

# **Global Health Webinar: Applying RE-AIM in Low- and Middle-Income Country Settings**

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**Russell E. Glasgow, PhD**

**University of Colorado School of Medicine**

**Meredith Fort, PhD, MPH**

**Colorado School of Public Health**

# Overview

Pragmatic research: rationale and characteristics

RE-AIM: ONE pragmatic framework for global health

- Early work: external validity and public health impact
- Recent past: policy, health equity, broad application
- Current and Future: context, replication, adaptation and costs

Global health issues in applying RE-AIM and example

Discussion; Resources; Q & A

# Need for Pragmatic Research

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## Usual Research is Slow

- Traditional RCTs are slow and expensive
- Most common reason for non-adoption...research **not seen as relevant**
- Rarely produce findings that are easily put into practice



It takes an average of **17 years** before **14% of research** findings lead to widespread changes in care.

# Pragmatic Research: Fewer Exclusions Allow for a Broader Subset of Settings, Staff, and Participants

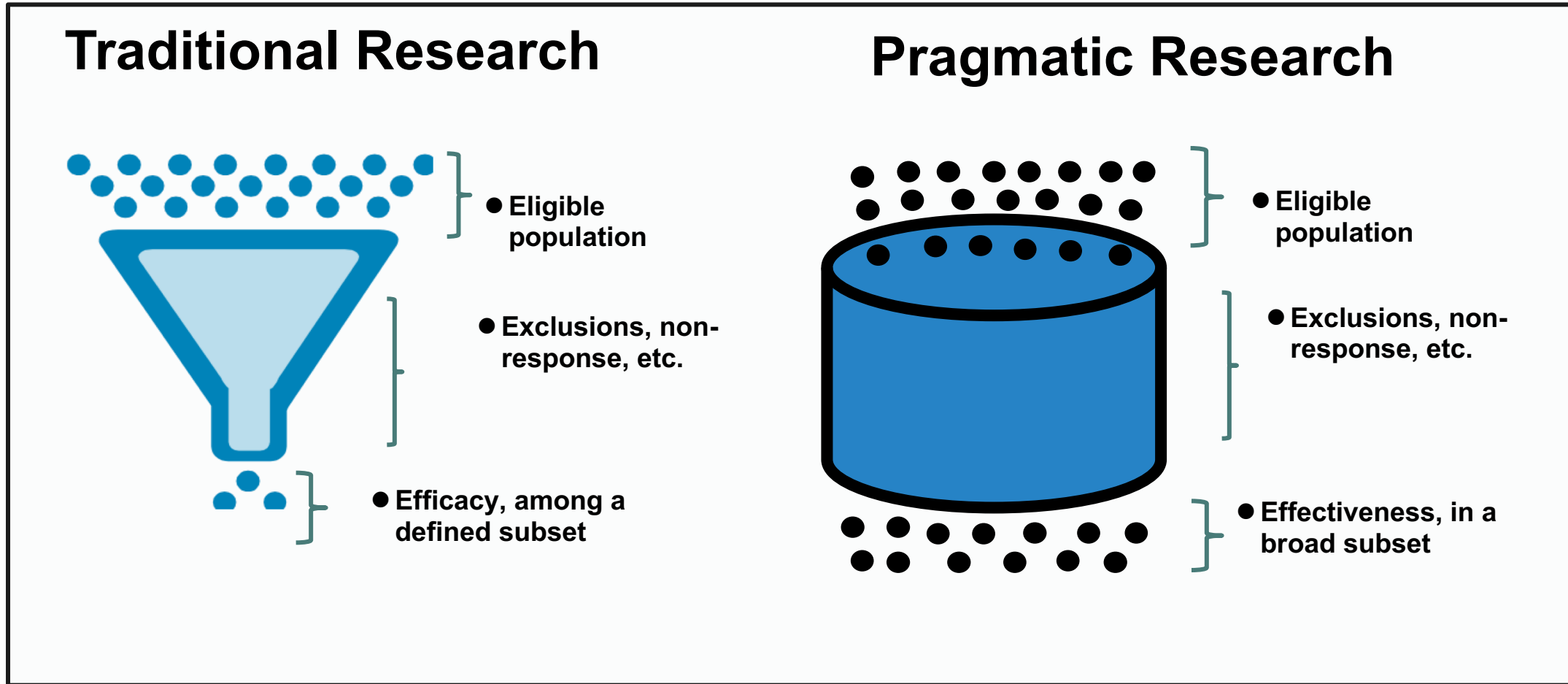


Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research



Too often we have assumed, “If you build it...and *if you have evidence*”...



# An Evidence-Based Cancer Prevention... or Hypertension Control... or (fill in blank) Story

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

- it is adopted - *and where it is not adopted*
- practitioners are trained to deliver it - *and who is not trained*
- trained practitioners consistently deliver it - *and who does not*
- eligible populations receive it - *and which do not*
- it can be sustained - *and where, why and when is it not*

If we **assume 50%** success for each step (even with perfect access/adherence/dosage/maintenance- *and equal benefit throughout*)

**Impact:** .5x .5x .5x .5 x .5 = **3% benefit**

# RE-AIM Questions for Planning or Evaluation

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- What percent and what types of patients or individuals are likely to *Receive* this program; (*Reach*)
- For whom among them is the intervention *Effective*; in improving what outcomes; what broader effects and potential negative consequences?
- What percent and what types of potential settings and delivery staff are likely to *Adopt* this program;
- How consistently are different parts of the program likely to be *Implemented* across settings, clinicians, and patient subgroups... at what cost, and how will/was the program adapted?
- And how well is the program or policy and its effects likely to be *Maintained*?

# Purpose and History of RE-AIM Framework

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- Intended to facilitate translation of research to practice
- Balance internal and external validity, and emphasize representativeness
- Individual and setting level factors - Public health impact depends on all elements (reach x effectiveness, etc.)



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

# RE-AIM Current Use Summary Points

- RE-AIM is not a determinants theory- but it tells you where to look; where things often break down
- RE-AIM is an evaluation/outcomes framework that can be used for planning and evaluation
- Each dimension is an opportunity for intervention
- All dimensions can be addressed within a given study (though likely not all intervened upon)
- RE-AIM can be used for observational, efficacy, effectiveness, and dissemination projects

