

Implementation Science Perspectives on Opportunities and Challenges for ISRII

Russell E. Glasgow, Ph.D., Deputy Director
Implementation Science
National Cancer Institute

ISRII 6th Scientific Meeting
Chicago – May 2013



Overview

- **Implementation Science Perspectives on ISRII**
 - Evidence Integration Triangle
 - RE-AIM and Health Equity Issues
- **Pragmatic Approaches and eHealth Review**
- **Reflections, Needs and Pragmatic Example**
 - My Own Health Report (MOHR) study
- **Funding, Conclusions, Q&A**



NCI Implementation Science Team Vision

To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.

IS Team Website: <http://cancercontrol.cancer.gov/IS/>

RE-AIM Realist* or Precision Medicine Question

- What percent and types of patients are **Reached**;
- For whom among them is the intervention **Effective**; in improving what outcomes; with what unanticipated consequences;
- In what percent and types of settings and staff is this approach **Adopted**;
- How consistently are different parts of it **Implemented** at what cost to different parties;
- And how well are the intervention components and their effects **Maintained**?

*Pawson R, et al. *J Health Serv Res Policy* 2005;10(S1):S21-S39.

Gaglio B, Glasgow RE. Evaluation approaches...In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-356.

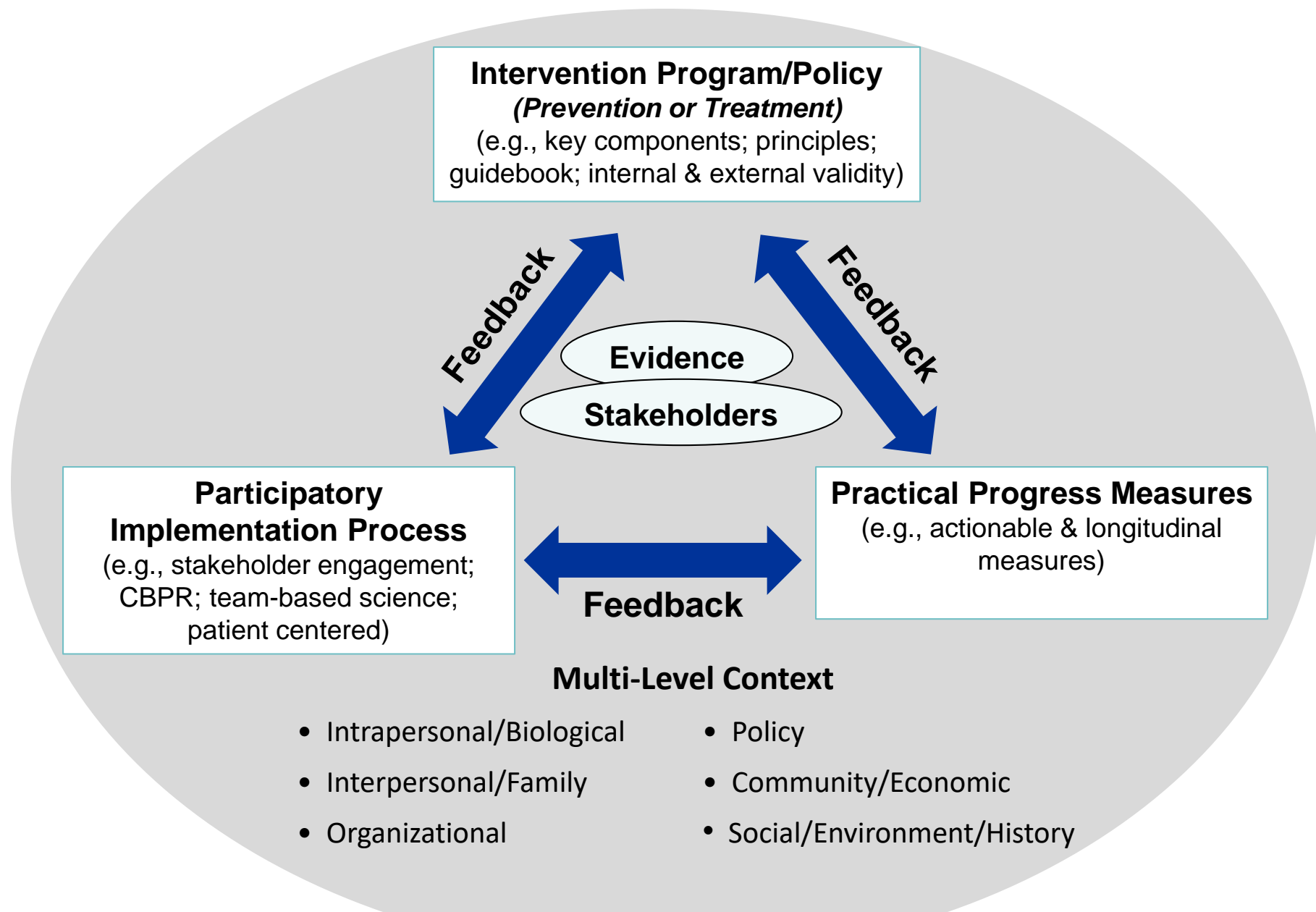


RE-AIM—Health Equity Implications

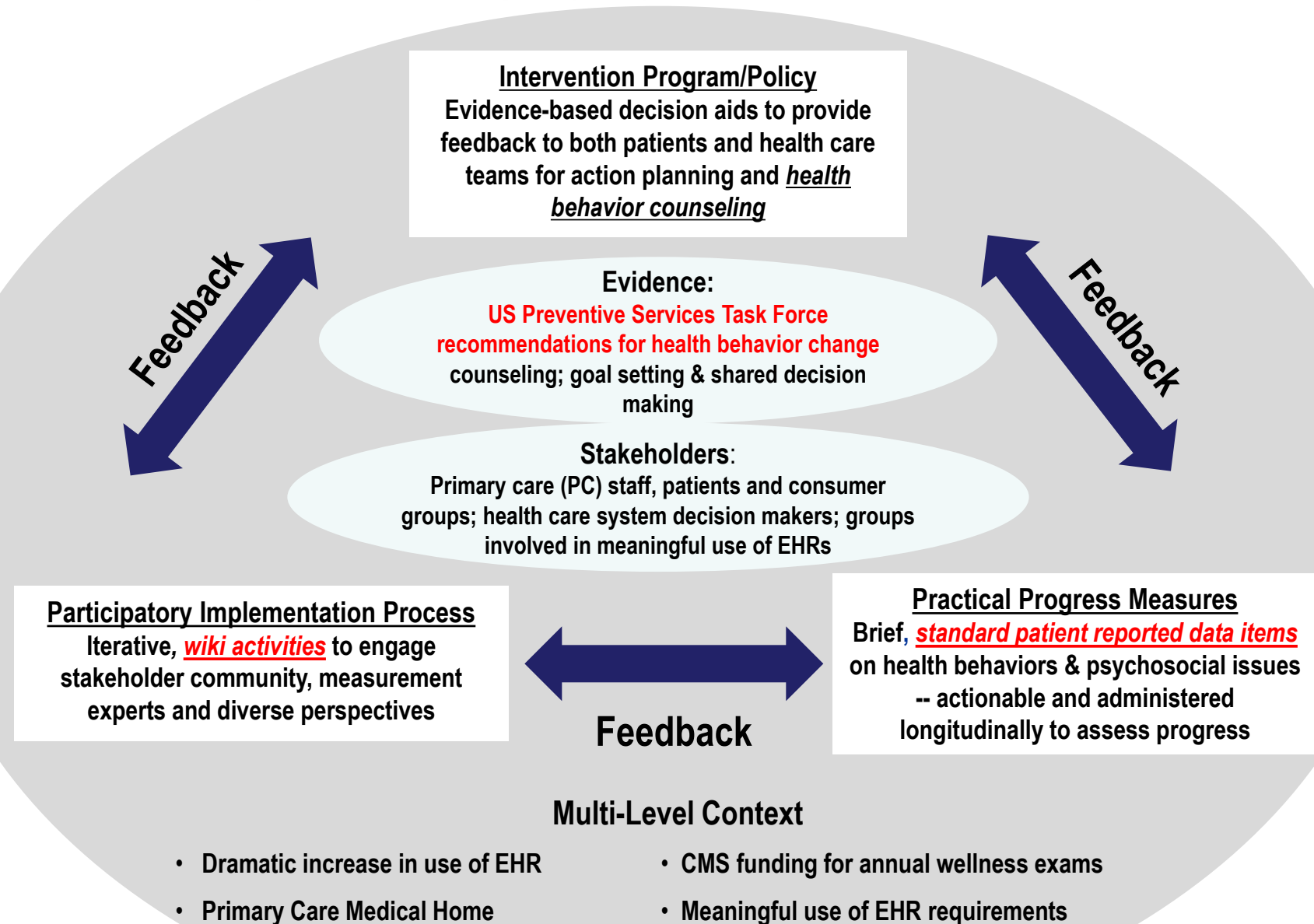
<u>RE-AIM Issue</u>	<u>Disparity</u>	<u>Overall Impact</u>
Reach	30%	70% of benefit
Effectiveness	0 (equal)	70% of benefit
Adoption	30%	49% of benefit
Implementation	30%	34% of benefit
Maintenance	30%	24% of benefit

