

Outcomes and Evaluation in Implementation Research: Key Issues and Examples from RE-AIM

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Acknowledgments and Conflicts of Interest

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UNLABELED/UNAPPROVED USES DISCLOSURE

None

Overview

- How Implementation Research (IR) outcomes are different from other types of health outcomes research
- Key issues in implementation outcomes (my view)
- Representativeness/equity; costs; adaptations; sustainability
- Evaluation frameworks in Implementation Research
Example issues using RE-AIM

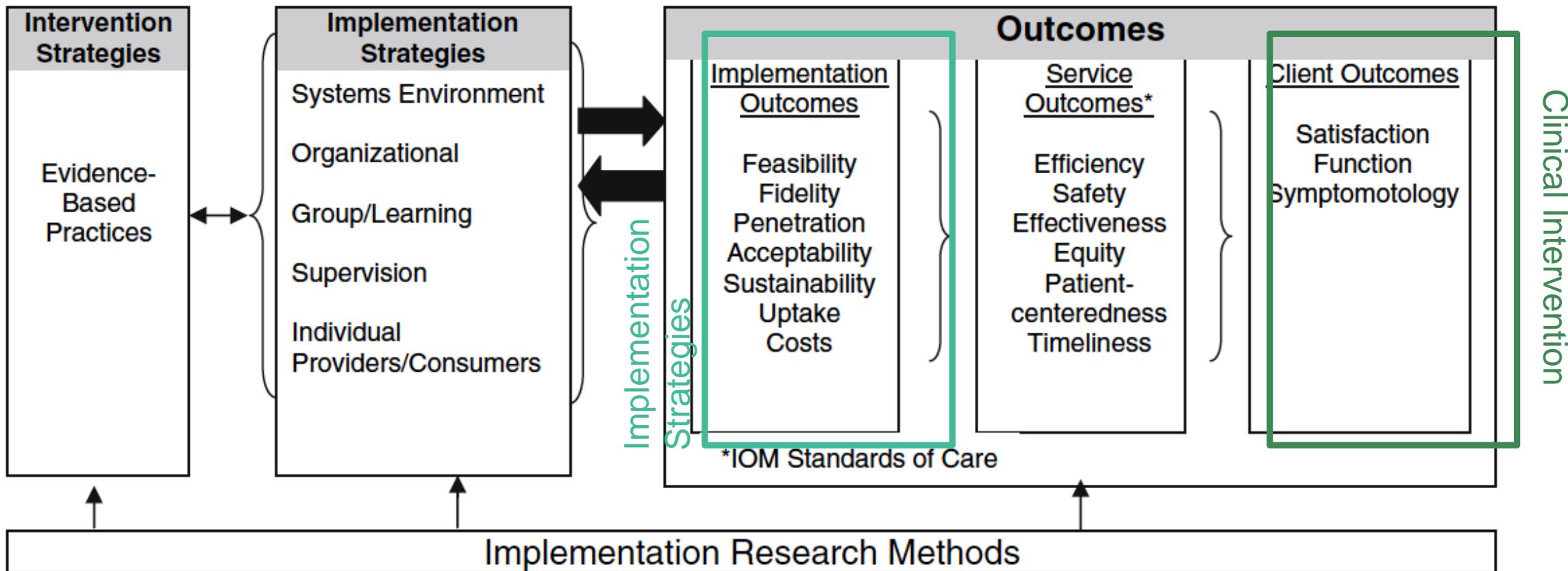


If an intervention works...

and nobody can use it...does it still make an impact?

IR Outcomes are Distinct from Clinical Outcomes

Short-term/proximal → Long-term/distal



Proctor, et al. 2009; 2011

Elements of an IR Logic Model

Implementation Outcomes

The effects of deliberate and purposive actions to implement new treatments, practices and services.

- indicators of **implementation success**
- proximal indicators of **implementation processes**
- key **intermediate outcomes** in relation to service or clinical outcomes



Interactions among IR outcomes

Proctor, et al. 2011

CHARACTERISTIC OF MEASURE & OUTCOME	IMPLEMENTATION OUTCOMES & MEASURES	HSR & CLINICAL EFFECTIVENESS OUTCOMES & MEASURES
FOCUS	Delivery and implementation issues (aka process: feasibility, fidelity, adoption, reach)	Clinical outcome or measure of control
BREADTH	Multiple levels , broad focus, systems perspective	Narrower focus; often a single primary outcome
PREFERRED MODALITY	Multiple- observation, interview, tracking forms	Biological (e.g., BP, A1c); more recently, data in the EHR
EXPENSE and INTENSIVENESS of ASSESSMENT	Brief, low burden , pragmatic	Often expensive , requires expert assessment, emphasis on blinding when possible
LEVEL and WHO IS ASSESSED	Setting, staff	Usually patients

Evidence-Based...on what?