# Using RE-AIM for Planning

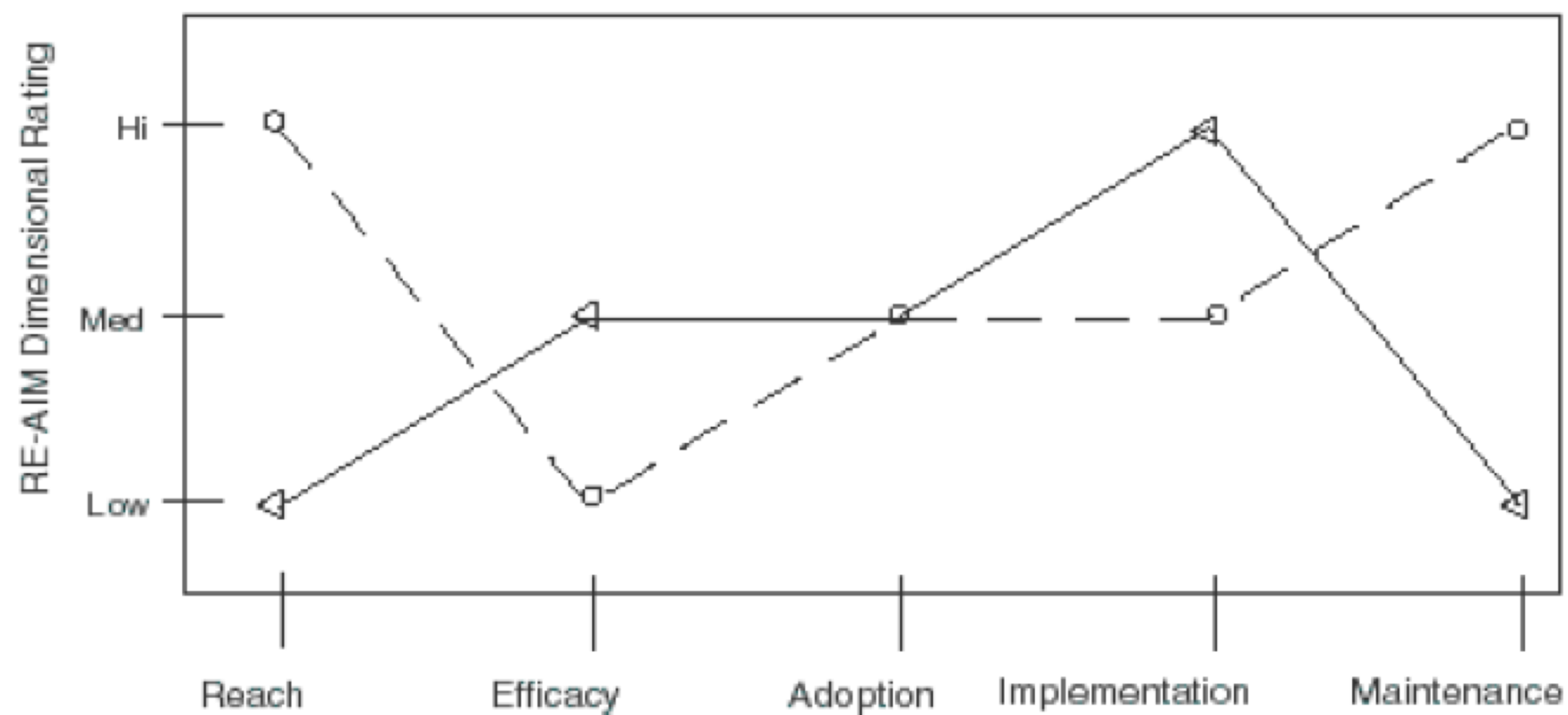
- Do initial ESTIMATES of results on different RE-AIM dimensions -with your stakeholders
- Include multiple **perspectives** on ongoing basis
- Often helpful to compare two or more program or policy options (create RE-AIM ‘profiles’)
- Expect different programs or interventions to do well on different RE-AIM dimensions

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

Klesges et al. Annals of Behavioral Medicine, (2015) 29:66S-75S.

## Ratings on RE-AIM Dimensions

—△— Hospital-based Group Counseling  
—○— System-wide Health Policies



# RE-AIM—Health Equity Implications

<u>RE-AIM Issue</u>	<u>Disparity</u>	<u>Overall Impact</u>
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



# Pragmatic Use of RE-AIM- *What is Feasible?*

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

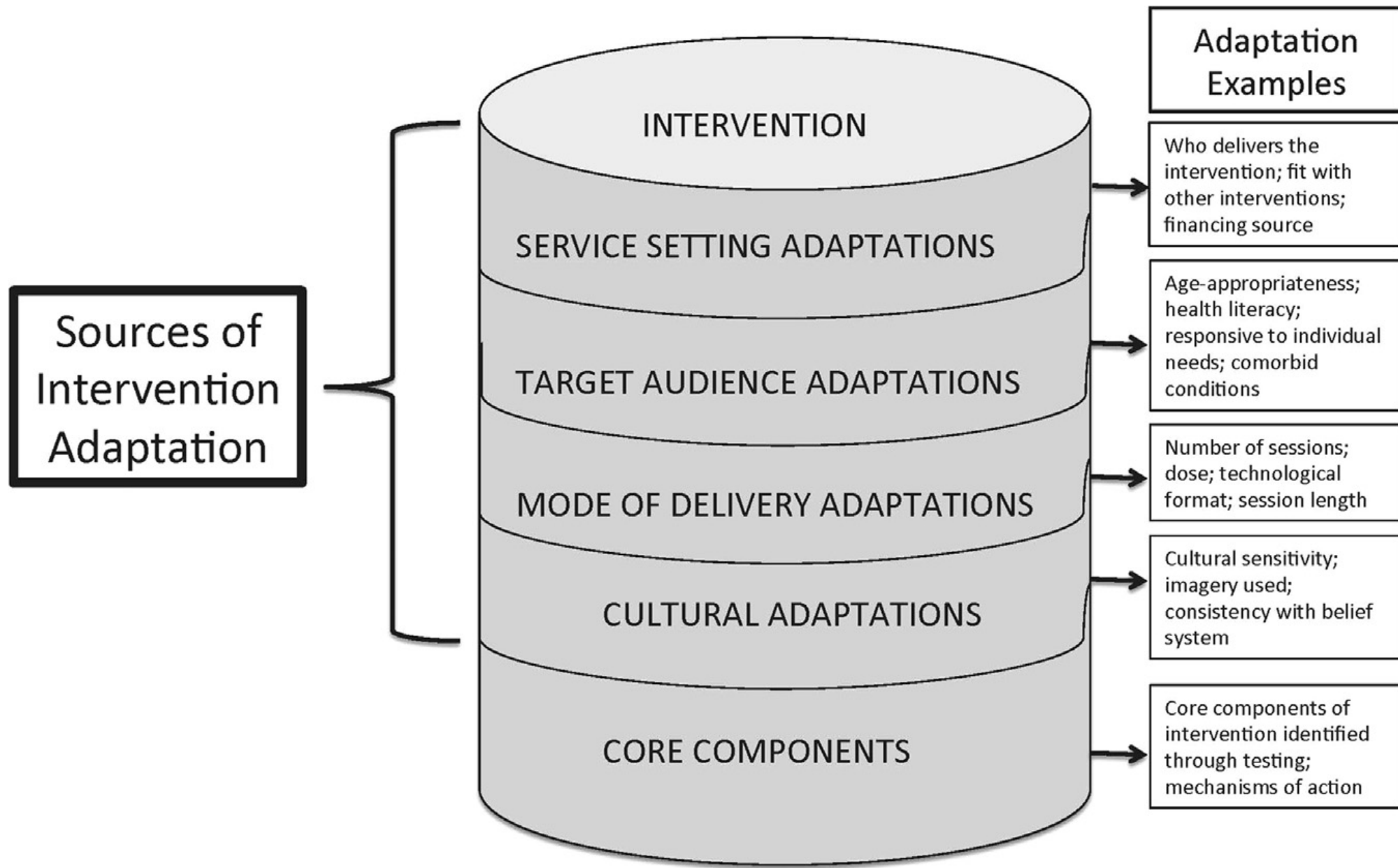
# Resource Informative

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- Need to know *implementation costs* (as conducted) and *replication costs* (under different conditions)
- Need to report staff time, training, *recruitment*, supervision, delivery costs
- Do NOT need complete, comprehensive societal analyses of downstream consequences, etc.- unless for nationwide

