

# Overview and Examples of Dissemination and Implementation (D&I) Research

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## *Acknowledgments*

Ross Brownson, David Chambers, Amy Kilbourne, Borsika Rabin  
and the other great researchers cited throughout this talk



ACCORDS

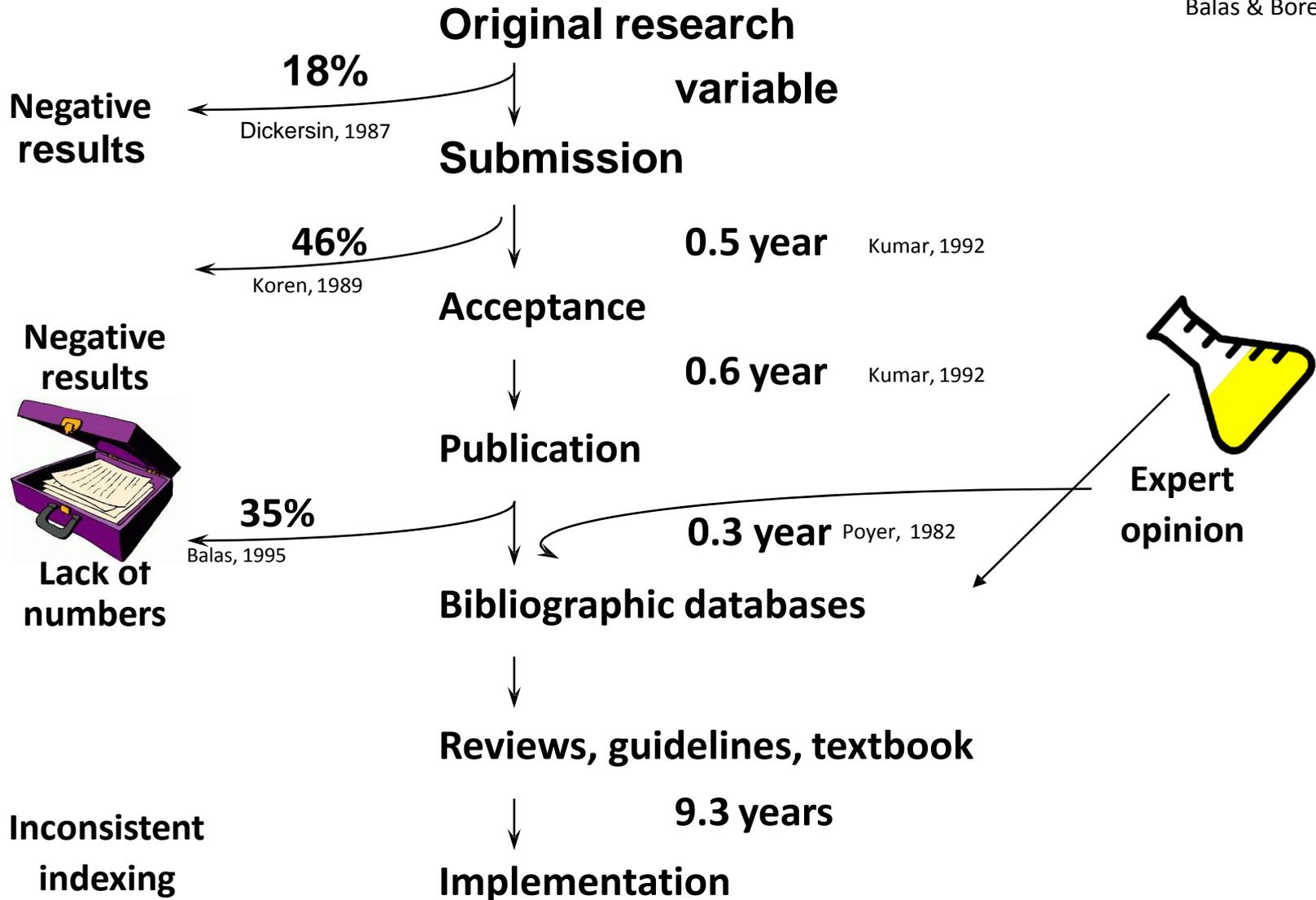
ADULT AND CHILD CONSORTIUM FOR HEALTH OUTCOMES  
RESEARCH AND DELIVERY SCIENCE

UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO

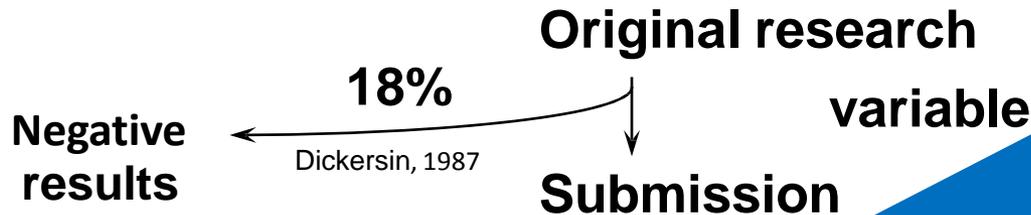
# Objectives

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1. Describe the rationale for and key characteristics of D&I research
2. Discuss the differences among D&I, pragmatic and effectiveness research
3. Discuss the RE-AIM framework and example applications pertaining to equity
4. Introduce current concepts central to D&I research including adaptation  
.....
5. Planning D&I research- key issues in applying the above to your research
6. Share resources and future opportunities



“PUBLICATION PATHWAY” and associated lag times



Negative results



opinion

**It takes 17 years to transform  
14% of original research  
into the benefit of patient care**

Incompleteness, textbook

9.3 years

index implementation

“PUBLICATION PATHWAY”

# Need for Pragmatic D&I Research

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- Traditional biomedical RCTs study the effectiveness of treatments delivered to carefully selected populations **under ideal conditions**
- Even when we do implement a tested intervention into **everyday clinical practice**, we often see a “voltage drop”...a dramatic decrease in effectiveness
- Most common reason evidence-based programs are not adopted...they are **not seen as relevant**

“If we want more evidence-based practice, we need more practice-based evidence.”

Green LW

*Am J Pub Health* 2006

# Some Remedies and Key Terms

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- **Implementation science** is the study of methods to promote the *integration of research findings and evidence* into healthcare policy and practice.
- **Dissemination research** is the scientific study of *targeted distribution of information and intervention materials* to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.
- **Implementation research** is the scientific study of the *use of strategies to adopt and integrate* evidence-based health interventions into clinical and community settings to improve patient outcomes and benefit population health.
- **Pragmatic research** is the use of *real-world tests* in real-world populations and situations.

# A Big Tent of Terms (and ovals)\*

Health (and Community) Services

Health Services Research

Dissemination  
Research

Health  
Communication  
Research

Implementation  
Research

Quality  
Improvement  
Science

Pragmatic  
Research

Implementation Science

QI

\* The terms according to D.A.C.

Adapted from Mitchell S, Chambers, D. <https://doi.org/10.1200/JOP.2017.024729>;

# Key Characteristics of D&I Science

Point #	Characteristic	Implication
<b>SYSTEMS PERSPECTIVE</b>		
1	Context is critical	Research should focus on and describe context
2	Multilevel complexity	Most problems and interventions are multilevel and complex
3	Focus on systems characteristics	More emphasis needed on interrelationships among system elements and systems rules
<b>ROBUST, PRACTICAL GOALS</b>		
4	Representatives and reach	Focus on reaching broader segments of population and those most in need
5	Generalizability	Study generalization (or lack of such) across settings, subgroups, staff, and conditions
6	Pragmatic and practical	Producing answers to specific questions relevant to stakeholders
7	Scalability and sustainability	From outset, greater focus on scale-up potential and likelihood of sustainability

Glasgow RE, Chambers D. Developing robust, sustainable, implementation systems using rigorous, rapid and relevant science. *Clin Transl Sci.* 2012;5(1):48

# Key Characteristics of D&I Science (cont)

Point #	Characteristic	Implication
<b>RESEARCH METHODS TO ENHANCE RELEVANCE</b>		
8	Rigorous	Identify and address plausible threats to validity in context of questions. Greater focus on replication.
9	Rapid	Approaches that produce faster answers
10	Adaptive	Best solutions usually evolve over time, as a result of informed hypotheses and mini-tests with feedback
11	Integration of methods; triangulation	For greater understanding, integrated Quantitative and Qualitative methods are often required
12	Relevance	Relevance to stakeholders should be top priority
<b>FLEXIBILITY</b>		
13	Multiplicity	Encourage and support diverse approaches with the above characteristics (all models are wrong)
14	Respect for diverse approaches; humility	Different perspectives, goals, methods and approaches are needed. Continuing the same existing approaches will produce the same unsatisfactory results.

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



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

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**Even if 100% effective...** is only so 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:**  $.5x .5x .5x .5x .5 = 3\%$  benefit

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

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

# Types of Outcomes in Implementation Research- focus on setting and staff delivery

Implementation Outcomes	Service Outcomes	Client Outcomes
Acceptability	Efficiency Safety	Satisfaction
Adoption	Effectiveness	Function
Appropriateness	Equity	Symptoms
Costs	Patient-centeredness	
Feasibility	Timeliness	
Penetration		
Sustainability		

Proctor E, Silmere H, Hensley M, et al. Outcomes for implementation research: *Administration and policy in mental health*. 2011;38(2):65-76.



IF AN INTERVENTION WORKS

AND NOBODY CAN USE IT.....

DOES IT STILL MAKE AN IMPACT?

# Outcomes In D&I Science vs. Effectiveness Research

Characteristics of Outcomes and Measures	D&I Outcomes and Measures	HSR and Clinical Effectiveness Outcomes and Measures
<b>Focus</b>	<b>Delivery</b> and implementation issues (aka process: feasibility, fidelity, adoption, reach)	<b>Clinical outcome</b> or measure of control
<b>Breadth</b>	<b>Multiple</b> levels and outcomes, broad focus, systems perspective	Narrower focus; often a <b>single primary outcome</b>
<b>Preferred Modality</b>	<b>Multiple</b> - observation, interview, tracking forms	<b>Biological</b> (e.g., BP, A1c); more recently data in the EHR
<b>Expense And Intensiveness Of Assessment</b>	Brief, low burden, <b>pragmatic</b>	Often expensive, requires expert assessment; emphasis on blinding when possible
<b>Level And WHO Is Assessed</b>	<b>Setting, staff</b> and end users	Usually <b>patients</b>

# A Different Approach: Pragmatic Research for Population Health

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## **Explanatory (Efficacy or Effectiveness) trial:**

Specialized experiment in a **specialized population**

**Pragmatic trial: Real-world** test in a real-world population

## **Pragmatic designs emphasize:**

- Participation or reach
- Adoption by diverse settings
- Ease of Implementation
- Maintenance

**Generalizability**

Maclure, M. (2009). Explaining pragmatic trials to pragmatic policy-makers. *Canadian Medical Association Journal*, 180(10), 1001-1003.