IS Team Presentation on Health Inequities: <http://cancercontrol.gov/IS/presentations.html>

Evidence Integration Triangle (EIT)



Evidence Integration Triangle (EIT) - A Patient-Centered Care Example



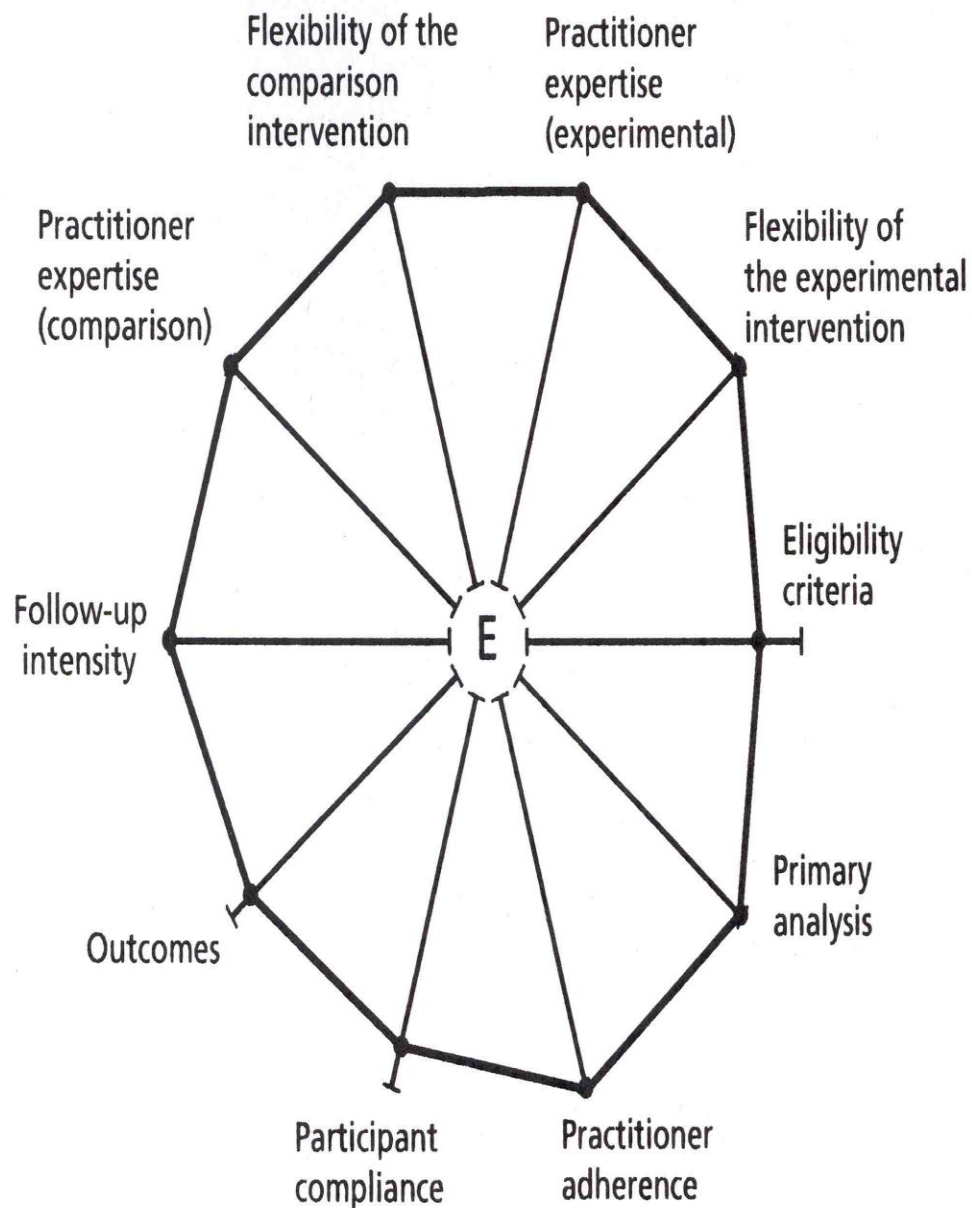
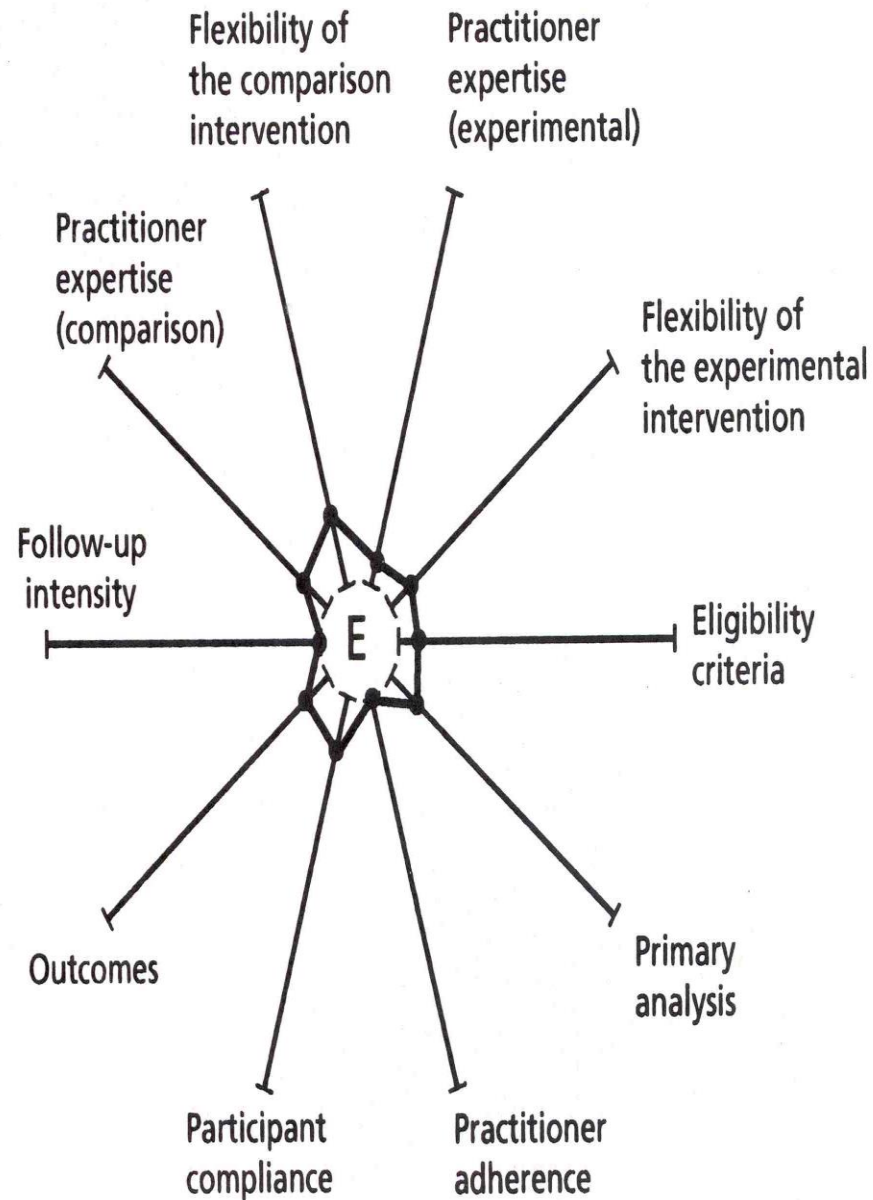
PRAGMATIC METHODS