# Implementing complex interventions: *“Adaptation happens”*

- Complex interventions usually **can be, will be** and **should be** adapted
- Adaptation should be:
  - embraced, studied, and guided *rather than*
  - ignored, and/or
  - suppressed



# Evolution of RE-AIM

- Applied to many different content areas- over 450 articles
- Setting level factors reported much less often (e.g., adoption)
- Guides for application and reporting; other resources at [www.re-aim.org](http://www.re-aim.org)
- Focus on transparent reporting and replication

Focus on  
Context!

## NEW AREAS

Costs and resources

Adaptations

Patient centered  
outcomes research

Qualitative RE-AIM  
assessments

## FIT among:

- Intervention
- Implementation strategy
- Context
- -----
- You can't have it all- interactions

## Changing Outer Context

PRISM External Environment (e.g., policy, guidelines, incentives)



## Changing Internal Context

PRISM factors of

- Organizational & Patient Characteristics
- Organizational & Patient Perspectives (values)
- Implementation & Sustainability Infrastructure

## Crosscutting issues

- Proportion who benefit
- Representatives of the who benefit
- Reasons: how and why they benefit
- Adaptations made
- Costs incurred

All models (and methods) are wrong...  
Some are useful

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*“To every complex question,  
there is a simple answer...  
and it is wrong.”*

~H. L. Mencken



# Implementing a Multicomponent Intervention to Improve Hypertension Control in Central America

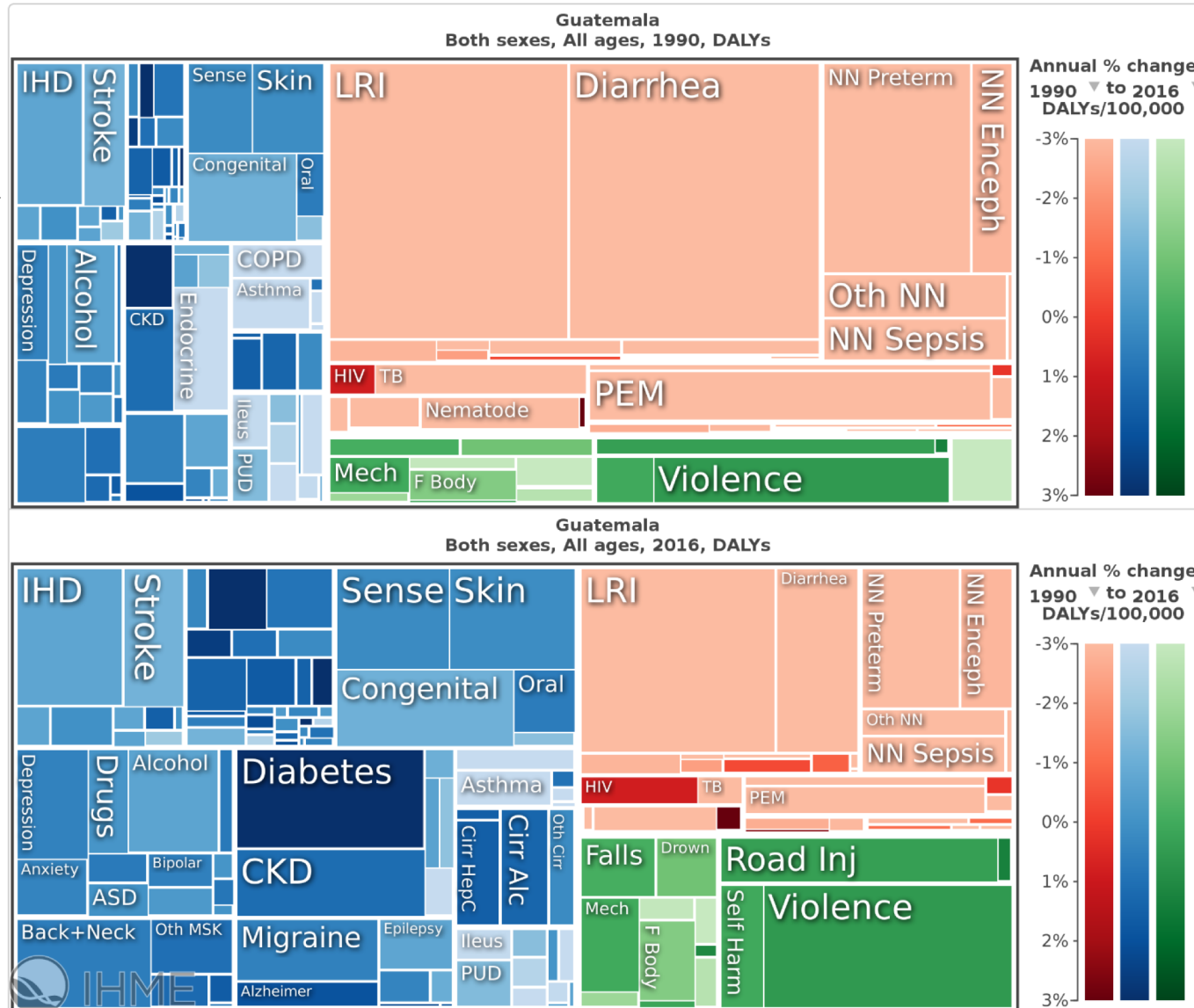


- Evidence-based program implemented in Argentina
- Adaptation to Guatemalan context
- Institutions: Institute of Nutrition of Central America and Panama (INCAP), Institute for Clinical Effectiveness and Health Policy (IECS), Tulane, U. of Colorado, Guatemalan Ministry of Health and Social Welfare
- Funded by NHLBI (HyTREC)