Glasgow (2012). What does it mean to be pragmatic? *Health Education and Behavior*, June;40(3):257-65.

# Main Difference

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- A pragmatic trial is a **real-world** test in a real-world population, whereas an explanatory (efficacy) trial is a **specialized experiment** in a specialized population
- Pragmatic **does not mean** being less rigorous

# Differences Between Traditional RCTs and Pragmatic Controlled Research 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 and <b>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>
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

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

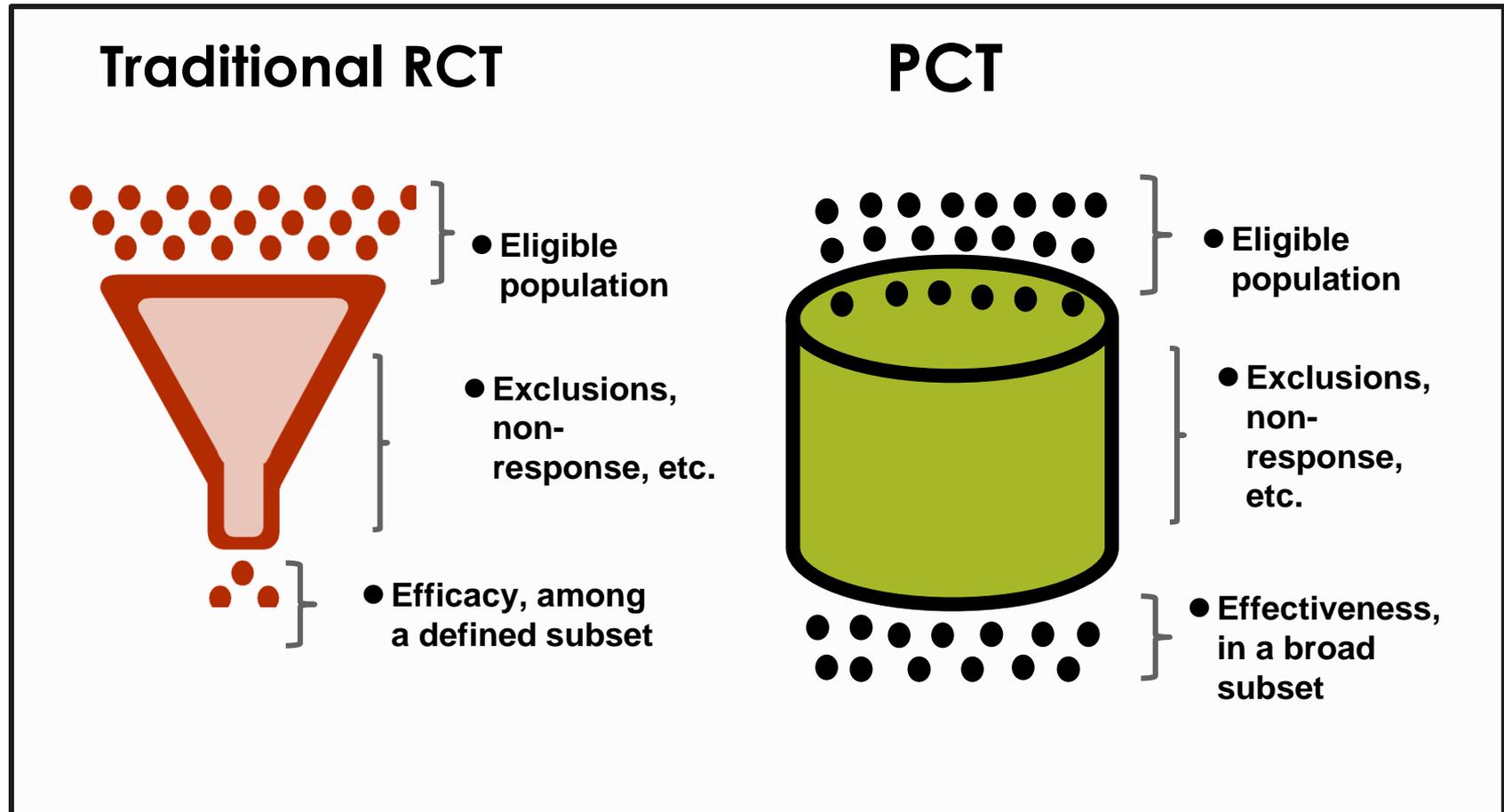


Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research

# Pragmatic vs. Explanatory (efficacy) trials

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Among families in a rural Wisconsin town, can receiving primary care from a nurse-practitioners (compared to a family physician) produce high levels of physical, social, and emotional function (as good as those achieved by a family physician)?

# An explanatory (efficacy/effectiveness) question

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- Can nurse practitioners produce good health outcomes under IDEAL circumstances
  - Comprehensive training of the trial nurses, with frequent refresher courses and close monitoring
  - Who are caring for highly compliant patients who have one chronic condition of interest (e.g., diabetes)- no other
  - Who see their patients very frequently, offer long visits and out of hours care etc.

# Conclusions from an explanatory trial

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- A 'no' answer is informative BUT,
- A 'yes' answer doesn't settle the pragmatic issue:
  - Would NPs be effective under the usual circumstances (less intensive training and monitoring, caring for typical patients, and seeing them only during illnesses or for routine preventive care)?

# A Pragmatic Question

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- Will NPs produce good health outcomes under usual circumstances?
  - Routine training of the trial nurses with no refresher courses or monitoring
  - Who are caring for typical, 'complex' comorbid patients
  - Who are seen only when ill or for routine preventive care

# Conclusions from a pragmatic trial

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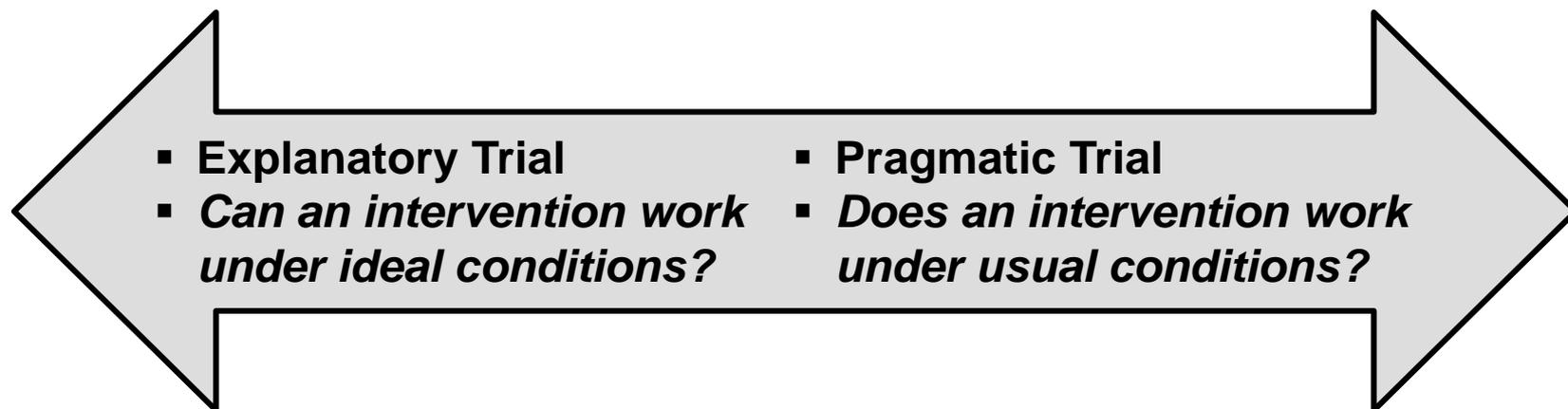
- A 'yes' answer is informative BUT,
- A 'no' answer does not settle the question:
  - Are NPs not capable or was their training defective, their patients nonadherent, or their patients subjected to an unusually high burden of illness?

# The Efficacy RCT-PCT Continuum

## Important Points about Pragmatic Research

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- PCTs are not an abandonment of the scientific methods that have led to countless breakthroughs.
- They don't take away from basic science or diminish the importance of traditional RCTs—we just need a balance.
- ***No study is completely explanatory or pragmatic.*** RCTs and PCTs exist on a continuum.