External Validity and Implementation (often Ignored)

- Participant representativeness
- Setting representativeness
- Context and setting
- Community/setting engagement
- Adaptation/change
- Sustainability
- Costs/feasibility of treatment

Evaluation & Reporting in Implementation Research

Context and Representativeness ([Expanded CONSORT](#))*

Implementation - including fidelity, [adaptation](#), and variability

[Costs](#) - stakeholder perspective, replication costs, feasibility

Standards for Reporting Implementation Studies ([StaRI](#))**

*Glasgow R, et al. Expanded CONSORT Figure....*Amer J Prev Med*, 2018.

DOI: <https://doi.org/10.1016/j.amepre.2018.04.044>

**Pinnock H, et al. *StaRI reporting standards*. *BMJ* 2017;356:i6795

Widely Used Implementation Evaluation Models

PRECEDE-PROCEED (Green LW & Kreuter MW. *Health program planning...*(2005) www.lgreen.net

- PRECEDE for planning and context- PROCEED for intervention and summative evaluation
- Social and epi/ecological assessment: predisposing, enabling, reinforcing factors
- Implementation, process, impact, and outcome assessment

Evaluability Assessment (Leviton, et al. *Ann Rev Public Health* 2010;31:213-33)

- Pre-evaluation to assess likelihood that intervention, guidelines or policy could realistically be successful (e.g., feasible, affordable,
- Key to involve stakeholders

Medical Research Council Guidance for **Complex Interventions** (UK)

<https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/>

- Process evaluation
- Implementation; mechanisms; and context
- Steps involve planning; design and conduct; analysis; and reporting

- **RE-AIM** www.re-aim.org; Gaglio and Glasgow. Ch.19 in Brownson et al. *DIRH in health*

Too often we have assumed, “If you build it...”



An Evidence-Based Obesity Intervention (or HIV prevention, or depression Tx) Story

Even if 100% effective...it's only as good as how and whether:

- it is adopted widely and in low-resource settings
- practitioners choose to deliver it
- trained practitioners deliver it well
- eligible populations, including those at highest risk, receive it
- it can be sustained

If we assume 50% threshold for each step...(even with perfect access/adherence/dosage/maintenance)

Impact: .5x .5x .5x .5 x .5 = 3% population based benefit

www.re-aim.org Glasgow RE, Vogt TM, Boles SM. *Am J Public Health*. 1999;89(9):1322.

Glasgow RE, et al. *Frontiers Public Health* 2019 7:64. doi: 10.3389/fpubh.2019.00064

Pragmatic Outcome Models- Example Issues using RE-AIM



www.re-aim.org

Pragmatic Use of RE-AIM- What is Feasible?

RE-AIM Dimension	Key Pragmatic Priorities to Consider and Answer
Reach	WHO is/was intended to benefit and who actually participates or is exposed to the intervention?
Effectiveness	WHAT is/was the most important benefit you are trying to achieve and what is/was the likelihood of negative outcomes?
Adoption	WHERE is/was the program or policy applied and WHO applied it?
Implementation	HOW consistently is/was the program or policy delivered, HOW will it be/was it <u>adapted</u> , HOW much will/did it <u>cost</u> , and WHY will/did the results come about?
Maintenance	WHEN will/did the initiative become operational; how long will it be/was it sustained (setting level); and how long are the results sustained (individual level)?