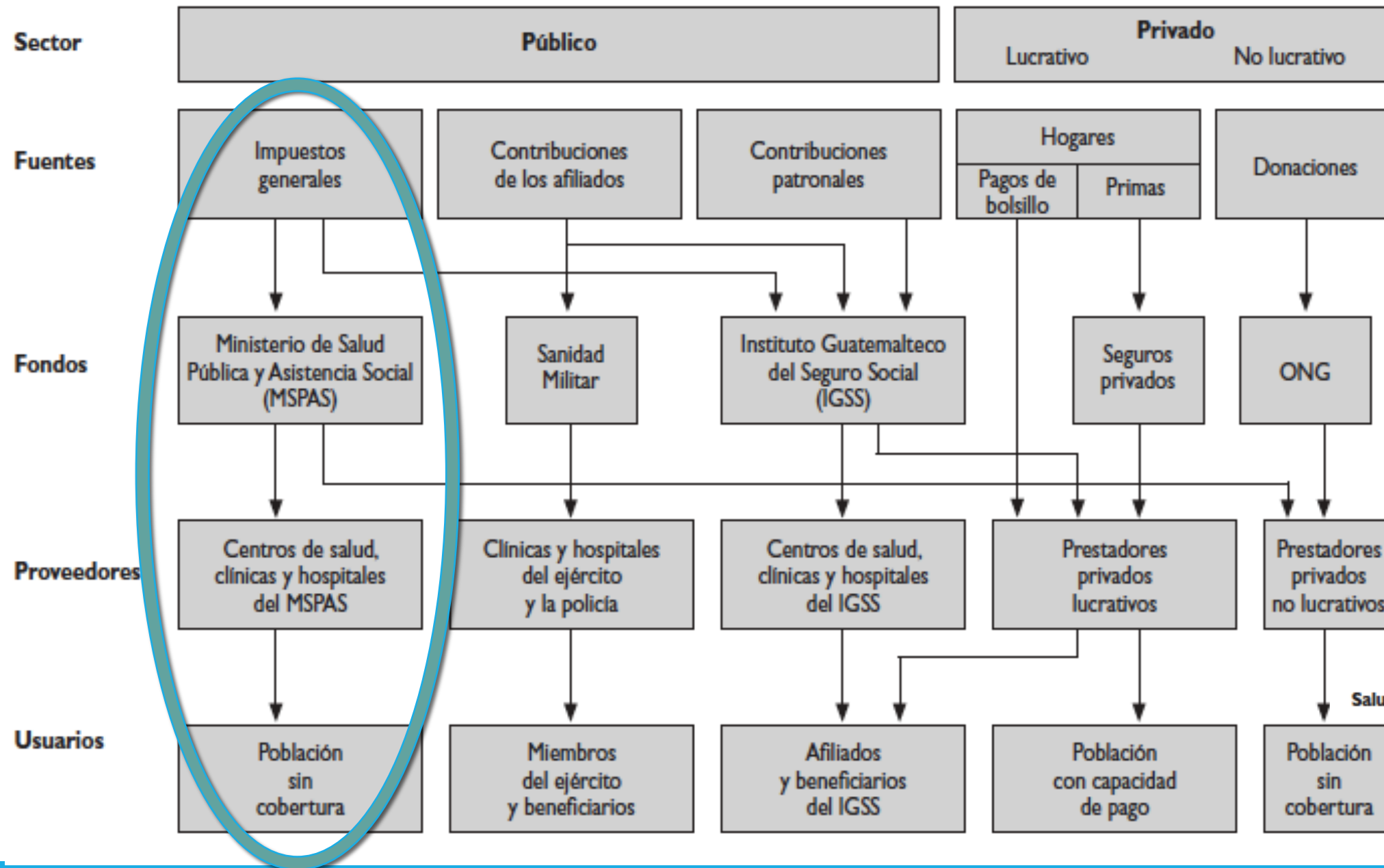




# Double Burden of Disease



Source:  
Institute of Health Metrics and  
Evaluation (IHME). GBD Compare  
Data Visualization. Seattle, WA:  
IHME, University of Washington,  
2017. Available from:  
[http://www.healthdata.org/data-  
visualization/gbd-compare](http://www.healthdata.org/data-visualization/gbd-compare)  
(Accessed: October 3, 2018)



# Health System Overview

Source:

Becerril-Montekio V, López-Dávila L.  
Sistema de salud de Guatemala.  
Salud Publica Mex 2011;53 supl 2:S197-S208.

# Multi-Component Intervention Program

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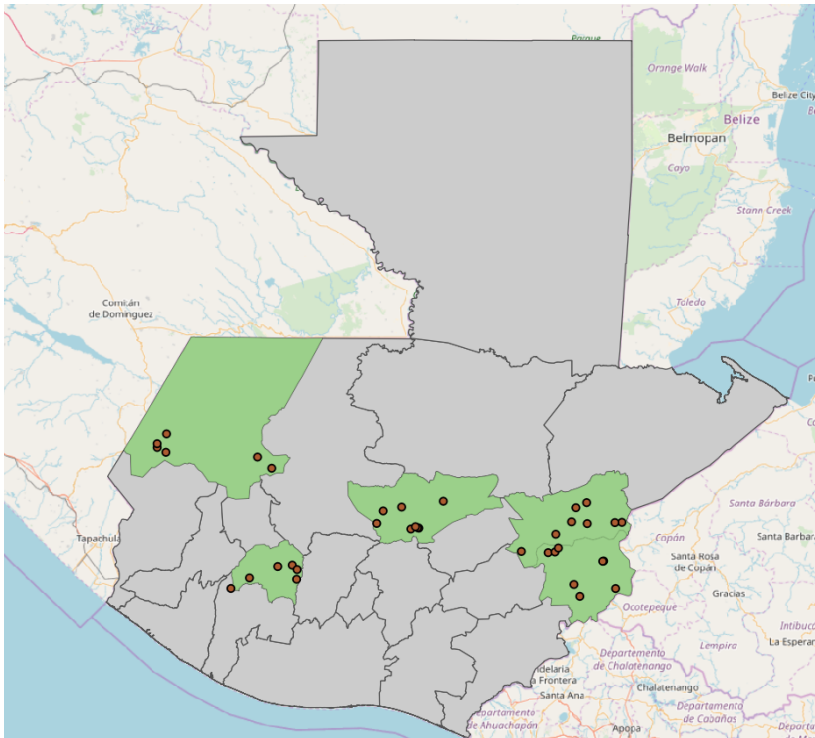
1. Protocol-based treatment (stepped-care protocol using a standard-treatment algorithm)
2. Education for health care workers
3. Team-based collaborative care
4. BP audit and feedback
5. Home BP monitoring
6. Health coaching (auxiliary nurses)



Drawing on materials developed in a previous NHLBI-funded project implemented in Guatemala.

# Setting and Design

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- Hybrid Type 2 Effectiveness-Implementation
- Cluster Randomized Trial (beginning in 2019)
- 36 districts in Guatemala's public primary health care system.
  - 5 departments/Health Areas
  - Health center, 2 health posts per district
  - About 10 languages spoken (24 in the country)



Health post within the primary care level of Guatemala's public sector, staffed by 1-2 auxiliary nurses.