# The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) Planning Tool

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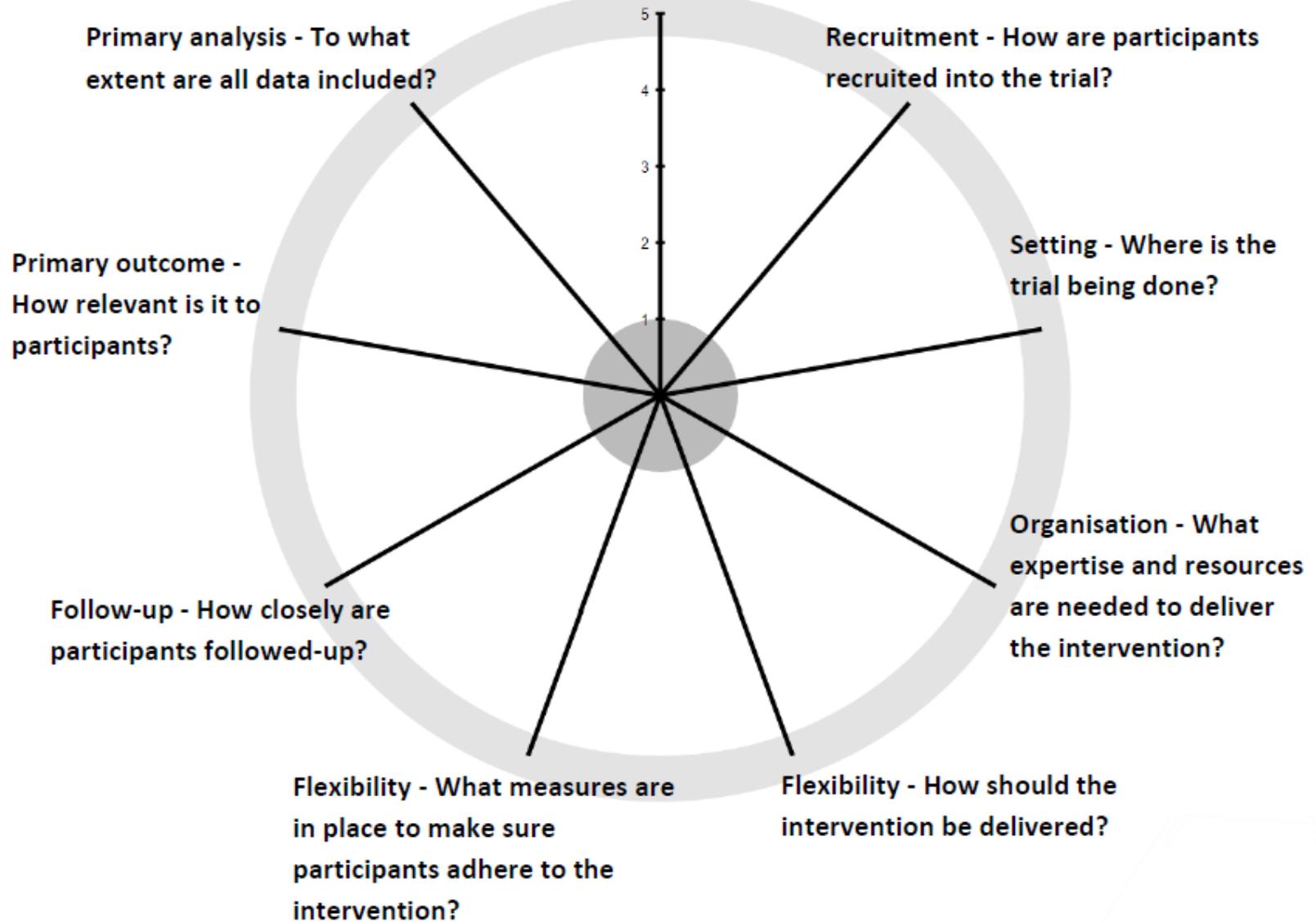
- How pragmatic is your study?
- Continuum along 9 dimensions: Not all or none (no completely pragmatic study)
- Tool to help in **planning** and **reporting** (see next slide)

Gaglio, B, et al. (2014). How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. *Implementation Science*, 9(1), 1.

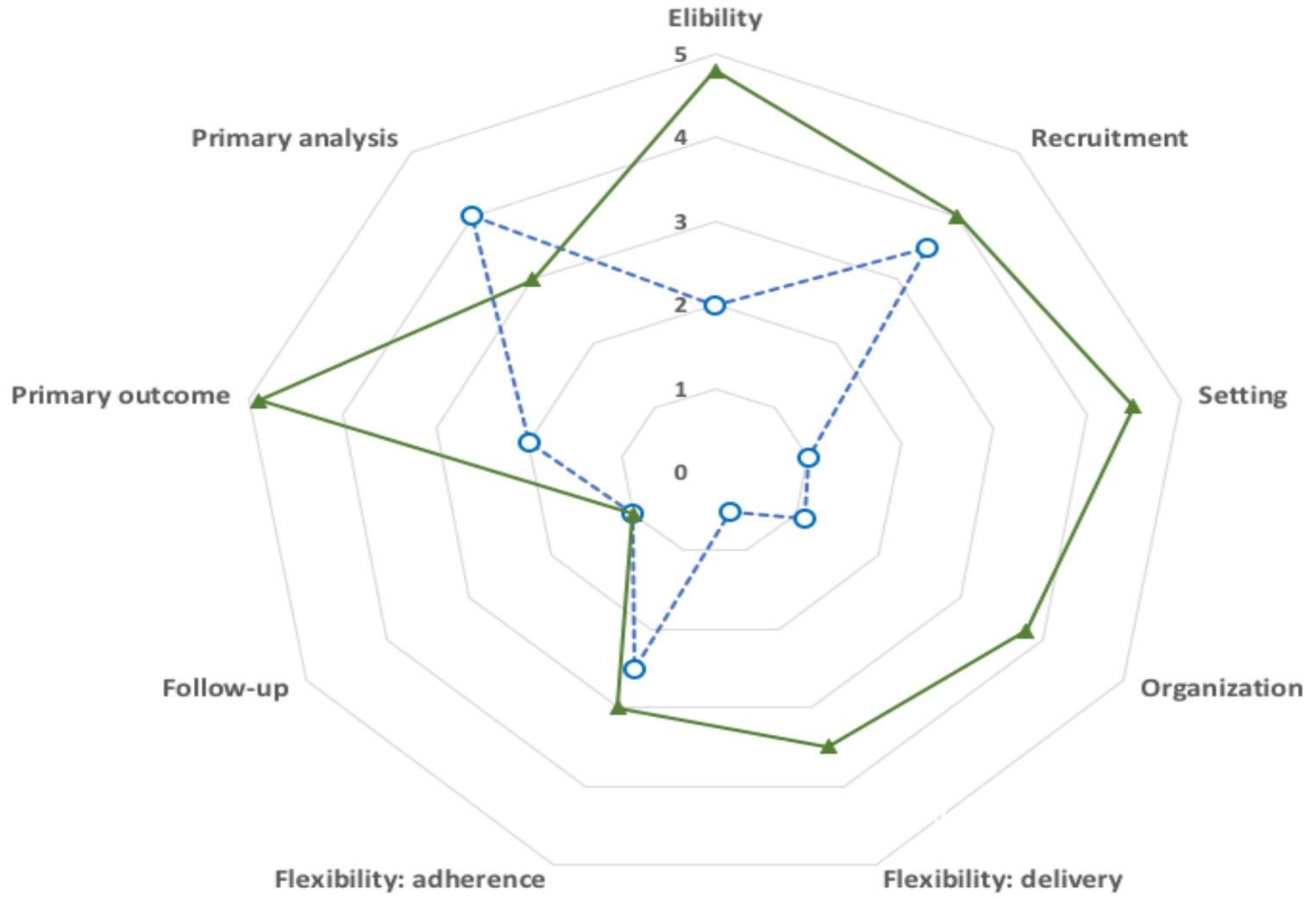
Thorpe KE, et al. A pragmatic-explanatory continuum indicator summary (PRECIS)...*CMAJ* 2009;180(10):E47-57.

Loudon K, Treweek S, Sullivan F, et al. (2015) The PRECIS-2 tool: Designing trials that are fit for purpose. *BMJ* 350:h2147.

**Eligibility – Who is selected to participate in the trial?**



# Example Studies on PRECIS-2 Wheel



# Lessons from PRECIS-2 Research

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- PRECIS-2 can be used to reliably rate protocols and completed studies
- The PRECIS-2 figure is a concise way of representing pragmatism across dimensions
- Discussion of (independently made) PRECIS-2 ratings among staff can help clarify design planning

<https://www.precis-2.org/> for rating criteria, figure, examples, etc.

# Pragmatic Study Methods: Key Characteristics

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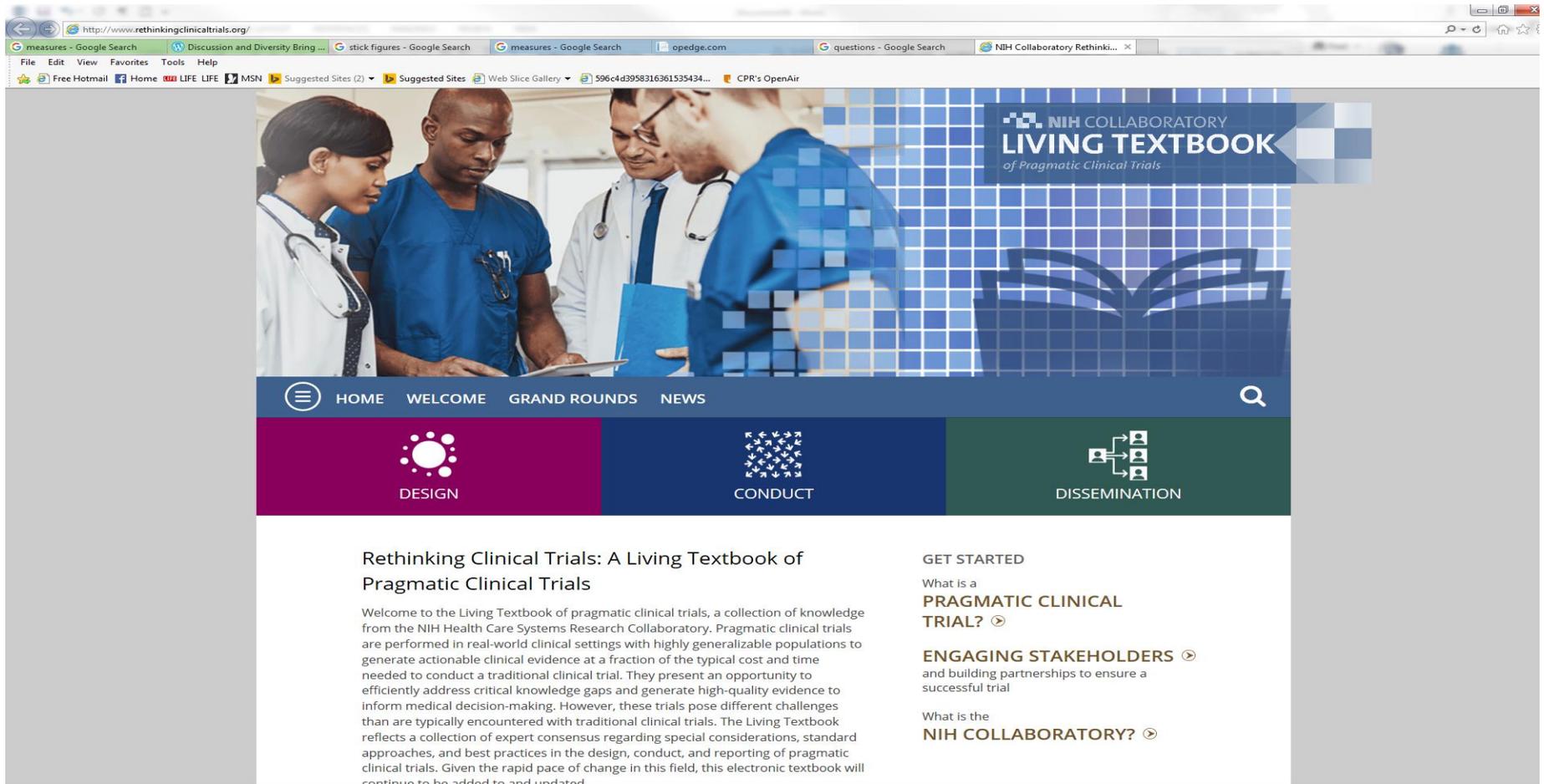
- Questions from and important to **stakeholders**
- Multiple, **heterogeneous settings**
- **Diverse** populations
- Comparison conditions are **real-world alternatives**
- Multiple outcomes **important to decision and policy makers**