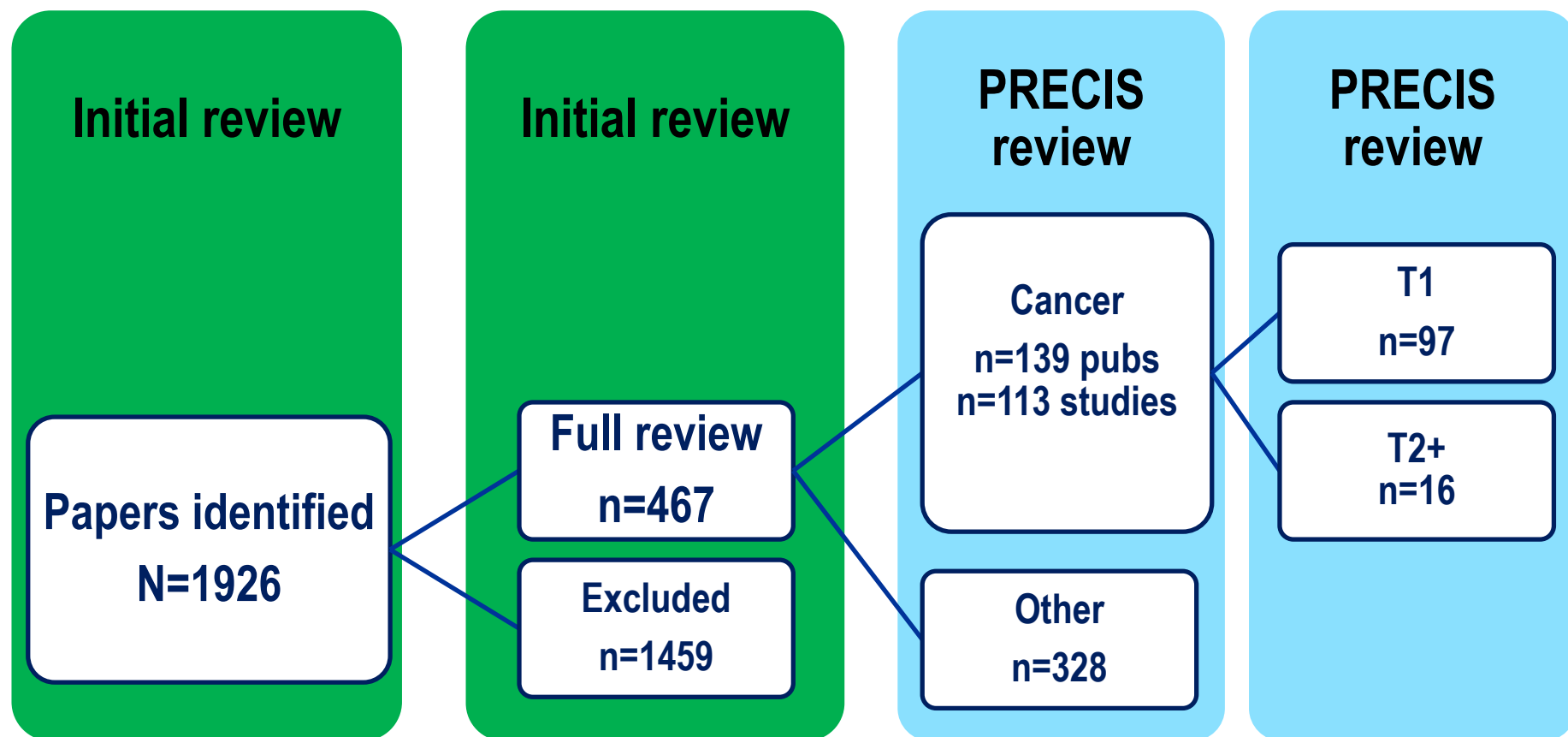
The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

Describes ten domains that affect the degree to which a trial is pragmatic or explanatory.

- 1. Participant eligibility criteria**
- 2. Experimental intervention flexibility**
- 3. Practitioner expertise (experimental)**
- 4. Comparison intervention**
- 5. Practitioner expertise (comparison) outcome**
- 6. Follow-up intensity**
- 7. Primary trial outcome**
- 8. Participant compliance**
- 9. Practitioner adherence**
- 10. Analysis of primary**