# Needs Assessment

Building block	Long-term needs	Needs that may be addressed through the intervention
Service delivery	<ul style="list-style-type: none"> <li>• Insufficient coverage</li> <li>• Limited supplies and physical infrastructure</li> <li>• Limited emphasis on the primary level of care</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment guidelines are not available to all providers</li> <li>• Hypertension is detected by chance</li> <li>• Communication gaps between levels of care</li> </ul>
Human resources	<ul style="list-style-type: none"> <li>• Auxiliary nurses (key primary care providers) have basic training with an MCH emphasis</li> <li>• Contracts vs. budgeted positions increasingly common</li> <li>• Staff turnover</li> </ul>	<ul style="list-style-type: none"> <li>• Limited training in NCDs</li> </ul>
Information system	<ul style="list-style-type: none"> <li>• Lack of electronic infrastructure/connectivity</li> <li>• NCDs do not have indicators that are routinely tracked</li> <li>• Focus on service production</li> </ul>	<ul style="list-style-type: none"> <li>• Forms and processes used for clinic visits are not standardized</li> <li>• Undercounting</li> <li>• Providers do not have a list of patients with hypertension – controlled/uncontrolled</li> </ul>
Medications and technologies	<ul style="list-style-type: none"> <li>• Lack of laboratory capacity</li> </ul>	<ul style="list-style-type: none"> <li>• Variability in the availability of medications (early/late in the year)</li> <li>• Limited administrative capacity to request needed quantity of medications</li> </ul>
Financing	<ul style="list-style-type: none"> <li>• Low public investment in health</li> <li>• High out-of-pocket costs</li> <li>• No estimate of the cost of care for patients with hypertension</li> </ul>	
Leadership/governance	<ul style="list-style-type: none"> <li>• Lack of a national plan (changes with each administration)</li> <li>• Absence of high-level support for NCDs</li> <li>• Lack of investment in regulation/health promotion</li> <li>• Need to increase inter-sectoral collaboration</li> </ul>	<ul style="list-style-type: none"> <li>• Patients with hypertension have not demanded treatment</li> </ul>

Source: WHO. *Everybody's Business: Strengthening Health Systems to Improve Health Outcomes* (Geneva: World Health Organization, 2007).



# Adaptation Workshops (June-August)

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# RE-AIM Assessment

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- Assessing Patient, Provider, and Systems Levels
- Mixed Methods
- Data capture:
  - Every 6 months
  - 18-20 local data gatherers, central-level research team members (patient and provider levels), 2 Research Assistants (system level)

# RE-AIM Measures

RE-AIM	Patient	Provider	System
<b>R</b>	<ul style="list-style-type: none"><li>• # participants/total eligible</li><li>• <b>Representativeness:</b> age, M/F, language, literacy, SES, distance (home to health post)</li></ul>		
<b>E</b>	<ul style="list-style-type: none"><li>• BP control</li><li>• Increased knowledge about heart healthy behavior</li><li>• Quality of life</li><li>• Stage of change</li><li>• Adherence to medications</li><li>• Heterogeneity of effects</li></ul>	<ul style="list-style-type: none"><li>• % of patients who achieve BP control</li><li>• Provider's increased knowledge about heart healthy behavior/guidelines</li><li>• % patients who achieve adequate adherence to medications</li></ul>	



# RE-**AIM** Measures

RE-AIM	Patient	Provider	System
<b>A</b>		<ul style="list-style-type: none"> <li>• # aux. nurses participating/trained</li> <li>• Provider age &amp; years of experience</li> <li>• Provider characteristics: non-, early, &amp; late adopters</li> </ul>	<ul style="list-style-type: none"> <li>• Composition of teams</li> <li>• Distance: health posts to health center</li> <li>• Setting characteristics: non-, early, &amp; late adopters</li> </ul>
<b>I</b>	<ul style="list-style-type: none"> <li>• # home BP monitor readings/patient</li> <li>• Defined health goal</li> <li>• # &amp; location coaching sessions</li> <li>• Family member participation</li> </ul>	<ul style="list-style-type: none"> <li>• # of coaching sessions provided/ aux. nurse</li> <li>• Delivery location of coaching sessions</li> <li>• Referrals to support &amp; supervision team</li> <li>• <b>Adaptations</b> by providers</li> </ul>	<ul style="list-style-type: none"> <li>• Availability of medications, supplies</li> <li>• Process to coordinate w/district</li> <li>• Adaptations by district</li> </ul>
<b>M</b>	<ul style="list-style-type: none"> <li>• Sustained adherence to medications over time (12 and 18 months)</li> <li>• Sustained BP control over time (12 and 18 months)</li> </ul>	<ul style="list-style-type: none"> <li>• Intention to continue implementation beyond the project period.</li> </ul>	<ul style="list-style-type: none"> <li>• Intention to continue implementation beyond the project period.</li> <li>• Cost-effectiveness</li> </ul>

# Current Study Considerations

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## Recruiting with **equity** in mind

- “Inverse care law”; Tudor Hart J. The inverse care law. *Lancet*. 1971 Feb 27;1(7696):405–12.

## **Data collection instruments:**

- Auxiliary nurses and district team vs. research study team
- Qualitative and quantitative data capture

## **Adaptations:** up-front and during the intervention

## Defined opportunities for review and feedback by authorities, health staff and patients

- Community Advisory Board, local level feedback sessions

## **Sustainability:**

- Integrate the intervention into primary health care teams' workflow
  - Task shifting vs. task multiplication (Pfeiffer J and Chapman R. The art of medicine: an anthropology of aid in Africa. *Lancet*. 2015 May 30 (385): 2144-5.)
- Contribute to a virtuous cycle of health system strengthening/ increased focus on NCDs
- Consider ways to address long-term system level needs



IF AN INTERVENTION WORKS

AND NOBODY CAN USE IT.....

DOES IT STILL MAKE AN IMPACT?