Thorpe KE et al., *Can Med Assoc J*, 2009;180:E47-57

Tunis SR et al. Practical clinical trials...*JAMA* 2003;290:1624-1632

Glasgow RE et al. Practical clinical trials...*Med Care* 2005;43(6):551-557

# “Key New Pragmatic Resource from NIH Collaboratory on Pragmatic Trials”



measures - Google Search Discussion and Diversity Bring... stick figures - Google Search measures - Google Search opedge.com questions - Google Search NIH Collaboratory Rethinki... x

File Edit View Favorites Tools Help

Free Hotmail Home LIFE LIFE MSN Suggested Sites (2) Suggested Sites Web Slice Gallery 596c4d3958316361535434... CPR's OpenAir

NIH COLLABORATORY  
**LIVING TEXTBOOK**  
*of Pragmatic Clinical Trials*

HOME WELCOME GRAND ROUNDS NEWS

DESIGN CONDUCT DISSEMINATION

## Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials

Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials are performed in real-world clinical settings with highly generalizable populations to generate actionable clinical evidence at a fraction of the typical cost and time needed to conduct a traditional clinical trial. They present an opportunity to efficiently address critical knowledge gaps and generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than are typically encountered with traditional clinical trials. The Living Textbook reflects a collection of expert consensus regarding special considerations, standard approaches, and best practices in the design, conduct, and reporting of pragmatic clinical trials. Given the rapid pace of change in this field, this electronic textbook will continue to be added to and updated.

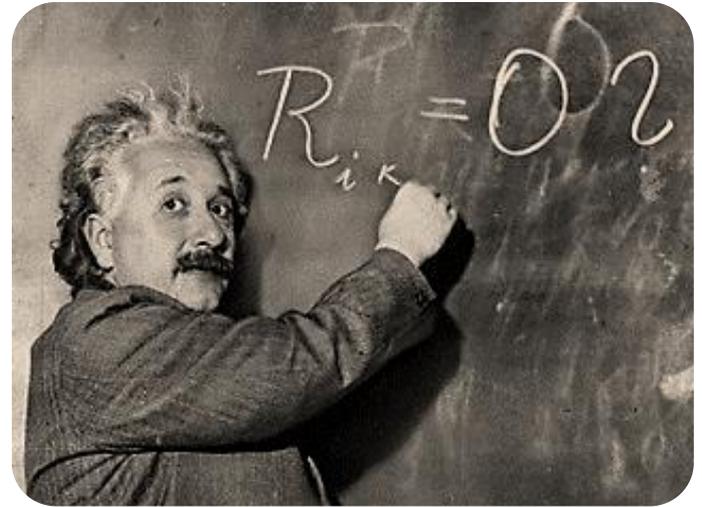
### GET STARTED

What is a **PRAGMATIC CLINICAL TRIAL?** >

**ENGAGING STAKEHOLDERS** >  
and building partnerships to ensure a successful trial

What is the **NIH COLLABORATORY?** >

<http://www.rethinkingclinicaltrials.org/>



*“The significant problems we face cannot be solved by the same level of thinking that created them.”*

Albert Einstein

# Pragmatic Models: RE-AIM and Expanded RE-AIM/PRISM

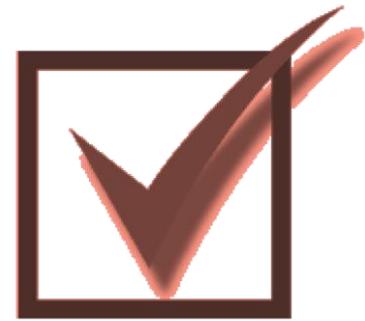


[www.re-aim.org](http://www.re-aim.org)

# 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 emphasizes representativeness/equity**
- Individual (RE) and Multi-level Setting (AIM) factors- community, organization, staff
- **Public health impact depends on all elements** (reach x effectiveness, etc.)



[www.re-aim.org](http://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 WHO applied it?
Implementation	HOW consistently is (was) the program or policy delivered? HOW will (was) it be <u>adapted</u> ? HOW much will (did) it <u>cost</u> ? WHY will (did) the results come about?
Maintenance	WHEN will (was) the initiative become operational; how long will (was) it be sustained (setting level); and how long are the results sustained (individual level)?

# RE-AIM—Health Equity Implications

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

**Take Home Message:** Equity issues at EACH STAGE of RE-AIM process



Be Fit Be Well: 24-month **randomized web-based weight loss** and hypertension self-management intervention trial among low-income urban primary care clinics) FQHCs).

- RE-AIM used to plan for and assess reduction in disparities, as well as evaluate outcomes



Bennett, et al. Obesity treatment for socioeconomically disadvantaged patients in primary care practice. *Arch Intern Med.* 2012;172(7):565-74

# Baseline Characteristics of Be Fit Be Well Participants

Characteristic	Usual Care (n=185)	Intervention (n=180)
Female	122 (66%)	128 (71%)
Non-Hispanic Black/African-American	131 (71%)	129 (71%)
Hispanic	23 (12%)	25 (14%)
Language n(%) Spanish	22 (12%)	23 (13%)
< High School Education	73 (40%)	47 (26%)
Unemployed	87 (47%)	86 (47%)
Medicare or Medicaid	99 (54%)	99 (55%)

One in-person visit, introduction to website with follow-up phone calls

Self-monitoring and feedback via CHOICE of

- Web,
- IVR and print

The screenshot shows the Be Fit Be Well website. At the top, there is a logo with a green stick figure and the text "Be Fit Be Well". To the right, a date box displays "Friday, April 18". Below the logo are three navigation tabs: "Tracking", "Healthy Habits", and "Action Plans".

**Main Menu**

- Home
- Tracking
- Healthy Habits
- Your Neighborhood
- Strength Training
- Recipes
- Logout

**Tasty and Delicious**

From soups and stews to desserts and drinks, we've got healthy recipes for every taste. See them all here!

**Your Raffle Points** **17**

Click here for more!

**Search this site**

search... Search

**Login**

Logout

**Welcome, Erica**

We hope you're enjoying Be Fit, Be Well!

Take a look at the boxes below. How are you doing so far? Are you getting close to your goals?

To enter your information, click on "Track this goal."

**Sugary Drinks**

We recommend that you avoid all sugary drinks.

Over the last 7 days, you had an average of 2 sugary drink(s) a day.

You're near your goal! Try to cut down on sugary drinks next week.

YOU HAVE TRACKED THIS GOAL TODAY

Track this goal

**Walking**

We recommend that you walk 10,000 steps every day. Your goal right now is 5,000 steps a day.

Over the last 7 days, you've walked an average of 5,709 steps(s) a day.

You're doing great! Keep up the good work.

YOU HAVE TRACKED THIS GOAL TODAY

Track this goal

**Your Medicine**

We recommend that you take your blood pressure medicine the right way every day.

It looks like you missed some days this week. Remember to enter your information on the site every day!

YOU HAVE TRACKED THIS GOAL TODAY

Track this goal

# Results



## REACH

- 60% of eligible population was invited to participate (604). **Of those, 365 (60%)** completed baseline and were randomized. Those who participated vs. those who did not, were younger and had a higher mean BMI. *No other differences* were found on demographics.

## EFFECTIVENESS\*

- At 24 months, intervention participants had **greater weight losses** compared with those receiving usual care (difference,  $-1.03$  kg; 95% CI,  $-2.03$  to  $-0.03$  kg)
- Mean systolic **blood pressure** was significantly lower in the Ix arm compared with usual care

\* *No differential patterns in outcomes observed for minority vs. non-minority or disparity- related sub-groups.*

# Results (cont.)



## ADOPTION

- All three centers invited, participated. Four centers were excluded for lack of EHR system
- 19 of 20 primary care physicians (**95%**) **referred** their patients to the program

## • IMPLEMENTATION

- **71% completion rate** for counseling calls; 63% of participants completing >70% of their calls
- English speakers were more likely to have goals, barriers and strategies documented ( $P < 0.0001$ ), as were participants making more than \$10,000 ( $P < 0.001$ )

## • MAINTENANCE

- Strong individual-level maintenance with ***no sub-group differences***, but at the setting-level **none of the centers** maintained the program components.

# Evolution of RE-AIM

Focus on  
Context!