A**PRAGMATIC STUDY****B****EXPLANATORY STUDY**

eHEALTH PRAGMATIC REVIEW



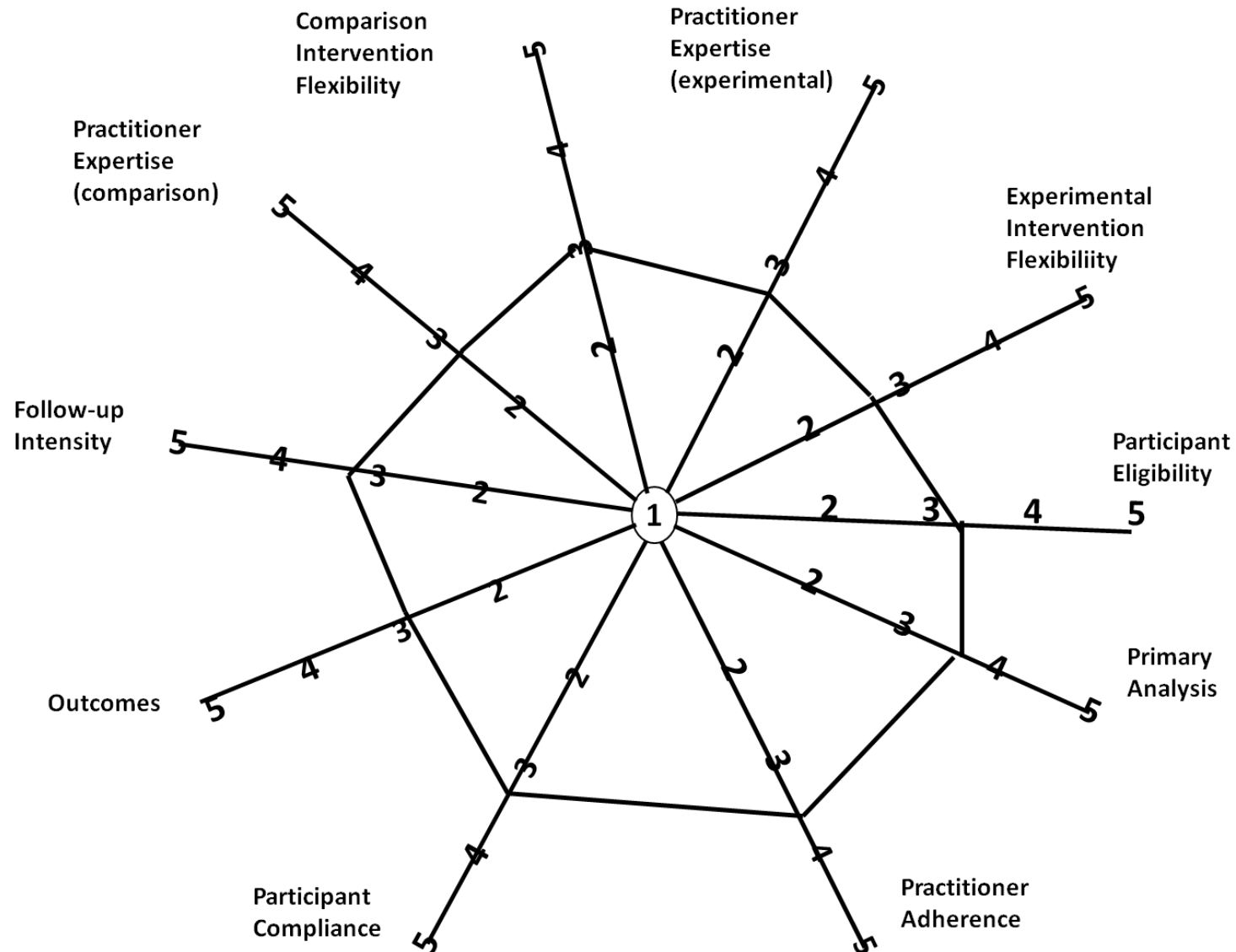
Rabin & Glasgow, Dissemination of interactive health communication programs, in Noar & Harrington, Interactive Health Communication Technologies: Promising Strategies for Health Behavior Change. 2012

Sanchez et al. A Systematic Review of eHealth Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Revision Under Review.

eHealth RESULTS

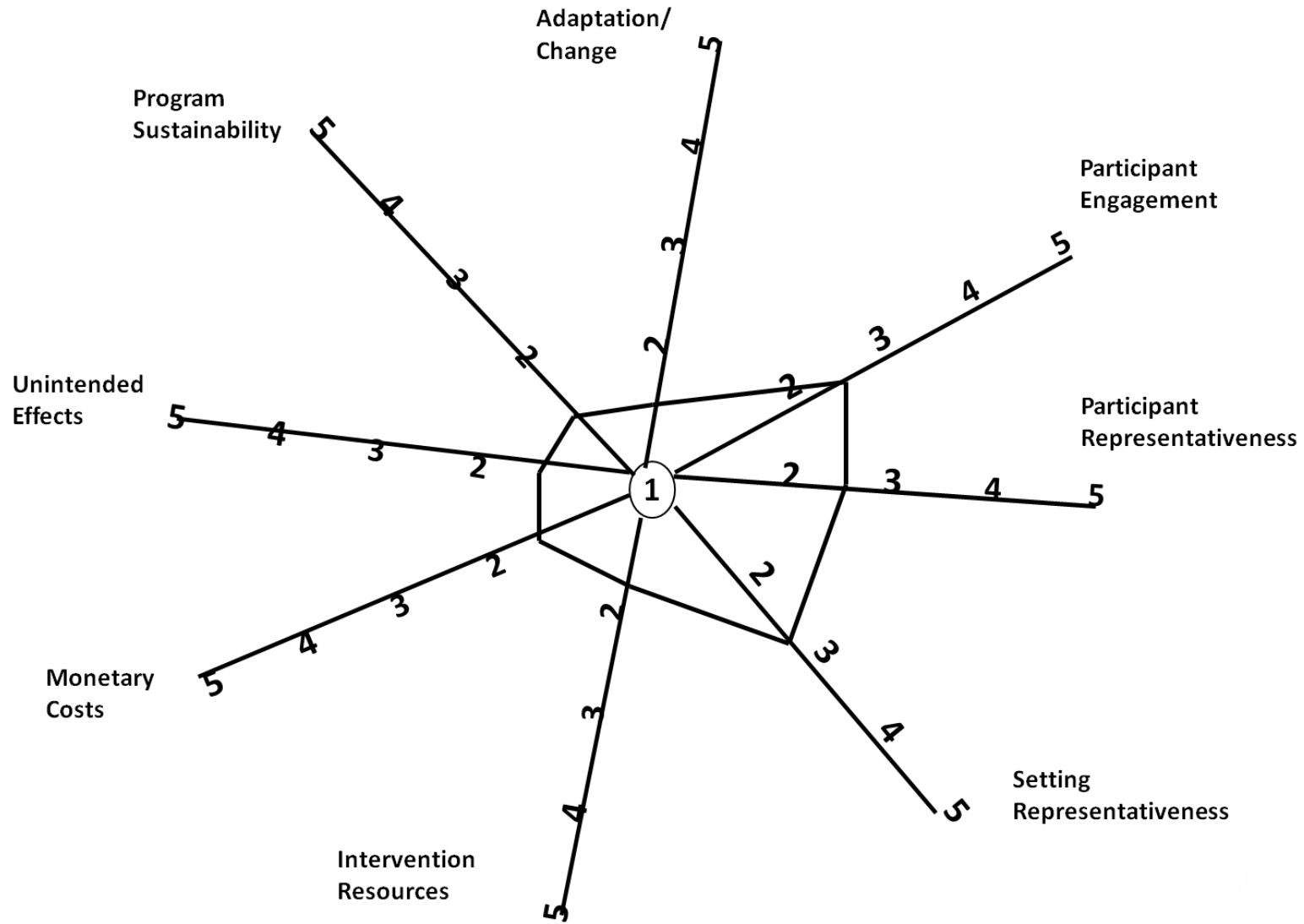
- *Little variability in PRECIS scores across all studies*
- Most fell midway along the PRECIS continuum
composite mean = 3.12 (domain range, 2.7-3.6)
- Few reported practical feasibility criteria
composite mean = 1.98 (domain range, 1.5 to 2.8)
- *Practical feasibility scores rated lower than PRECIS*
- Significant differences by intervention settings, target population, year published, and translation phase
- Trend analysis
 - *Significant increase—Experimental intervention flexibility domain*
 - *Significant decrease—Intervention resources domain*

Average PRECIS Scores for All Studies by Domain



Sanchez et al. A Systematic Review of eHealth Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Under Review.