Cross-Walk of Proctor and RE-AIM Outcomes

D&I Outcome	Level of Analysis	Theoretical Basis (RE-AIM)
Reach	Individual	RE-AIM: Reach
Acceptability	Individual	RE-AIM: implicit; needed for Reach
Appropriateness	Individual, Organization, Policy	
Feasibility	Individual, Organization, Policy	
Adoption	Individual, Organization, Policy	RE-AIM: Adoption
Fidelity	Individual	RE-AIM: part of Implementation
Cost	Individual, Organization, Policy	RE-AIM: part of Implementation
Penetration	Organization, Policy	RE-AIM: necessary for Reach
Sustainability	Organization, Policy	RE-AIM: Maintenance

Adapted from: Brownson R. C., Colditz, G. A. & Proctor, E. K. (Eds.) (2018). Dissemination and Implementation Research in Health: Translating Science to Practice (Second edition). p232. Oxford; New York: Oxford University Press. - Table 14.1

Purpose and History of RE-AIM Framework

- Intended to facilitate translation of research to practice
- Internal and external validity, and emphasizes representativeness
- Multi-level: Individual and organizational factors - experimental and observational
- Public health impact depends on all elements (reach x effectiveness, etc.)

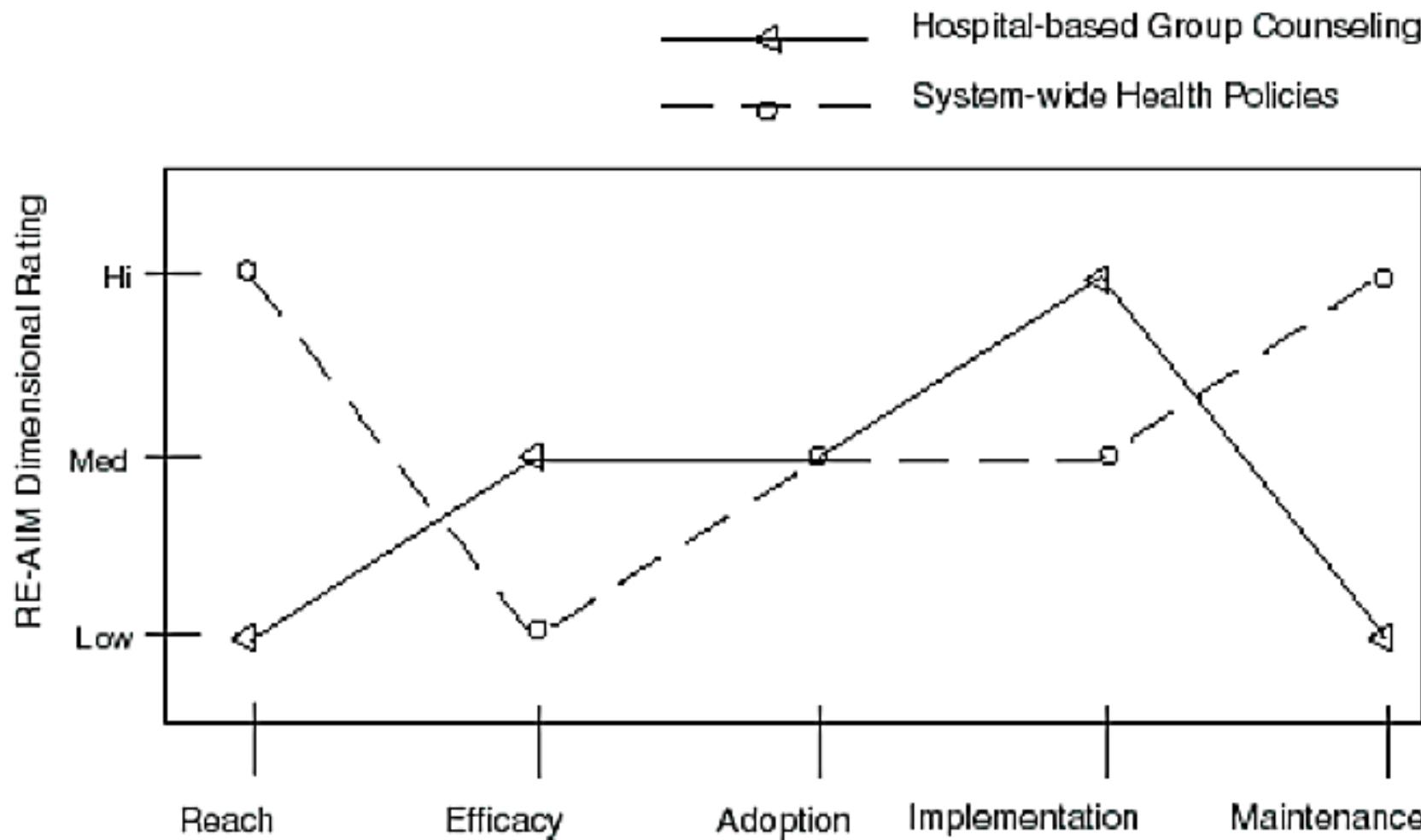


www.re-aim.org

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 with other frameworks**
- Each dimension is **an opportunity** for intervention
- All dimensions can be addressed within a given study (though likely not all intervened upon)
- RE-AIM and Implementation Outcomes are complex, dynamic, interrelated (**often cannot have it all**)