- Applicability to many different content areas...more than 700 articles
- Used for both **planning and evaluation**
- Underreporting of key components:
  - **Setting level factors** reported much less often (e.g., adoption, maintenance)
- Increasing use of **qualitative measures and mixed methods approaches**

## NEW AREAS

Costs and resources

Adaptations

Patient centered  
outcomes research

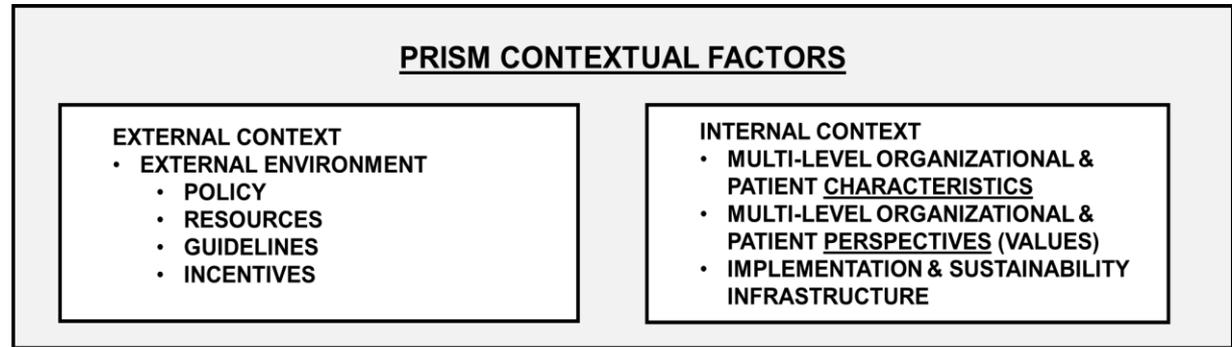
Qualitative RE-AIM  
assessments

# Context Issues from RE-AIM Perspective

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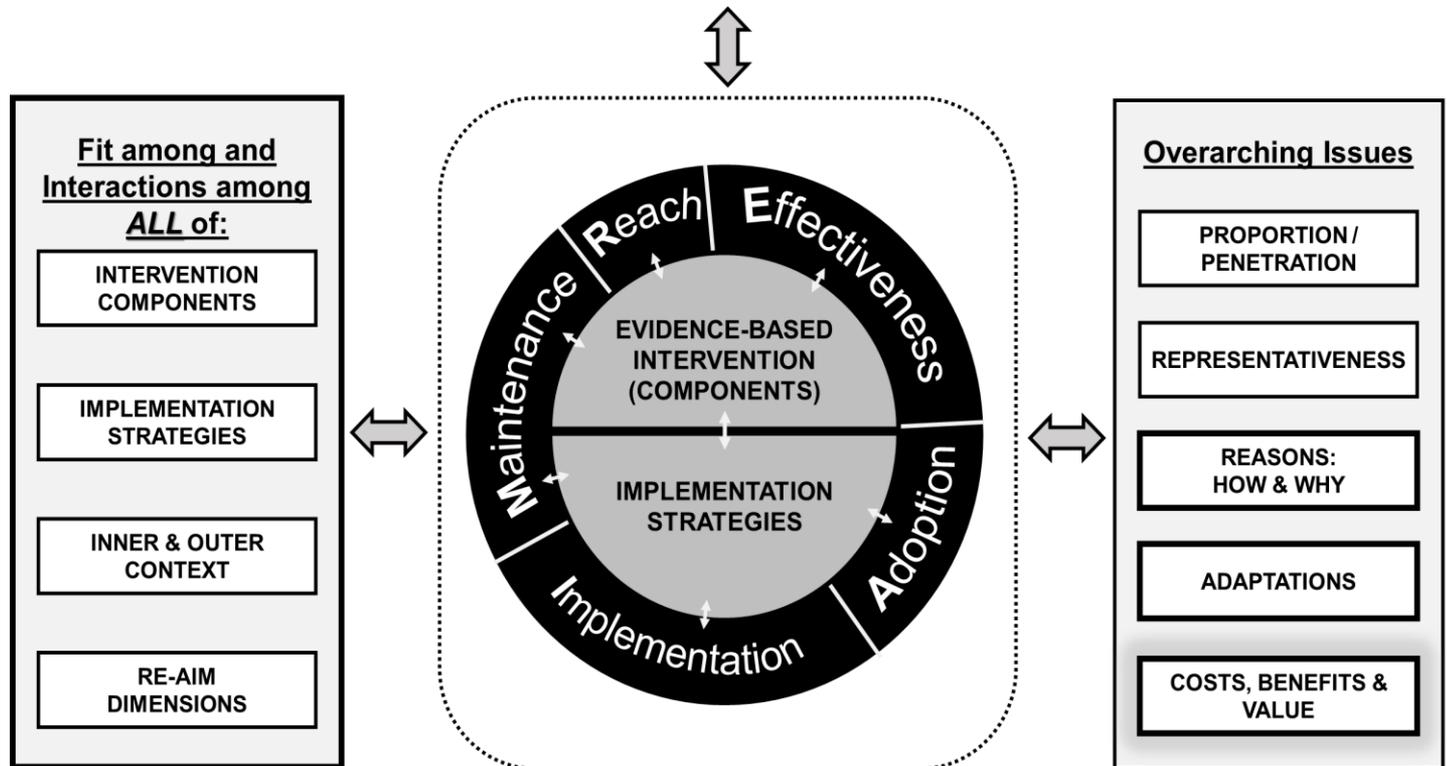
- **People exist in the context of culture and places in which they work, live, study and play**
- Context is **multi-level and dynamic** - not just places, but also history and relationships (trust, etc.) (***Take Home Message***)
- Challenges of studying and understanding context:
  - So many factors...which are most important for which issues, for which settings, for which populations?
  - Complexity almost demands mixed methods approaches
  - Need for brief, validated pragmatic measure

**CONTEXT**- assessed via "PRISM" in **Expanded RE-AIM/PRISM**



PRISM = Pragmatic Robust Implementation and Sustainability Model

Feldstein & Glasgow (2008). *Joint Commission J on Qual. & Patient Safety*, 34: 228-43.



This is recommended **RE-AIM graphic** to use:  
[www.re-aim.org](http://www.re-aim.org)



CONTENT IS KING, BUT  
**CONTEXT IS QUEEN**  
AND SHE RUNS THE  
HOUSEHOLD

[FACEBOOK.COM/GARY](https://www.facebook.com/gary)

# RE-AIM Summary Points

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- 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 iteratively**
- 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 implementation science** projects

# D&I Science, Pragmatic Models and RE-AIM Questions and Comments; Brief Discussion



## Take Home Message: Adaptations Happen (and are not bad)



Evaluating complex interventions: Confronting and guiding (vs. ignoring and suppressing) **heterogeneity** and **adaptation**

Brian S. Mittman, PhD Oct. 2018  
Department of Research and Evaluation, Kaiser Permanente  
Southern California

# Implementing Evidence Based Practices and Implementation Strategies

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

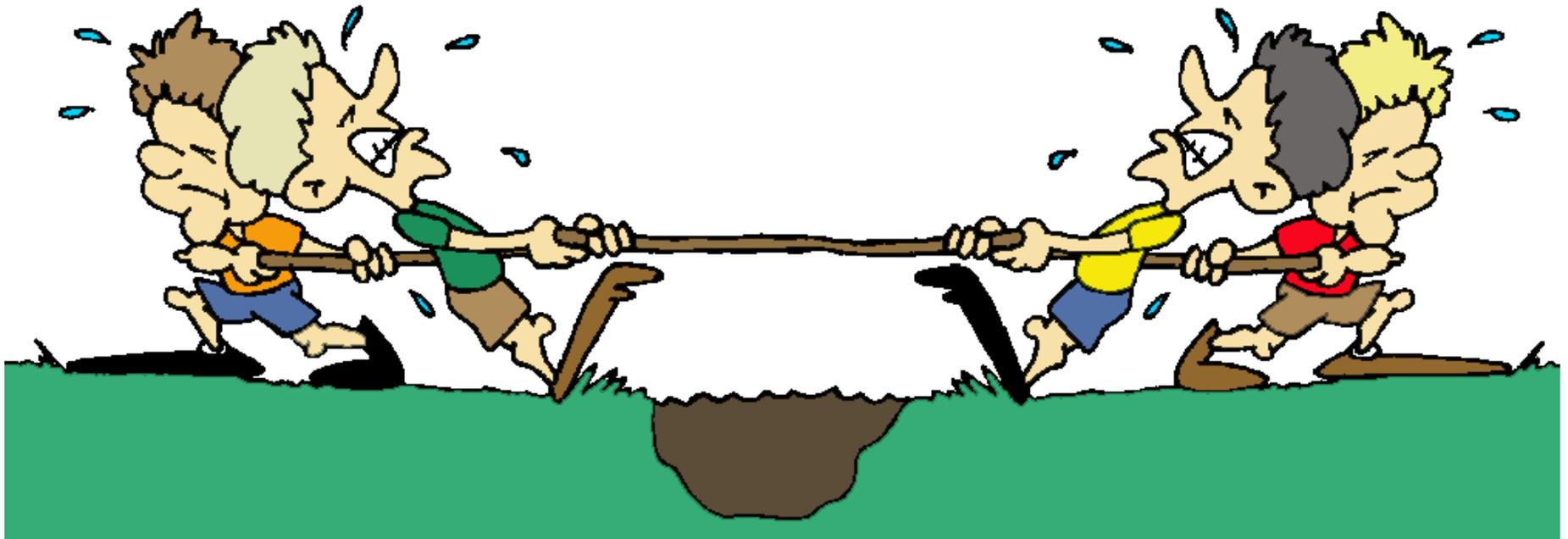
# 'Tug of War'

**Internal  
Validity**

**Fidelity**

**Adaptation**

**External  
Validity**



# PCORI Methodology Guideline SCI-3:

Specify how adaptations to the form of the intervention and comparator will be allowed and recorded

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- Researchers should specify:
  - **allowable adaptations** in form and/or function
  - a description of how planned and unplanned **adaptations will be managed**, measured and reported over time
- Any **planned adaptations** should:
  - have a clear rationale
  - ideally be supported by theory, evidence or experience
  - maintain fidelity to the core functions of the intervention
- Upon study conclusion, researchers should provide guidance on:
  - **allowable adaptations, or**
  - **unproductive adaptations**

# Types of Adaptations – Cultural; Resources; AND Local: ALL WITH *AND DRIVEN BY STAKEHOLDERS*

Focus of Adaptation	Timing of Adaptation (point in the project)		
	Planning	During	Sustainment- Dissemination
Intervention			
Implementation Strategy			
Setting			



# The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions

Shannon Wiltsey Stirman<sup>1\*</sup> , Ana A. Baumann<sup>2</sup> and Christopher J. Miller<sup>3,4</sup>

## Abstract

**Background:** This paper describes the process and results of a refinement of a framework to characterize modifications to interventions. The original version did not fully capture several aspects of modification and adaptation that may be important to document and report. Additionally, the earlier framework did not include a way to differentiate cultural adaptation from adaptations made for other reasons. Reporting additional elements will allow for a more precise understanding of modifications, the process of modifying or adapting, and the relationship between different forms of modification and subsequent health and implementation outcomes.