Average Practical Feasibility Scores for All Studies by Domain



Sanchez et al. A Systematic Review of eHealth Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Under Review.

PRECIS SUMMARY

- PRECIS: An efficient way to summarize how pragmatic vs. explanatory projects are on multiple dimensions
- For comprehensive reporting, *parallel external validity/ pragmatic criteria are needed/helpful*
- Both sets of criteria can be coded reliably after minimal training and can detect differences in study design
- *Helps to increase TRANSPARENCY* and inform researchers, potential adopting settings, and decision makers

Pragmatic Measures

1. Required Criteria

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

2. Additional Criteria

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

Dissemination and Implementation Measures Initiative



GEM-D&I Homepage:

www.gem-beta.org/GEM-DI

D&I workspace launched on GEM in March 2012

120 measures available, across 45 constructs.

- To engage research community and stakeholders in sharing, commenting on, and rating measures of key D&I constructs.
- To provide a resource for investigators in writing grants and designing studies, and eventually, data sharing among interested parties to advance science



Pragmatic EHR Measures for Primary Care

Domain	Final Measure (Source)
1. Overall Health Status	1 item: BRFSS Questionnaire
2. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. <i>Am J Prev Med</i> 2011;40(1):67-71]
3. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. <i>Br J Sports Med</i> 2011;45(6):473-474]
4. Stress	1 item: Distress Thermometer [Roth AJ, et al. <i>Cancer</i> 1998;15(82):1904-1908]
5. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. <i>Psychosomatics</i> 2009;50(6):613-621]
6. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL [Item PQSLP04]
7. Smoking/Tobacco Use	2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]
8. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. <i>J Gen Int Med</i> 2009;24(7):783-788]
9. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. <i>Arch Int Med</i> 2010;170(13):1155-1160]
10. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, IOM, and <i>National Health Interview Survey (NHIS)</i>

Pragmatic Study Methods: Key Characteristics

- 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

My Own Health Report (MOHR) Automated Assessment Tool

Patient Fills Out Tool

Patient Health Update

Check the box next to your answer.

Q1. Over the past **7 days**:

a. How many times did you eat **fast food meals or snacks**?

less than 1 time ☐ 1-3 times ☐ 4 or more times ☒

b. How many servings of **fruits/vegetables** did you eat each day?

5 or more ☐ 3-4 servings ☒ 2 or less ☒

c. How many **soda** and **sugar sweetened drinks**
(regular, not diet) did you drink each day?

Less than 1 ☐ 1-2 drinks ☒ 3 or more ☒



Database of
text messages
and triggers

Summary display and
printout for patient

Action Plan printout

Summary display and
printout for physician

Report data
stored in
database

Research analysis

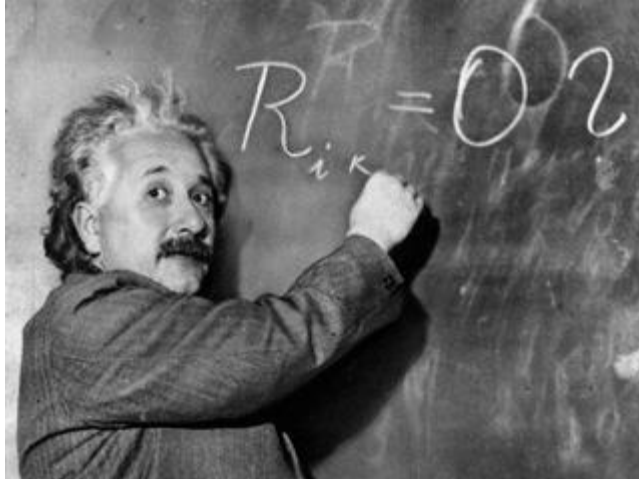
<http://www.myownhealthreport.org/>

-
- A map of the United States with arrows pointing to specific states labeled with two-letter codes: OR (Oregon), CA (California), VA (Virginia), NC (North Carolina), and TX (Texas).

Pragmatic Features

Relevant	Diverse, real-world primary care settings; and staff who do all the intervention
Rigorous	Cluster randomized, delayed intervention design
Rapid	One year from concept, planning, and execution, low cost, and cost informative
Resource Informative	Low cost; studying costs and cost-effectiveness under different delivery conditions
Transparent	Report on adaptations, failures, lessons learned

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



A. Einstein

Observations and Reflections

... On Evidence



Types of Evidence Needed: A New “Bold Standard”? The 5 R’s

- **R**elevant (to stakeholders)
- **R**apid
- **R**igorous (redefined to include robustness and replication)
- **R**esources Reported
- **R**ecursive—iterative; ongoing learning

Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request

Relevance

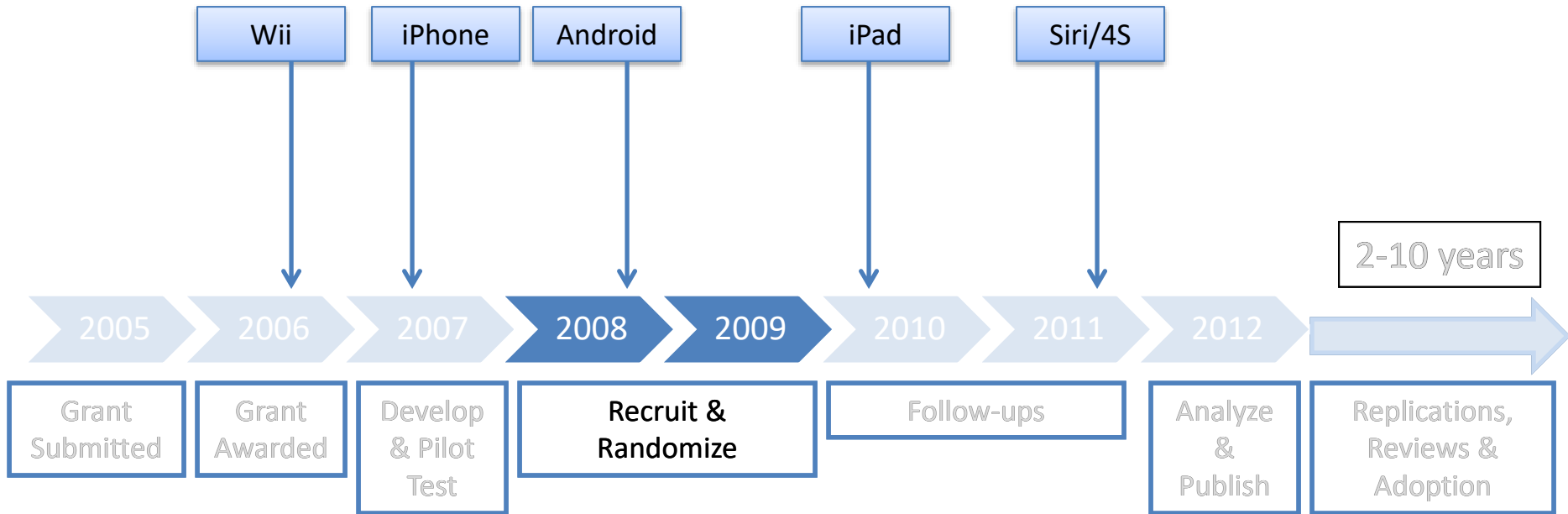
- Studies with or generalizable to:
 - Real-world settings, including low- cost sites
 - Range of staff intervention models
 - Range of end users, consumers, participants
 - Typical conditions of administration and assessment
- Can get quick idea from CONSORT PRECIS criteria