Ratings on RE-AIM Dimensions



Evolution of RE-AIM



- Applicability to many different content areas- over 430 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

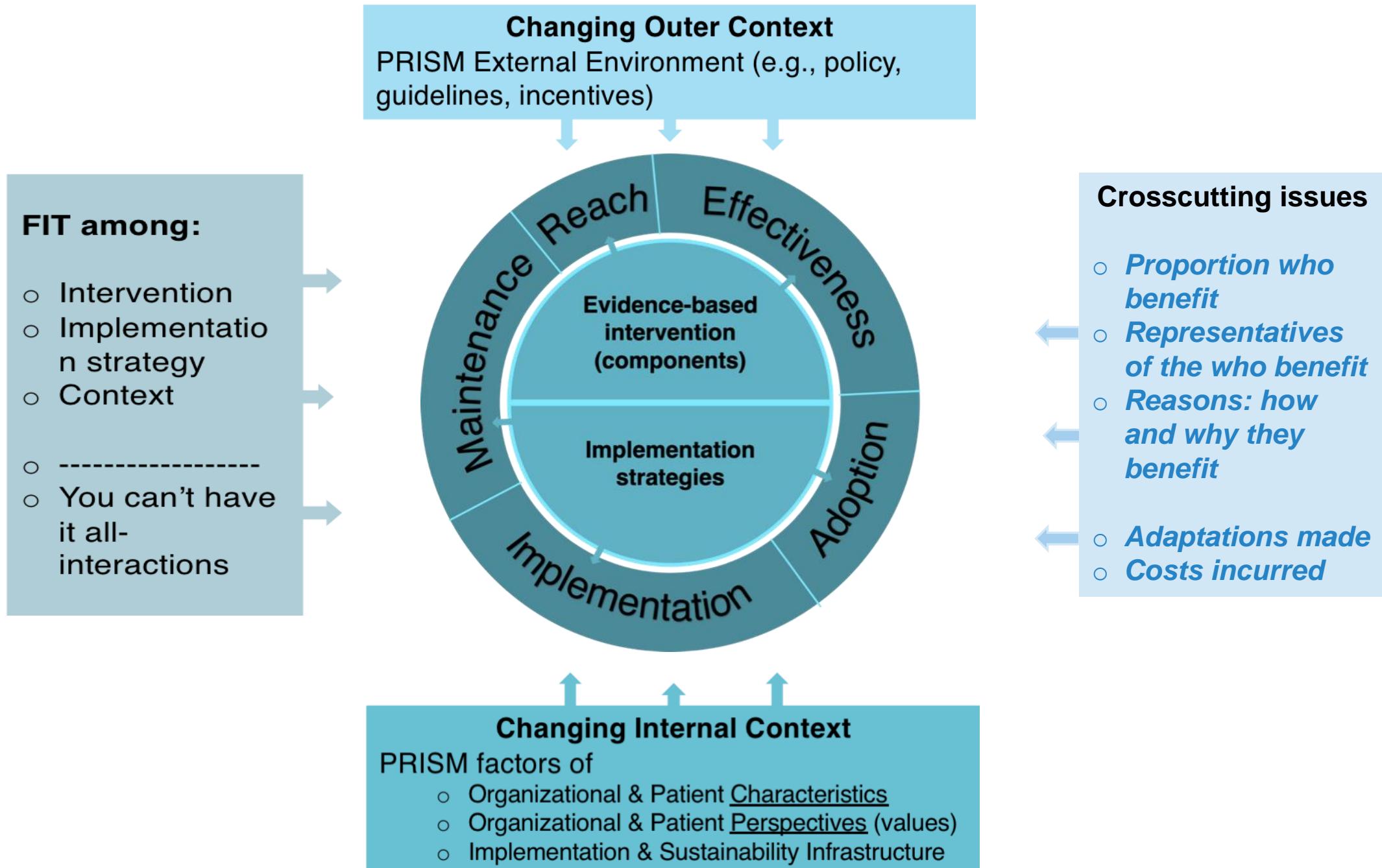
Adaptations

Patient centered outcomes research

Qualitative RE-AIM assessments

Gaglio, et al. The RE-AIM framework....*AJPH* 2013; 103:38-46.