# Future Evidence Needs and Opportunities— Keys to Advance Translation

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- Health equity impacts
- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice

# THE FUTURE OF RE-AIM?

Application to Comparative Effectiveness Research  
(CER- T)

Transparency focus ('Expanded CONSORT figure\*')

What it means to “Use RE-AIM”

Possible Directions:

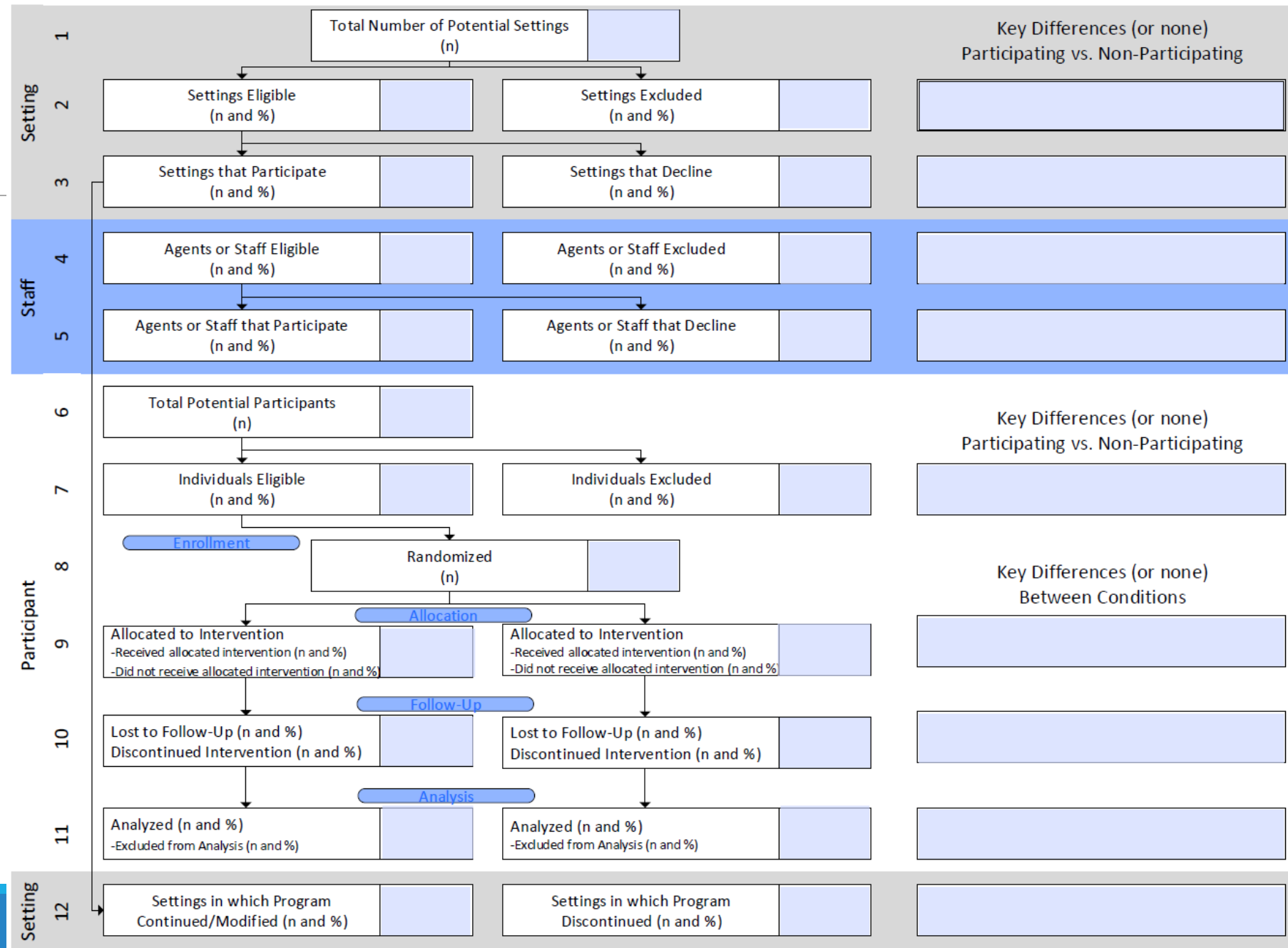
Merge with PRECIS-2 model\*?

**Your IDEAS WELCOMED!**



\*Glasgow RE, Huebschmann A, Brownson RC. (2018) *American Journal of Preventive Medicine*  
Kessler RS, et al. What Does It Mean to "Employ" the RE-AIM Model? *Eval Health Prof.*, 2012 Mar;36, 44-46

# Expanded Consort Figure



# General Resources

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- Brownson RC, Colditz GA, & Proctor EK (2018). *Dissemination and implementation research in health: Translating science to practice*. Oxford University Press. 2<sup>nd</sup> Edition.
- [re-aim.org](https://re-aim.org)
- <https://rtips.cancer.gov/rtips/index.do>
- [www.ucdenver.edu/accords/implementation](http://www.ucdenver.edu/accords/implementation)
- [www.Dissemination-Implementation.org](http://www.Dissemination-Implementation.org)

# EVIDENCE-BASED PROGRAM AND RE-AIM RESOURCES

## Highlights

**Purpose** Designed to increase breast cancer screening among low-income Korean-American women (2010)

**Program Focus** Awareness building, Behavior Modification and Self-efficacy

**Population Focus** Medically Underserved

### Self-rating Quiz Summary

Now that you've completed the self-rating, look at your score for each RE-AIM dimension. Each score can range from 0 to 10 -- the higher the better. You'll want to pay particular attention to areas related to the lowest scores.

**Scores should be interpreted using this scale:**

- 9-10: Excellent
- 7-8: Good, but could use a little work
- 5-6: Fair, needs additional planning
- < 5: Poor, needs serious attention

It may be helpful to have several members of your team take this self-rating quiz and then compare and discuss your answers.

Find more [resources](#) for improving your scores.

[Printable Version](#)

### RE-AIM Scores

Reach	80.0%
Effectiveness	33.3%
Adoption	83.3%
Implementation	66.7%

### RE-AIM Notes

Use this area to take notes about how this program might work for you. [Read More about RE-AIM.](#)

- ▶ Reach
- ▶ Effectiveness
- ▼ Adoption
  - Absolute number, proportion and representativeness of settings and intervention agents willing and able to initiate the program.
  - Your overall rating of this program's **potential adoption** in your situation:  
☆☆☆☆☆
  - Barriers to adoption by sites and organizations:  
(No max # of characters)
- ▶ Implementation
- ▶ Maintenance