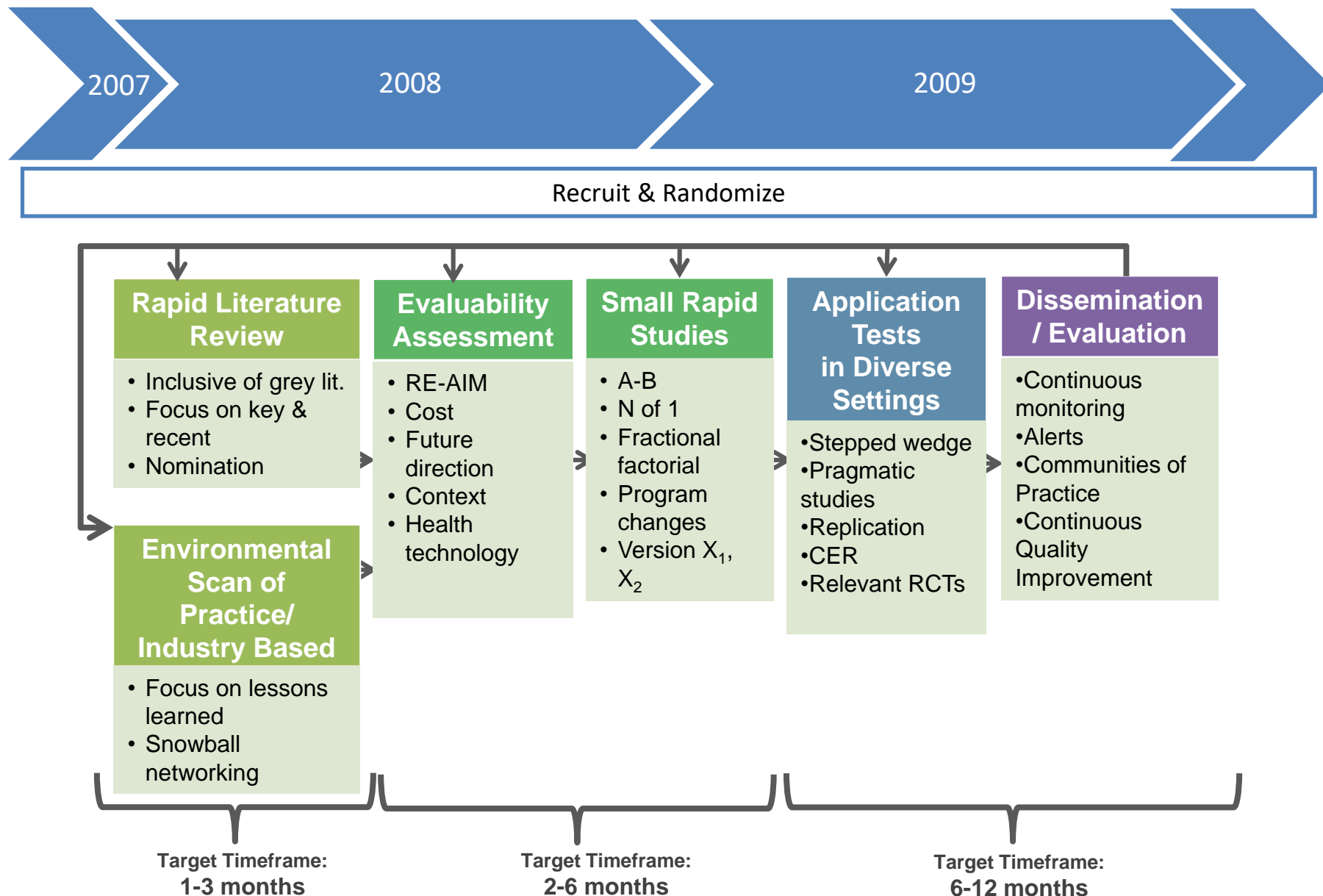
Rapid

- Pace of research (17 years for 14% of data to translate) is way too slow
- Need changes in design, review, measures, publication, and culture
- Many evolving, adaptive designs; several from different fields

Riley WR, Glasgow, Etheredge, Abernathy, revision under review 2013



Development/Validation Steps Involving Rapid eHealth Learning Networks



Acronyms: RE-AIM= Reach Effectiveness, Adoption, Implementation, and Maintenance
CER= Comparative Effectiveness Research
RCT= Randomized Control Trial

Rigorous (Devil is in the Details)

- *Replication is sine qua non of causality—and severely unappreciated*
- Balance of internal and external validity
- Consider and address most likely potential confounding factors



Resource Informative

- 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.

Recursive (Iterative)

- Across the T1-T4 cycle
- In Quality Improvement (QI) sense of continuous improvement
- Programs and policies hardly ever work perfectly when initially implemented, or as in the efficacy study
- Evidence Integration Triangle captures some of the needed iteration

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

Types of Evidence Needed: A New “Bold Standard”? The 5 R’s

- **R**elevant (to stakeholders)
- **R**apid
- **R**igorous (redefined to include robustness and replication)
- **R**esources Reported
- **R**ecursive—iterative; ongoing learning

Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request

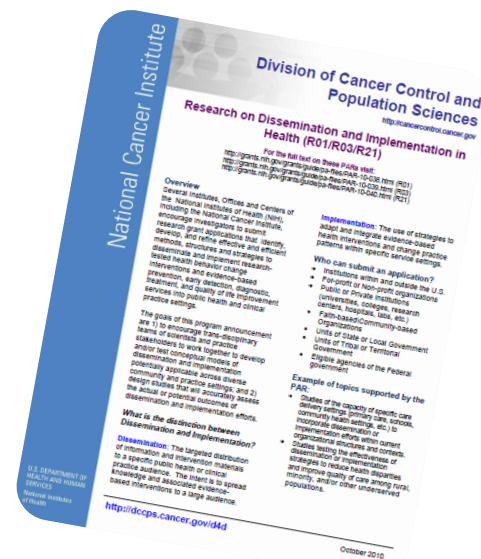
Funding and Resources



The Trans-NIH D&I Funding Announcement (International Investigators Eligible)

- R01 - PAR 13-055 (\$500k per annum up to five years)
R03 - PAR 13-056 (\$50K per annum up to two years)
R21 - PAR 13-054 (\$275K up to two years)
- Participating Institutes: NIMH, NCI, NIDA, NIAAA, NIAID, NHLBI, NINR, NIDDK, NINDS, NIDCD, NIDCR, NCCAM, NHGRI*, NIA* & Office of Behavioral & Social Sciences Research
- Standing review committee, Dissemination and Implementation Health Research
- Three submission dates per year: February, June, October
- New Institute Added to PAR in 2013

http://cancercontrol.cancer.gov/funding_apply.html#is



Implementation Science Funding Opportunities

- *PCORI—and “true” patient/family-centered research*
- *“Team Science” and collaborative approaches to care transformation*
- Guidelines implementation, especially across networks
- *Patient Health Records—patient portal to EHR*
- *Collection and meaningful use of patient report measures for care and research*
- Efficiency, CEA and CER on care planning, etc.