Holtrop, et al. *BMC Health Serv Res.* 2018 Mar 13;18(1):177. doi: 10.



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

Key Issues in Implementation Outcomes (my view)

- Representativeness/equity
- Costs
- Adaptations
- Sustainability

Health Equity Example from RE-AIM Perspective

RE-AIM Issue	Disparity	Overall Impact
Reach	30%	70% of benefit
Effectiveness	0 (equal)	70% of benefit
Adoption	30%	49% of benefit
Implementation	30%	34% of benefit
Maintenance	30%	24% of benefit

Costs: Reporting Resources Required

- Understand *from perspective of stakeholders*, including patients and decision makers
- Simple is fine – sophisticated economic analyses are not needed for most D&I purposes
 - Report costs of conducting or ***replicating interventions***
 - Beyond money, costs can include clinician and staff time, training, infrastructure, startup costs, opportunity costs

Ritzwoller, D P, et al. (2009). Costing behavioral interventions. *Annals Behav Medicine*, 37(2), 218-27.

Key Issues Regarding Adaptation

- Adaptations to evidence-based interventions or implementation strategies are **common and inevitable**. They should be assessed and **reported** - rather than this information being suppressed (PCORI guidelines).
- Adaptation of programs often occurs **to improve the fit** (or compatibility) of a program to a new setting, or to increase the cultural appropriateness of a program.
- Adaptations might **lessen the effectiveness** of the program if they compromise the core elements and underlying program functions.

Types of Adaptations

Focus of Adaptation	Timing of Adaptation (point in the study)		
	<i>Planning</i>	<i>During</i>	<i>Dissemination</i>
Intervention			
Implementation Strategy			
Setting			

Key Evaluation Questions- IR vs General HSR

- **Traditional science** and evidence question: (**necessary but not sufficient**): What intervention produces the largest average effect in tightly controlled trials on the major (clinical) outcome?
- **Implementation Research** question: (**contextual**)
What **program/policy components** are most effective for producing **what implementation outcomes** for **which populations/recipients** when implemented by **what type of persons** using **what strategies** under **what conditions**, with how many **resources** and **how/why** do these results occur?

Key Take Home Points

- Implementation Outcomes are different than usual HSR outcomes...they are multi-level, contextual and inter-related
- There are several good IR outcomes and evaluation models: Which is best depends...and may need to be adapted for your project or integrated with others
- Key issues are transparent reporting, equity/representativeness, costs, and sustainability

Questions?