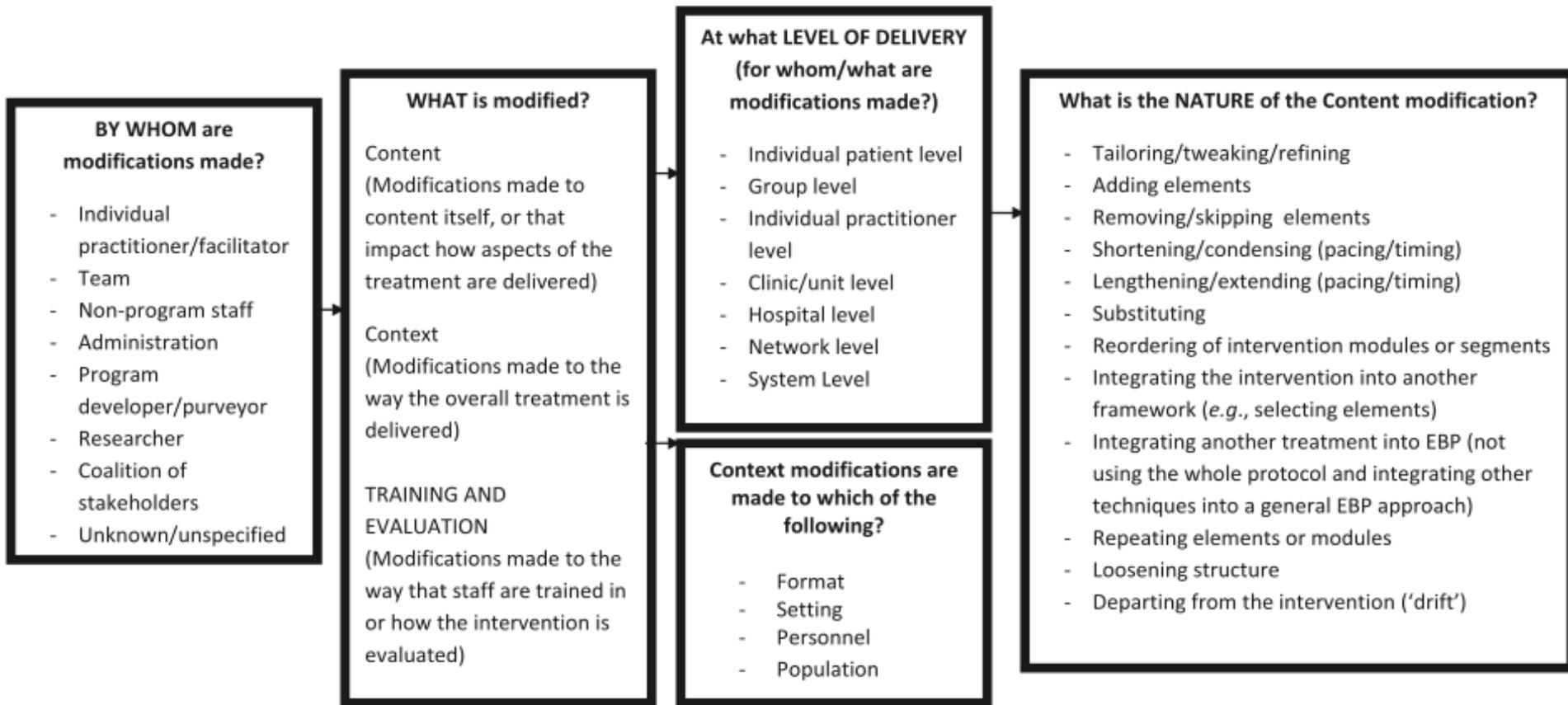
**Discussion:** We employed a multifaceted approach to develop the updated FRAME involving coding documents identified through a literature review, rapid coding of qualitative interviews, and a refinement process informed by multiple stakeholders. The updated FRAME expands upon Stirman et al's original framework by adding components of modification to report: (1) when and how in the implementation process the modification was made, (2) whether the modification was planned/proactive (i.e., an adaptation) or unplanned/reactive, (3) who determined that the modification should be made, (4) what is modified, (5) at what level of delivery the modification is made, (6) type or nature of context or content-level modifications, (7) the extent to which the modification is fidelity-consistent, and (8) the reasons for the modification, including (a) the intent or goal of the modification (e.g., to reduce costs) and (b) contextual factors that influenced the decision. Methods of using the framework to assess modifications are outlined, along with their strengths and weaknesses, and considerations for research to validate these measurement strategies.

**Conclusion:** The updated FRAME includes consideration of when and how modifications occurred, whether it was planned or unplanned, relationship to fidelity, and reasons and goals for modification. This tool that can be used to support research on the timing, nature, goals and reasons for, and impact of modifications to evidence-based interventions.

**Keywords:** Modification, Adaptation, Cultural adaptation, Implementation outcomes

Stirman, S. W., Baumann, A. A., & Miller, C. J. (2019). The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Science*, 14(1), 1-10.

## Adapting the Stirman adaptations framework using the RE-AIM model and clinical experience



### WHY – What is the purpose of the adaptation?

- Increase **reach, participation, access**
- Increase **effectiveness**
- Increase **adoption** by more clinics/settings or make intervention more aligned with organizational goals
- Increase **implementation**/ability of staff to deliver intervention successfully
- Increase **maintenance** – to make intervention more likely to be institutionalized

### IMPACT – What are (subjective) short term results of the adaptation?

- Are they positive, negative, no real impact?
- Did the changes impact:
  - Reach/participation/access
  - Effectiveness
  - Adoption
  - Implementation/ability of staff to deliver intervention successfully
  - Maintenance

# System/Patient Needs

Identified needs that motivate the development of the intervention\*.

Based on the clinical settings' structures, payment models and patient characteristics.

## Core Functions

The intended structural and procedural goals and purposes to reach the intervention goals.

Focus on *standard* macro competencies around change/transformation processes.

Fidelity is assessed at this level.

Absence of core functions challenges the integrity of the intervention and its implementation success.

## Forms

Specific steps and activities taken to carry out or perform each core function.

Forms are *customized* or tailored to each local setting and patient population.

Forms can evolve to account for ongoing change.

A single core function can have multiple forms.

Adaptations are assessed at this level.

Absence of a particular form does not compromise the integrity of the intervention as it can be replaced by another form.

## Form vs. Function

Core Functions and Forms of Complex Health Interventions: Perez Jolle et al *J Gen Intern Med* 34(6):1032–8

## EXAMPLE OF USING RE-AIM to PLAN for **EQUITY and ADAPTATION**: My Own Health Report (MOHR) Program

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Cluster randomized pragmatic trial of web-based, brief health behavior and mental health risk assessment and feedback intervention in 18 (9 pairs) of diverse, **low-resourced safety net primary care practices**

**RE-AIM Outcomes** included:

- **Reach** of the MOHR program across patients\*
- **Effectiveness** of the MOHR program on behavior change goal setting
- Whether safety net practices would **Adopt** MOHR\*
- How practices would **Implement and adapt** MOHR
- *Little time, few costs and burden to deliver* MOHR- MINC concept

\*Primary goals- along with documentation of adaptations to achieve these

Glasgow, et al. (2014). Conducting rapid, relevant, research. *Am J Prev Med*, August;47(2):212-9.  
Krist, et al. (2016). The impact of behavioral and mental health risk assessments. *Transl Beh Med* Jun; 6(2):212-9.



# MyOwnHealthReport

## Patient Health Summary Report

Date of Birth: 1/1/1970

Visit Date 1/30/2013	Height 6 ft. 1 in.	Weight 210 pounds	BMI 27.7
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### YOUR Health Behaviors and Mental Health

	Recommended Score	Your Score	Level of Concern	Ready to Change?	Want to Discuss?
<b>Overall Health Rating</b> Reason: I am working too hard at my job.	Good to Excellent	Poor	A Lot	✓	✓
<b>Body Mass Index</b>	20-25	27.7	Some		
<b>Health Behaviors</b>					
Fruit/Vegetable Intake	5+/day	Less than 2/day	A Lot	✓	✓
Fast Food Intake	Less than 1 time/week	1-3 times/week	Some	✓	✓
Soda/Sugary Beverage Intake	Less than 1/day	1 to 2/day	Some		
Physical Activity Participation	150+ minutes/week	175 minutes/week	None		
Sleep	Never/rarely sleepy	Often sleepy	Some		
Alcohol Intake	Never	Never	None		
Tobacco use	No	Yes	A Lot		
Illegal Drug/Prescription Use	Never misuse	Never misused	None		
<b>Mental Health</b>					
Stress	Less than 5	8	A Lot	✓★	✓
Anxiety/Worry	Not at all/rarely	Not at all/rarely	None		
Depression	Not at all/rarely	Not at all/rarely	None		

★ = Most important to you

Basic patient and clinician goal advice

(electronic) and goal-setting (paper)

Assessment and feedback **content is standard**

**How these are implemented is adapted**

# Example of Planning for Adaptation, Equity and Context using RE-AIM in the MOHR Study

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- **Reach\***: *Options* for clinics and patients in contact modalities (phone, e-mail, EHR, waiting room); in context of *regular visits*- remove barriers
- **Effectiveness**: Shared Decision Making on goals, including *social determinants of health* (most patients had 4 or more behavioral risk factors)
- **Adoption\***: *Fit with reimbursement* for annual wellness exams; CME; few resources required, largely automated intervention, *English and Spanish*
- **Implementation**: *Options* of where and when the *BRIEF* online session, real time feedback, and related counseling/goal setting occur and *who does this*
- **Maintenance**: *Not well done*- assumed reimbursement would be sufficient; needed to be integrated into the EHR

# Adoption

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18 Practices Agreed to Adopt MOHR

30 practices approached (**adoption 60%**)

Decliners were doing other studies, worried about workload, or doing HRAs

Participating practices represented a diverse spectrum of primary care

# Overall Reach: 1768 of 3591 patients (49.2%)

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## Reach of Different Approaches

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Mailed (patient completed)

*4 sites*

*average 30%*

Phone (nurse completed)

*1 site*

*64%*

Lobby (patient + staff completed)

*1 site*

*44%*

Lobby (MA or coordinator completed)

*4 sites*

*average 75%*

---

## Moral of this Example?

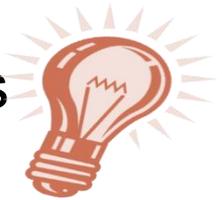
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- Success demands tailoring, customization and adaptation at the levels of:
  - patient
  - clinician
  - setting
- Feasible to collect patient report measures that are not usually available:
- Currently adding social determinants of health to MOHR

# THE FUTURE OF RE-AIM ([www.re-aim.org](http://www.re-aim.org))

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- Focus on **adaptations, costs, co-creation and ITERATIVE** use of RE-AIM
- Elaboration and focus on **PRISM context** elements
- Focus on **Equity and Transparency**
- What it means to “Use RE-AIM” - guidance, recommended slides, examples, FAQs, misconceptions-  
**[www.re-aim.org](http://www.re-aim.org)**
- ***Frontiers of Public Health***- special issue topic on RE-AIM- coming soon



Huebschmann A, et. al. (2019) Making health research matter. *Ann Review Public Health*: 40:45-63.