Research Tested Intervention Programs (RTIPs)

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



Research-tested Intervention Programs

RTIPs- Moving Science



SunWise
a program that **radiates** good ideas
A Partnership Program of the U.S. Environmental Protection Agency
www.epa.gov/sunwise

Use the link below to select a number of criteria, and see a list that contains programs from several topics.

[Select from 133 Intervention Programs](#)

New Moves

an alternative physical education program just for girls

RTIPs Community.



programs) by conducting systematic reviews of all available research in collaboration with partners. The Task Force on Community Preventive Services then uses the systematic review findings as the basis for their recommendations for practice, policy and future research. The symbol to the right links to Community Guide findings. Many Research-tested Intervention Programs (RTIPs) are listed in the Community Guide findings.

If you use tobacco and are trying to quit, look for general information on the Cancer Information Service at 1-800-4-CANCER.



RTIPs News:

- RTIPs turns 10! [Read more.](#)
- The N-O-T Program was featured 04/09/2013 on the "Exercise h..."

A Systematic Review of the National Cancer Institute's Research-tested Intervention Programs.

New Programs on RTIPs:

- Obesity
- ★ -Complete Health Improvement Program (C...)
- Smart Moves / Bright Bodies (Post date: M...)
- New programs are released periodically. Please

Tools Available:

Using What Works: a train-the-trainer course th...



Research-tested Intervention Programs

RTIPs- Moving Science into Programs for People

Worksite Internet Nutrition (WIN)



Research-tested Intervention Programs (RTIPs)

RTIPs- Moving Science into Programs for People

RTIPs Home RTIPs Archive Frequently Asked Questions Fact Sheet Contact Us



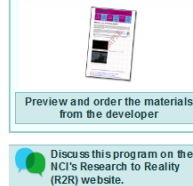
Cancer Control PLANE.T.Home

New Moves

On This Page

- The Need
- The Program
- Community Preventive Services Task Force Finding
- Time Required
- Intended Audience
- Suitable Settings
- Required Resources
- About the Study
- Key Findings
- Publications

Products



Preview and order the materials from the developer

Discuss this program on the NCI's Research to Reality (R2R) website.

Expand All Sections Below

The Need

Weight-related problems are prevalent among adolescent girls and tend to be somewhat more frequent among ethnic and racial minorities. Forty-five percent of African American adolescent girls are overweight or obese, compared to 37 percent of White girls. Girls from low socioeconomic status (SES) backgrounds are more likely to be obese than girls from high-SES backgrounds. Obese adolescent girls are more likely than normal-weight girls to exhibit problems such as inadequate physical activity. ... [Show more](#)

[Back to Top](#)

The Program

Highlights

Purpose Designed to promote healthy dietary habits and increase physical activity to reduce obesity. (2010)
Program Focus Behavior Modification and Motivation
Population Focus Overweight/Obese Individuals
Topic Obesity, Diet/Nutrition, Physical Activity
Age Adolescents (11-18 years)
Gender Female
Race/Ethnicity American Indian, Asian, Black, not of Hispanic or Latino origin, Hispanic or Latino, White, not of Hispanic or Latino origin
Setting School-based
Origination United States
Funded by NIDDK (Grant number(s): R01DK063107), NCRR (Grant number(s): M01RR00400)

RTIPs Scores

Research Integrity
4.3

Intervention Impact
3.0

Dissemination Capability
5.0

1.0 = low 5.0 = high

RE-AIM Scores

Reach
100.0%

Effectiveness
66.7%

Adoption
100.0%

Implementation
62.5%

RE-AIM Notes

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

Reach

Absolute number, proportion and representativeness of individuals who participate in the program.



Coming to RTIPs in 2013-2014:

More user interactive web-based interventions

COMING SOON

Criteria for Inclusion on RTIPs

- Intervention outcome finding(s) must be published in a peer-reviewed journal.
- The study must have produced one or more positive behavioral and/or psychosocial outcomes ($p \leq .05$) among individuals, communities, or populations.
- Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. The intervention must have messages, materials, and/or other components that include English and can be disseminated in a U.S. community or clinical setting.
- The intervention has been conducted within the past 10 years.



How You Can Get Involved:

1. Submit your intervention for RTIPs consideration:
<http://rtips.cancer.gov/rtips/register/index.do>
2. Contact the RTIPs team for questions, comments, additional information:
<http://rtips.cancer.gov/rtips/contact.do>
3. Coming to RTIPs in 2013-2014: More user interactive web-based interventions.

WE WANT YOU!

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

Screening

(s), Older Adults (65+ years)

(s): P30CA16042, R25CA87949), U.S. Army Medical Research and Development Command (Grant number(s): DAMD17-03-1-0676)

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

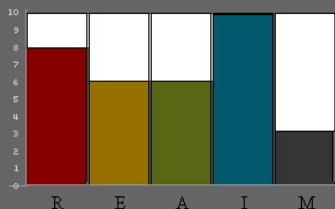
5-6: Fair, needs additional planning

< 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%

Dissemination Capability

1.0 = low 5.0 = high

RE-AIM Notes

Hide x



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

http://re-aim.org/resources_and_tools/index.html

Key Take Home Points

*Evidence means different things to different people
–is almost a cultural difference*

We need:

- **Balance and respect for different types of evidence**
- **To think and evaluate broadly**
- **To consider evidence from multiple perspectives, and especially of potential target audience**