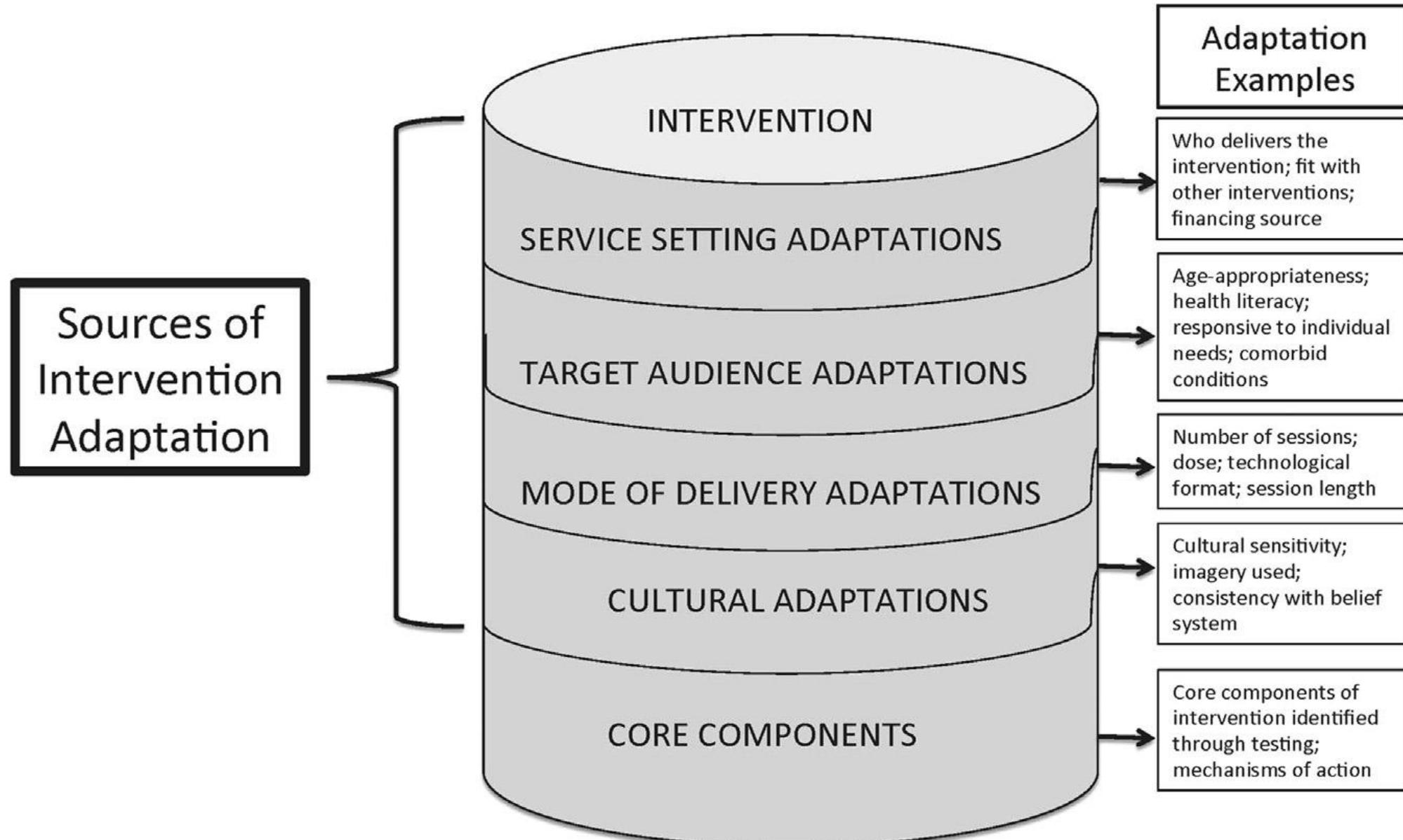
'I am all ears!'

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 and at what cost to different parties;
- And how well are the intervention components and their effects Maintained?

Gaglio B, Glasgow RE. Evaluation approaches...In: Brownson R, Colditz G, Proter E, (eds). *Dissemination and Implementation Research in Health: Translating science to practice*. New York: Oxford University Press; 2018. Pages 317-34



Chambers D, Norton W. The Adaptome. *Am J Prev Med* 2016;51(4S2):S124–S131.

Planning and ‘Evaluability’

- Do initial estimates of RE-AIM dimensions when no data exists (evaluability) - with stakeholders
- Often helpful to compare two or more program or policy options (create RE-AIM profiles)
- Expect different programs or interventions to do well on different RE-AIM dimensions
- Include multiple **perspectives** on ongoing basis

<http://www.re-aim.org/resources-and-tools/self-rating-quiz/>

Leviton L et al. Annual Review Public Health, 2010, 31, 213- 233.

Pragmatic Measures

Required Criteria

- Important to stakeholders
- Burden is low to moderate
- Broadly applicable, has norms to interpret
- Sensitive to change

Additional Criteria

- Actionable
- Low probability of harm
- Addresses public health goal(s)
- Related to theory or model
- Maps to “gold standard” metric or measure

Types of Outcomes in Implementation Research

Implementation Outcomes

- Acceptability
- Adoption
- Appropriateness
- Costs
- Feasibility
- Penetration
- Sustainability

Service Outcomes

- Efficiency safety
- Effectiveness
- Equity
- Patient-centeredness
- Timeliness

Client Outcomes

- Satisfaction
- Function
- Symptoms

Proctor E, Silmere H, Hensley M, et al. Outcomes for implementation research. *Administration and Policy in Mental Health* [serial online]. March 2011;38(2):65-76.