Glasgow et al; RE-AIM at 20. *Frontiers of Public Health*, 2019; 7:64.

# 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

# Steps in Designing D&I Research

(see separate file)

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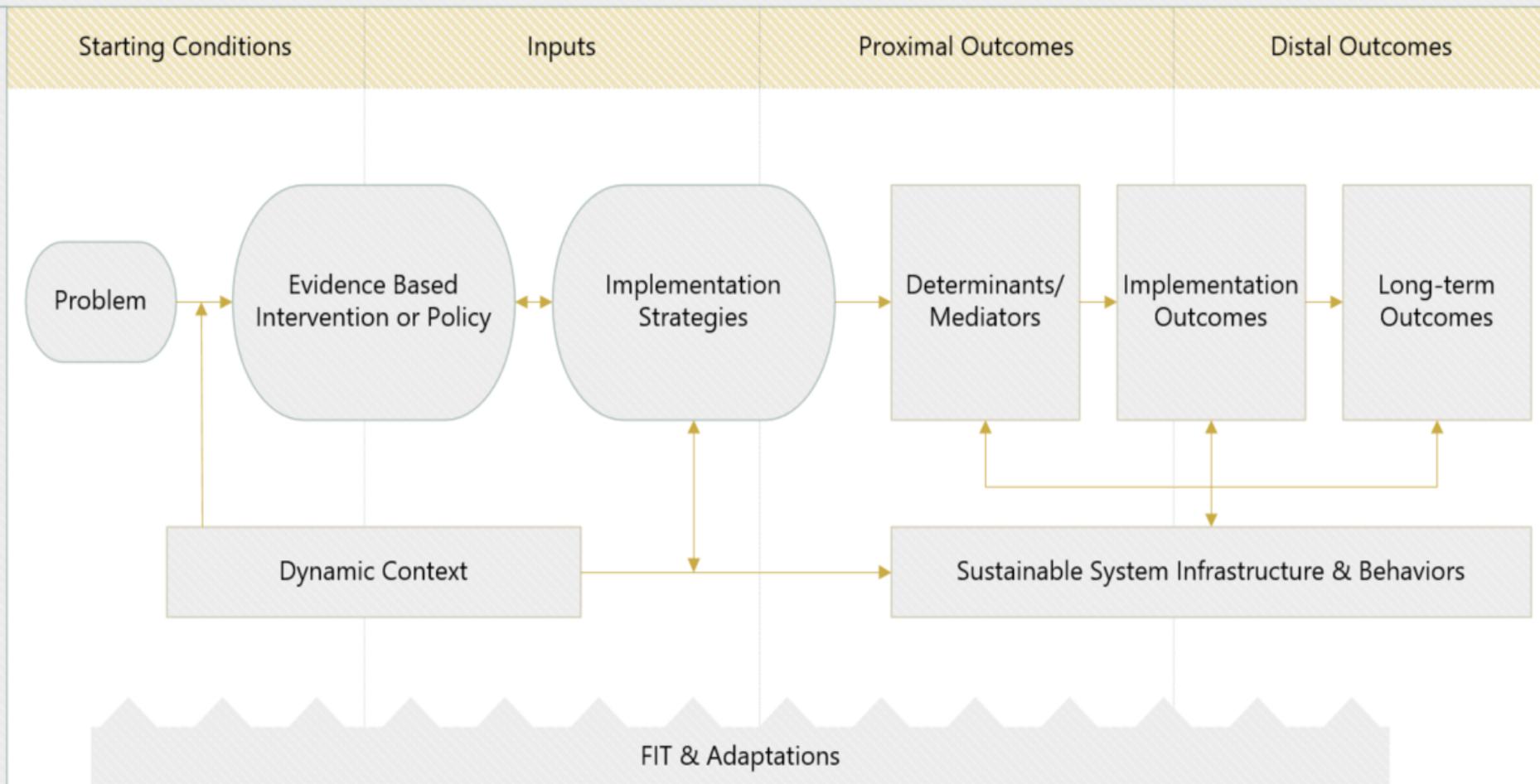
- Specify the ‘gap’ between need and current situation; and the Evidence Based Intervention (EBI) you are using or considering [www.rtips.org](http://www.rtips.org) for good EBIs
- Engage multiple types of stakeholders- both initially and ongoing
- Complete a ‘**Logic Model**’ –of Anticipated Conditions; Inputs (EBI and possible implementation strategies); and Outcomes (Process; Proximal; and Distal)- *see attachment and next slide*
- Decide on the theory, conceptual model or **framework** you will use <https://dissemination-implementation.org>
- Design evaluation (with stakeholders) and use **implementation strategies** that FIT your context (1)
- Decide on **Outcomes** and Pragmatic Evaluation Measures (2)
- Prepare for iteration and adaptations (“best laid plans”- 1<sup>st</sup> plan never works)

1. Proctor EK, Powell BJ, McMillen JC. Implementation strategies. *Implement Sci.* 2013;8:139.

2. Stanick et al *Translational Behavioral Medicine*, ibz164, <https://doi.org/10.1093/tbm/ibz164> Powell et al. *Implementation Science* (2017) 12:118

# Start with a Logic Model: Use this to select your conceptual framework

## Logic Model of Implementation Sequence



# D&I Theories, Models + Frameworks are Available!

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- Proliferation of models: now more than 159\*! (good news is there are *many similarities*)
  - 87% used in only 5 or fewer of 596 studies
  - Context is critical
  - Focus on external validity
  - Begin with stakeholders—take their perspective(s)
  - Find balance between fidelity to EB program and adaptation to local setting
  - Unlikely you need to create a new model

Tabak RG, et al. Bridging research and practice. *Am J Prev Med.* Sep 2012;43(3):337-350

\*Strifler L et al. *J Clin Epi* (2018) Vol. 100; 92-102

# Choosing Implementation Frameworks

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*“Theories inform the (frameworks) that provide the undergirding or infrastructure, much like the frame of a house.”*

- Explanatory: **how** implementation activities will affect a desired change
- Process: **what** implementation strategies should be planned
- Evaluative: to **assess** implementation outcomes

*“D&I theories are kind of like toothbrushes:  
Everybody has one and no one wants to use  
somebody else’s”*



Cara Lewis via Anne Sales via ??

# Dissemination & Implementation Models

*in Health Research & Practice*

[Home](#) > [Access the D and I Models Webtool](#)

## Getting Started

### Novice users:

If you are new to D&I models and their use, we **strongly recommend** starting with the Plan section and advancing in a linear manner.

### Experienced users:

If you have some experience working with D&I models, you might use the webtool in a non-linear manner, visiting sections that are most relevant to your research and/or practice problem.

### A few key tips to help you navigate the webtool:

A tutorial is available for each section of the webtool under the Tutorial section of the website.

In this webtool, the term 'Models' is used to refer to both theories and frameworks that enhance the dissemination and implementation of evidence-based interventions.

## Sections of the D&I Models Webtool

Plan

Select

Combine

Adapt

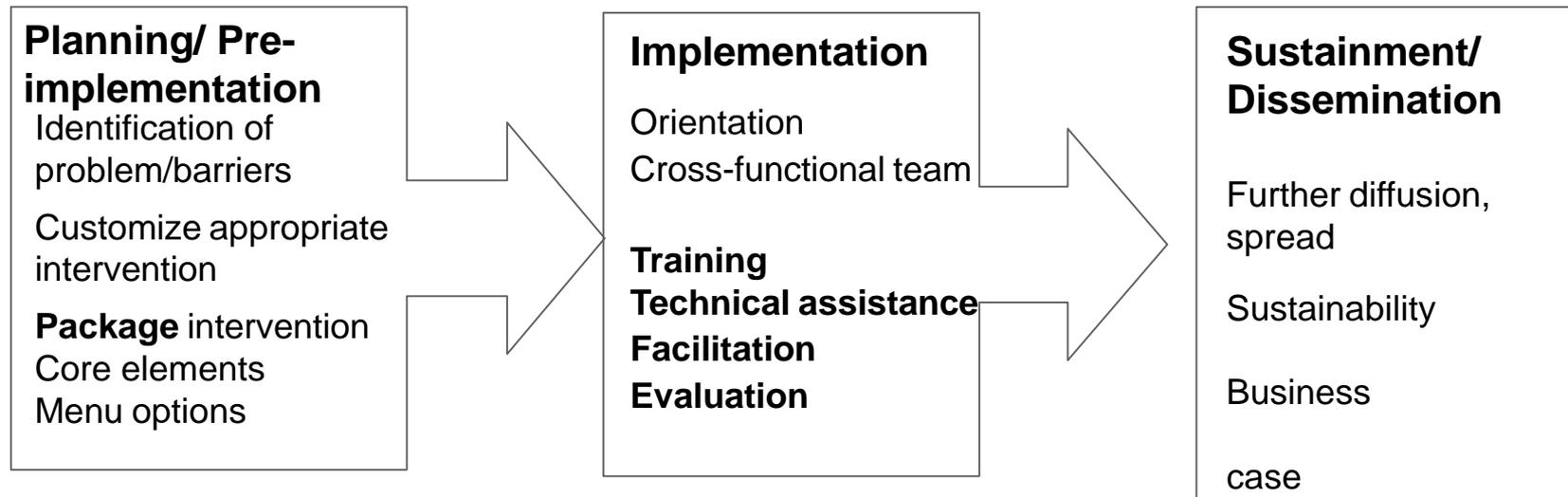
Use

Measure

[www.dissemination-implementation.org](http://www.dissemination-implementation.org)