Contact me: glasgowre@mail.nih.gov

IS Team Website:
<http://dccps.cancer.gov/is/>

IS Team Email:
NCIdccpsISteam@mail.nih.gov



ADDITIONAL SLIDES

RE-AIM *Evaluability* Questions or Planning for Dissemination

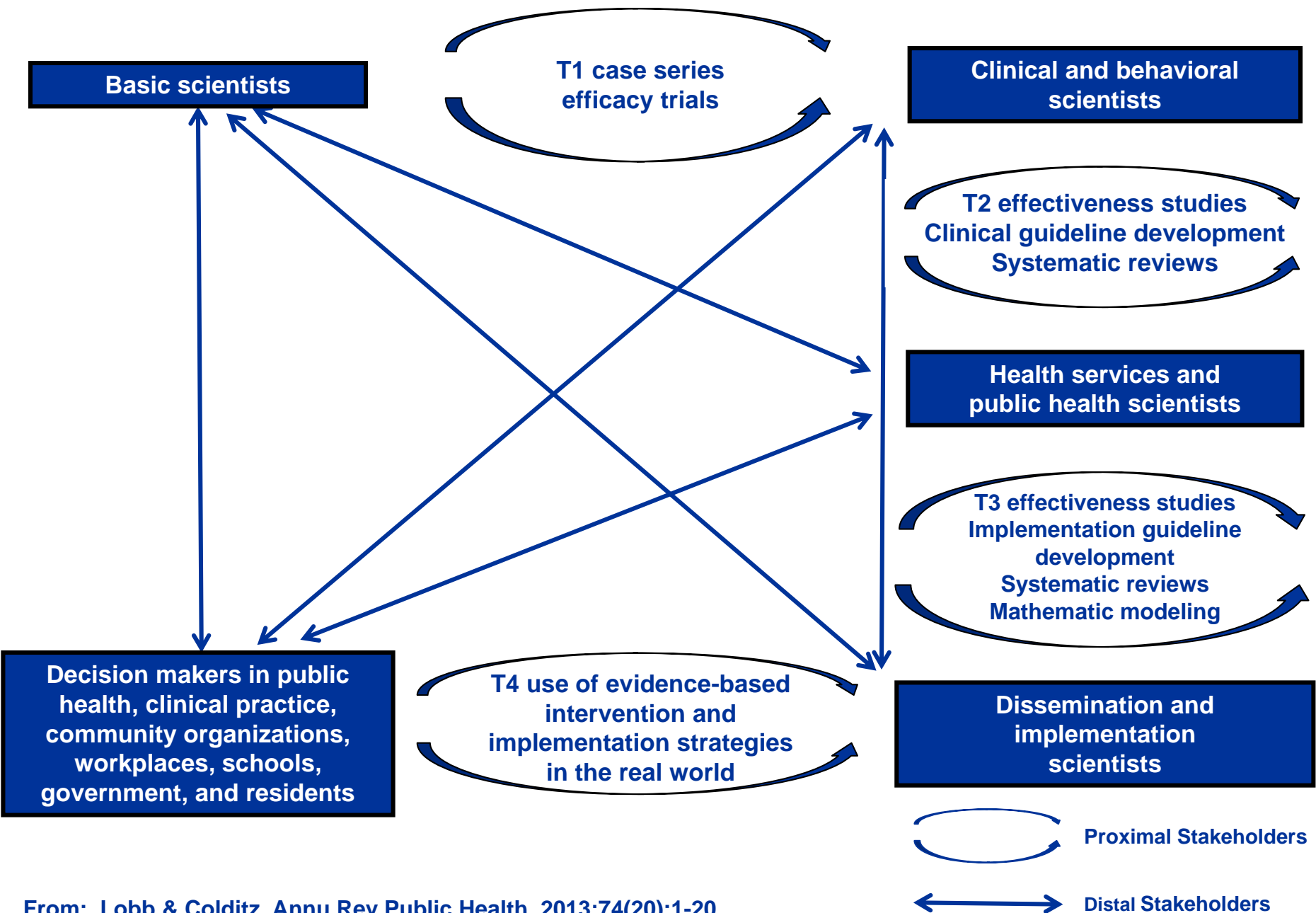
- What percent and what types of patients are likely to *Receive* this program;
- For whom among them is the intervention *Effective*; in improving what outcomes; what broader effects and potential negative consequences?
- What percent and what types of settings and practitioners are likely to *Adopt* this program;
- How consistently are different parts of the program likely to be *Implemented* across settings, clinicians, and patient subgroups...and at what cost;
- And how well is the eHealth program and its effects likely to be *Maintained*?

Future Evidence Needs and Opportunities— Keys to Advance Translation

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

Future Evidence Needs and Opportunities— Keys to Advance Translation (cont.)

- **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**

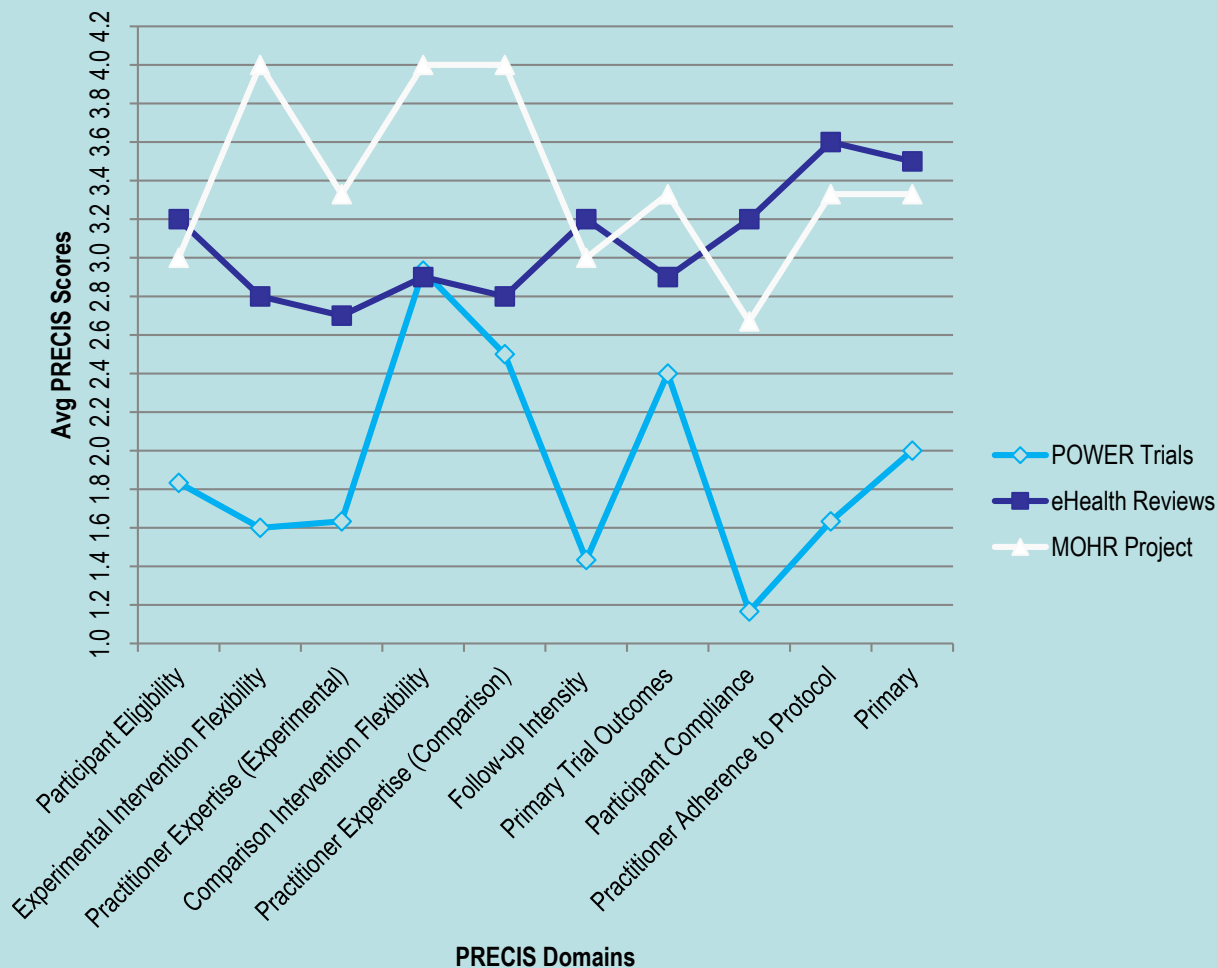


Gaglio et al (2013) submitted Summary: Experience Using PRECIS

Results: Consistent results were found across all three diverse applications. These pragmatic criteria can be **reliably rated, reveal differences across dimensions and studies**, and studies are rated as more pragmatic on the original PRECIS criteria than on the added external validity criteria.

Conclusions: Such measures should be used more consistently *to help plan pragmatic studies, evaluate progress, increase transparency of reporting*, and integrate literature intended to help translate research into practice and policy.

Average Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) scores for Practice-Based Opportunities for Weight Reduction (POWER) Trials, Systematic Review of eHealth Cancer Prevention and Control Interventions, and My Own Health Report (MOHR)



PRECIS Scoring Continuum: 0 = Explanatory, 4 = Pragmatic