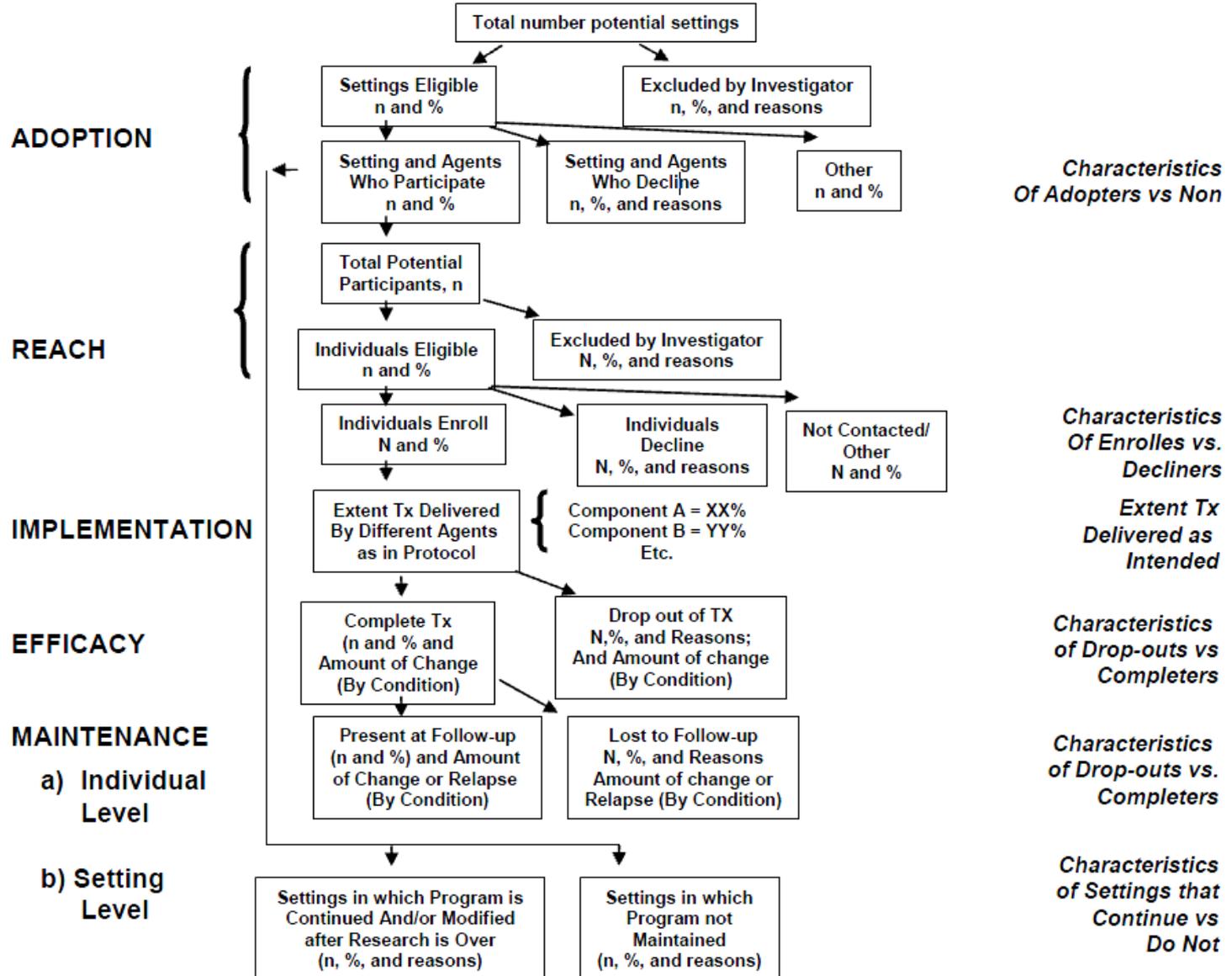


# EXTENDED CONSORT DIAGRAM

RE-AIM Issue

Content

Critical Considerations



\*At each step, record qualitative and quantitative information and factors affecting each RE-AIM dimension and step in flowchart

# External Validity Checklist for Researchers

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

Glasgow, R. E., Green, L. W., and Ammerman, A. (2007). A focus on external validity. *Evaluation & the Health Professions* 30(2): 115-117.



# Reporting External Validity

## Future Directions

- Document reliability of EV coding criteria
- Consider *summary metrics*, composite or overall EV quality scores
- 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

# 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 research into practice

# Questions?