# Strategy Example: Enhanced Replicating Effective Programs (REP) Framework

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REP was developed by the Centers for Disease Control to rapidly translate HIV prevention programs into community-based settings

Enhanced REP includes additional facilitation based on the PARiHS framework

# Evaluation and Reporting in D&I Research

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- 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. *Amer J Prev Med*, 2018; 55 (3), 422–430

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

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

<http://dx.doi.org/10.1136/bmj.i6795>

# Equity Issues in Evidence-Based Research: *Evidence on What?* (take home point)

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External Validity/Pragmatic Criteria, Often Ignored

- Participant **representativeness**
- **Setting and staff** representativeness
- **Multi-level context**
- **Adaptation/change** in intervention and implementation strategies
- What outcomes for whom over what time period
- **Reasons for participation and drop out**

# Everything I Know (about D&I Science)

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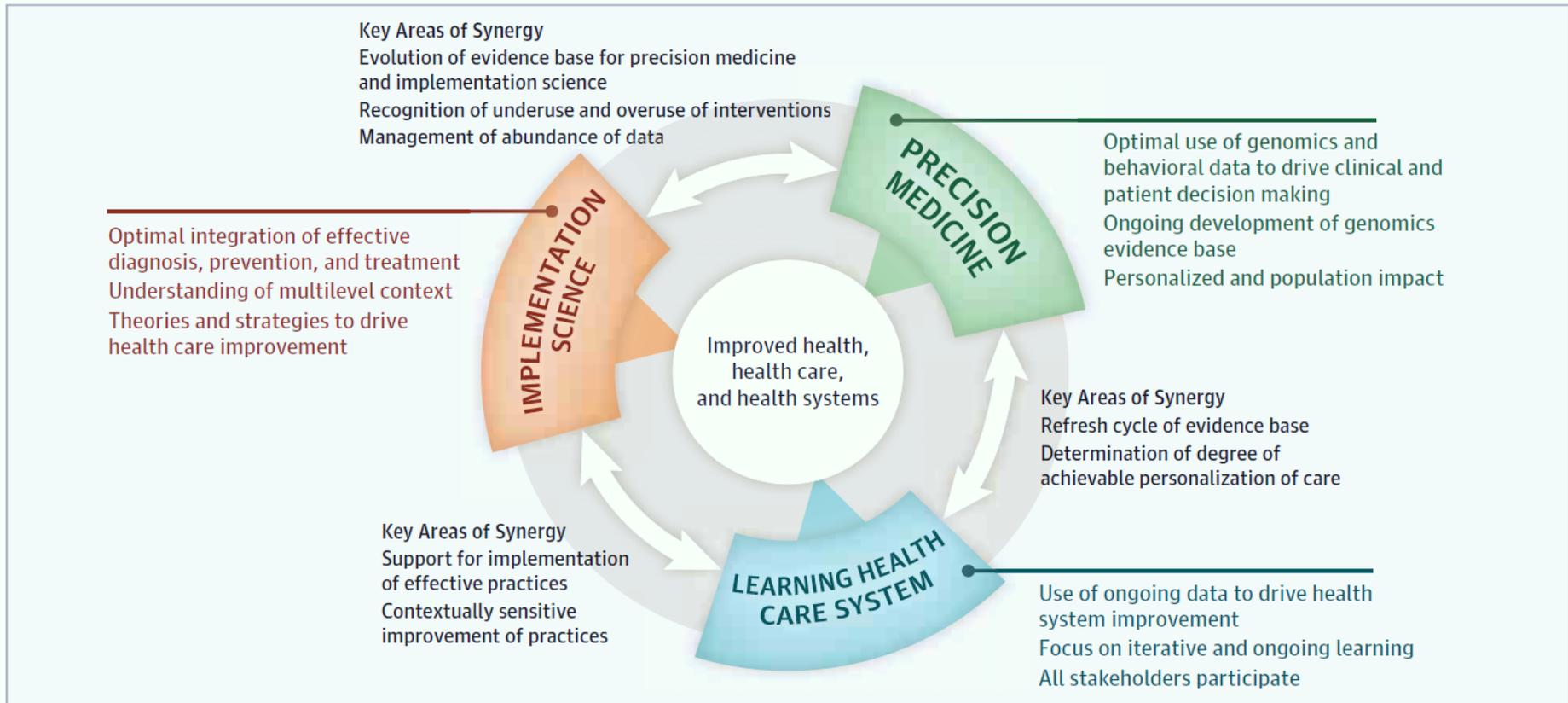
## Dissemination and Implementation Science is about:

- **Multi-level, contextual** issues, and external validity
- Relevant, **pragmatic** models, research methods and measures
- Real world implementation and **adaptation** (T3 and T4)
- Designing for **dissemination, sustainability and equity**

*(Normal science (T1– T2) is necessary but not sufficient)*

# Convergence of Precision Health, DIS & Learning Health Care Systems and Communities

Figure. Contributions of Implementation Science, Learning Health Care System, and Precision Medicine



Chambers DA, Feero WG, Khoury MJ. Conversion of implementation science, precision medicine, and the learning health care system. *JAMA*. 2016, 315: 1941-1942

# Example: Precision Medicine (PM)



National Institutes of Health  
All of Us Research Program

ABOUT ▾

FUNDING ▾

NEWS, EVENTS, & MEDIA

[JoinAllOfUs.org](https://www.joinallofus.org) ▶

Search



## The future of health begins with **All of Us**

The *All of Us* Research Program is a historic effort to gather data from one million or more people living in the United States to accelerate research and improve health. By taking into account individual differences in lifestyle, environment, and biology, researchers will uncover paths toward delivering precision medicine.

[WATCH VIDEO](#) ▶

- How does clinical practice incorporate PM findings?
- How do you implement evidence that will evolve?
- How do you train and support the workforce?
- How do you ensure that PM findings improve, **not exacerbate, health inequities?**

# RE-AIM Precision Medicine (PM- or Precision Health) Questions

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Determine:

- What percent and types of patients are **Reached** (*equity*);
- For whom among them is the PM intervention **Effective**, in improving what outcomes, with what unanticipated consequences (*is health equity improved or decreased*)?
- In what percent and types of settings is this approach **Adopted**;
- How consistently are different PM **Implemented** at **what cost** to different parties;
- And how well are the intervention components and their effects **Maintained** at both setting and individual levels?

Gaglio B, Glasgow RE. Evaluation approaches...In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health*. New York: Oxford University Press; 2018. 317-334.

## D&I, RE-AIM and Pragmatic Research Resources

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1. Brownson R et al. *Dissemination and implementation research in health*. (2018). Oxford Univ. Press, 2<sup>nd</sup> edit.- chapters on key D&I issues by leading experts
2. Glasgow, RE. What does it mean to be pragmatic? *Health Education & Behavior* (2013). 40(3) 257–265
3. [www.Dissemination-Implementation.org](http://www.Dissemination-Implementation.org) – select frameworks
4. [www.re-aim.org](http://www.re-aim.org) – guidance on applying RE-AIM
5. <https://rtips.cancer.gov/rtips/index.do>- repository of over 150 evidence based programs with implementation materials
6. [www.ucdenver.edu/accords/implementation](http://www.ucdenver.edu/accords/implementation) -frequently updated site with interactive resources

# Current D&I Funding Opportunities

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- PAR 19-274 (R01) CT optional <https://grants.nih.gov/grants/guide/pa-files/PAR-19-274.html> (17 institutes participate- not all in all 3 PARs)
- PAR 19-275 (R21) CT optional <https://grants.nih.gov/grants/guide/pa-files/PAR-19-275.html>
- PAR 19-276 (R03) clinical trial not allowed <https://grants.nih.gov/grants/guide/pa-files/PAR-19-276.html>

**PCORI:** Pragmatic Trials; Dissemination projects

**AHRQ:** Embedded research studies; new RFAs

**CDC:** especially Prevention Research Centers

**VA:** QUERI program

## Key Science Questions- New and Old

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**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?”

**Pragmatic D&I** question (*contextual*):

“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 occur?”

**Questions? 'I am all ears!'**



# Dissemination: What we know

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1. Dissemination generally does not occur spontaneously and naturally;
2. **Passive approaches** to dissemination (diffusion) are **usually ineffective**;
3. Single-source prevention messages are generally less effective than comprehensive, multi-level approaches;
4. **Stakeholder involvement** in the research or evaluation process is likely to enhance dissemination;
5. Theory and frameworks for dissemination are beneficial; and
6. The process of dissemination **needs to be tailored** to various audiences

# Designing for Dissemination (D4D)

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- The process of ensuring that evidence-based interventions are developed in ways that match well with adopters' needs, assets, and time frames
- Might apply to any actionable finding, guideline, policy or packaging/designing interventions (RTIPs, post hoc)

Timmings, C., Khan, S., Moore, J., Marquez, C., Pyka, K., & Straus, S. (2016). Ready, Set, Change!. *BMC Medical Informatics and Decision Making*, 16(24), 24.

Dearing JW, Smith DK, Larson RS, Estabrooks CA. (2013). Designing for diffusion of a biomedical intervention. *Amer J of Prev Med* 44: (1S2): 70-76.

# Improving D4D: Start Early!!

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- Think about dissemination at the **beginning and throughout** the project
  - Structures
    - In grant applications, are D4D principles embedded or a separate aim?
    - Do you have a conceptual model?
  - Processes
    - How to engage stakeholders early and often
  - Products
    - How to frame messages, develop brief summaries
  - Systems changes
    - How to shift and fit funder, academic priorities, and incentives