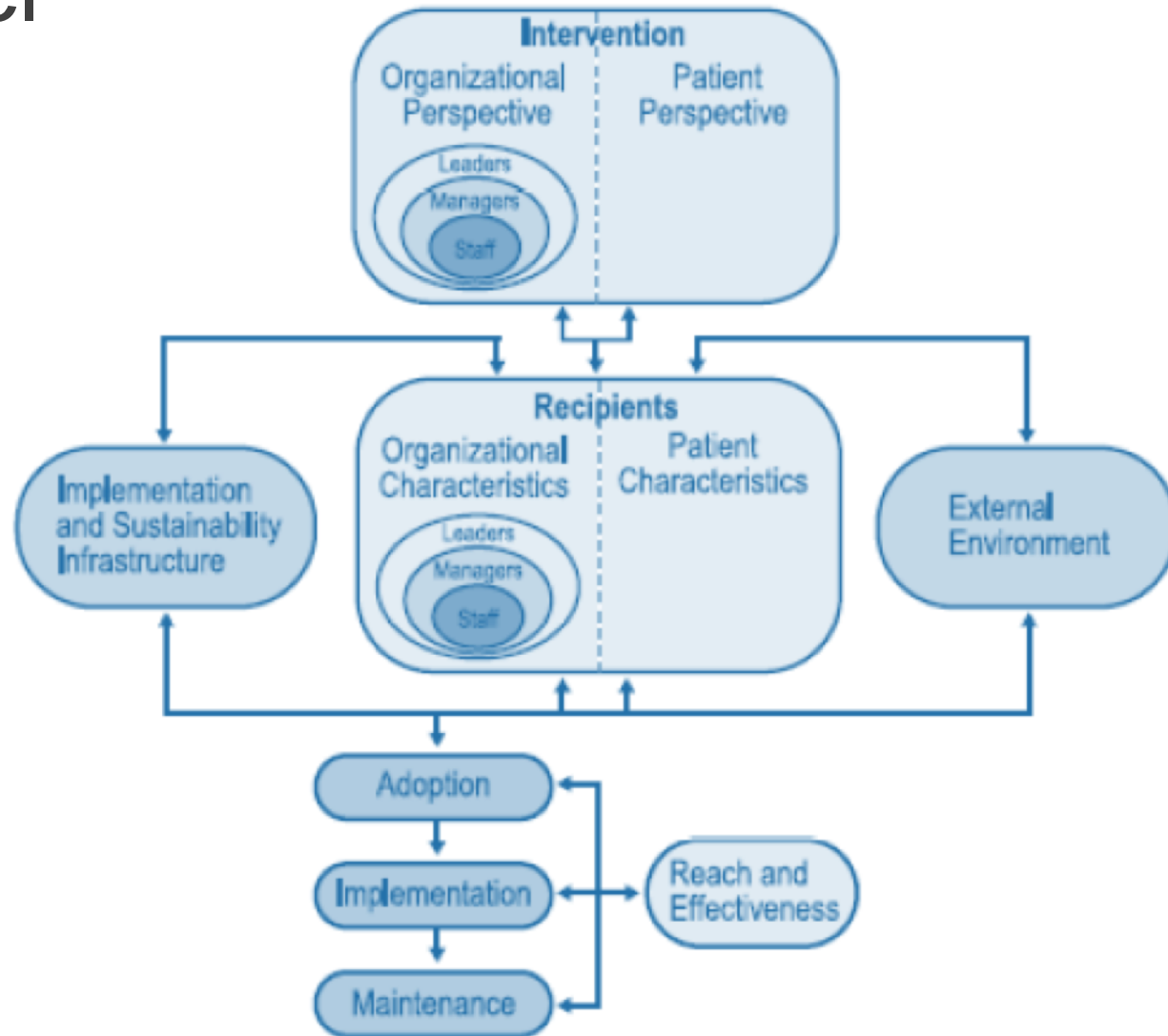
[http://re-aim.org/resources\\_and\\_tools/index.html](http://re-aim.org/resources_and_tools/index.html)

<http://rtips.cancer.gov/rtips/index.do>



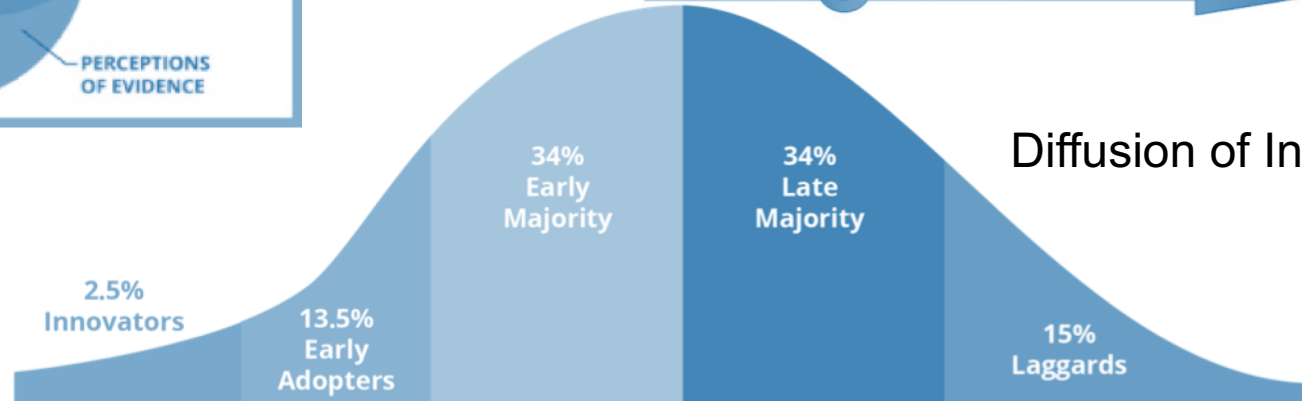
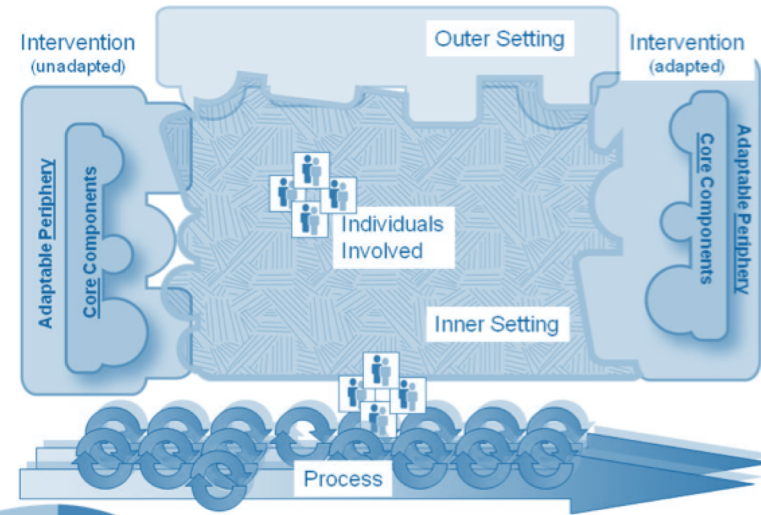
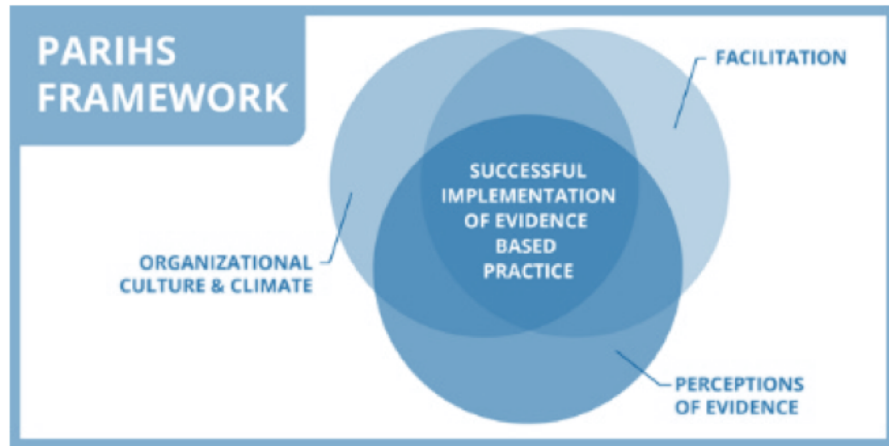
# Practical, Robust Implementation and Sustainability Model

Addresses Contextual  
Factors Impacting RE-AIM  
Outcomes



# Other Models

## Consolidated Framework for Implementation Research



Diffusion of Innovations

Over 91 D&I Frameworks: <http://dissemination-implementation.org/index.aspx>

Most Commonly used models in NIH grants: RE-AIM and DOI (now also CFIR)

**Many commonalities across models and theories**

# In Summary, D & I Science is about:

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- Multi-level, *contextual* issues and external validity
- Relevant, *pragmatic* models, research methods and measures
- Real-world implementation and *adaptation*
- Reducing, or at least not exacerbating *health inequities*
- *Designing* for dissemination, sustainability and equity
- *Normal science (T1– T2) is necessary but not sufficient*

# 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			

# Adaptation, Fidelity, and Tailoring Interest Group

- Began January 2016 as part of the IRG
- 61 members currently .... ***YOU ARE INVITED TO JOIN***
- Representation from many VA QUERI research programs
- Co-chaired by Borsika Rabin, MPH, PhD, PharmD and Russell Glasgow, PhD; Facilitated by Christine P. Kowalski, MPH
- Meet monthly to discuss topics related to adaptation, tailoring and fidelity with attention to clinical application. Discussions include how to define interventions and implementation strategies, as well as how to describe and document adaptations.

*For information or to join contact: [Christine.Kowalski@va.gov](mailto:Christine.Kowalski@va.gov)*

# Key Differences Between Traditional Efficacy RCTs and Pragmatic Controlled Trials (PCTs)

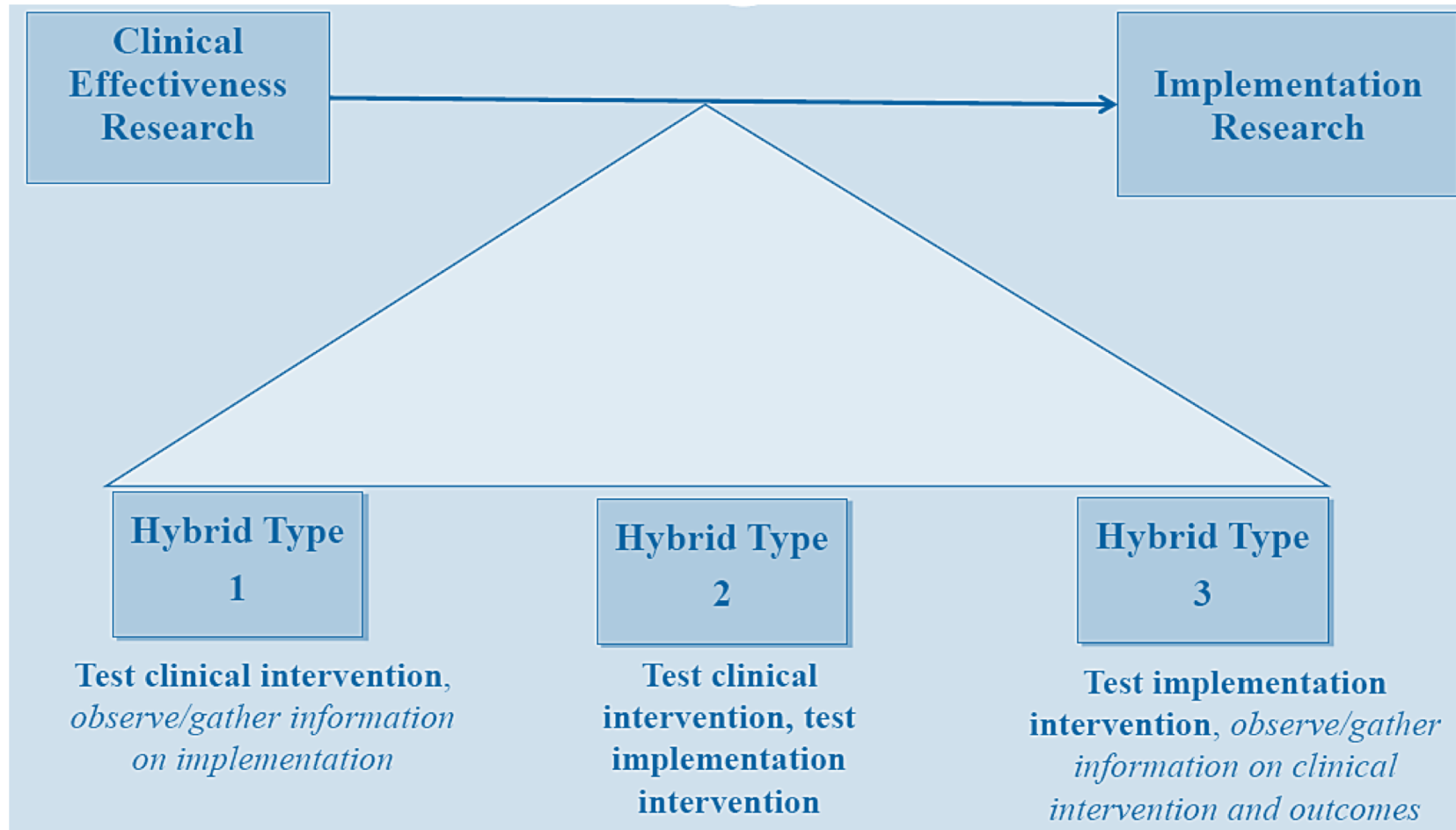
	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
GOALS	To <b>determine causes</b> and effects of treatment	To improve practice <b>and inform clinical and policy decisions</b>
DESIGN	Tests the intervention against <b>placebo, using rigid study protocols and minimal variation</b>	Tests two or more real-world <b>using flexible protocols &amp; local customization</b>

# Key Differences Between Traditional Efficacy RCTs and Pragmatic Controlled Trials (PCTs) - cont'd

	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
PARTICIPANTS	Highly defined and carefully selected	<b>More representative</b> because eligibility criteria are less strict
MEASURES	Require data collection outside routine clinical care	<b>Brief and designed so data can be easily collected in clinical settings</b>
RESULTS	Rarely relevant to everyday practice	Useful in everyday practice, especially clinical decision-making



# Effectiveness-Implementation Hybrid Designs



# Evidence-Based...on what?

## External Validity/ Pragmatic Criteria (often Ignored)

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

## Pragmatic D&I Bottom Line Question

***“What program/policy components are most effective for producing *what 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 come about?”***

NOT possible to address all these issues in any one study....  
BUT should consider each or them **pragmatically and transparently; then** select and report those most relevant.