

# Implementation Science in 2013

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

**ISRII 6<sup>th</sup> Scientific Meeting**  
**Chicago – May 2013**



# Overview

- **Implementation Science Perspectives on eHealth**
  - Evidence Integration Triangle
  - RE-AIM and Equity Issues
- **Pragmatic Approaches and eHealth Review**
- **Reflections, Needs and Pragmatic Example**
  - My Own Health Report 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.

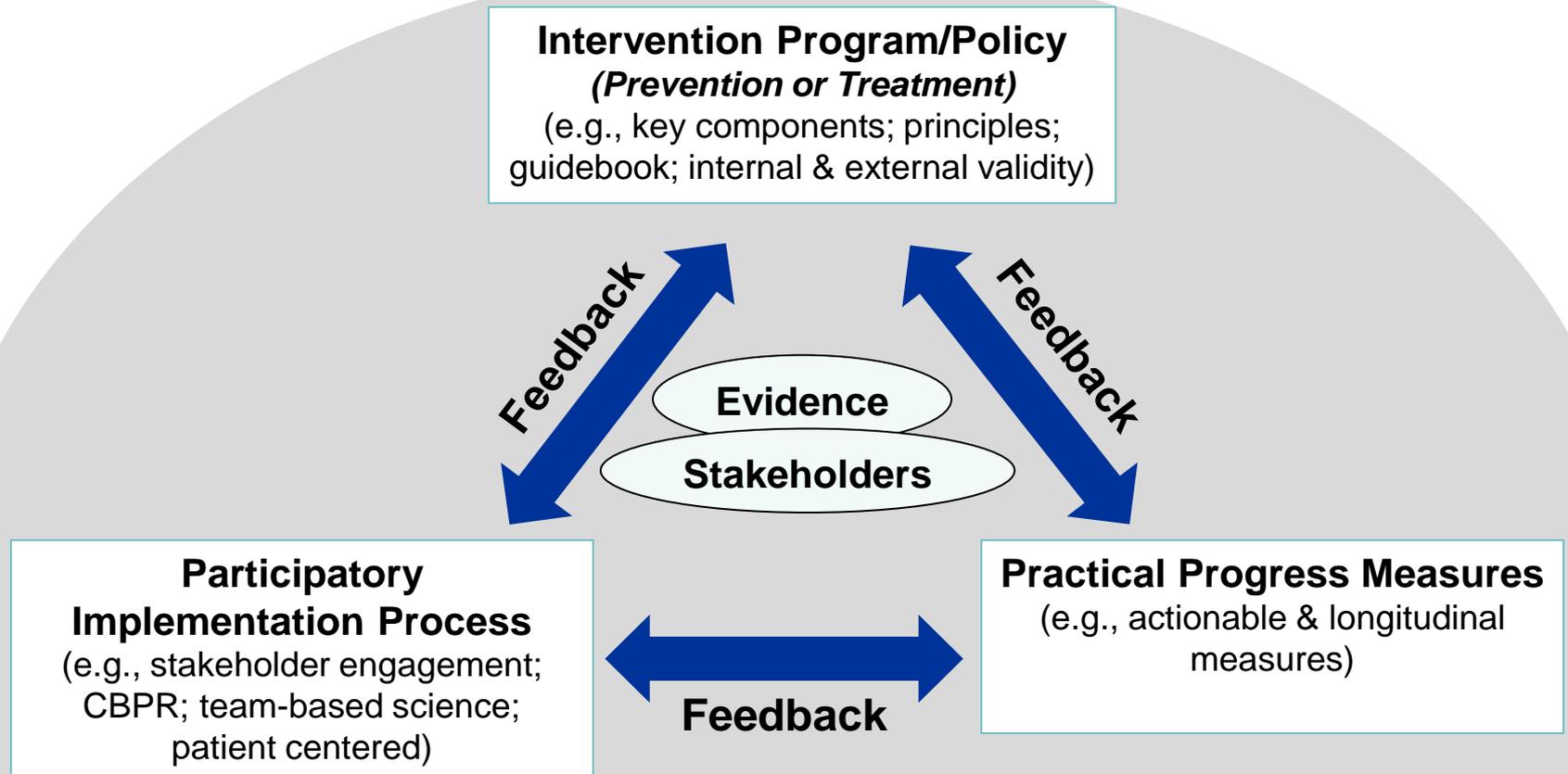
Gaglio B, Glasgow RE. Evaluation approaches...In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-356.



## RE-AIM—Inequity 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
<b>Implementation</b>	<b>30%</b>	<b>34% of benefit</b>
Maintenance	30%	24% of benefit

# Evidence Integration Triangle (EIT)



## Multi-Level Context

- Intrapersonal/Biological
- Interpersonal/Family
- Organizational
- Policy
- Community/Economic
- Social/Environment/History

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

## Intervention Program/Policy

Evidence-based decision aids to provide feedback to both patients and health care teams for action planning and *health behavior counseling*

## **Evidence:**

US Preventive Services Task Force recommendations for health behavior change counseling; goal setting & shared decision making

## **Stakeholders:**

Primary care (PC) staff, patients and consumer groups; health care system decision makers; groups involved in meaningful use of EHRs

## Participatory Implementation Process

Iterative, *wiki activities* to engage stakeholder community, measurement experts and diverse perspectives

## Practical Progress Measures

Brief, *standard patient reported data items* on health behaviors & psychosocial issues -- actionable and administered longitudinally to assess progress

**Feedback**

## **Multi-Level Context**

- Dramatic increase in use of EHR
- Primary Care Medical Home
- CMS funding for annual wellness exams
- Meaningful use of EHR requirements

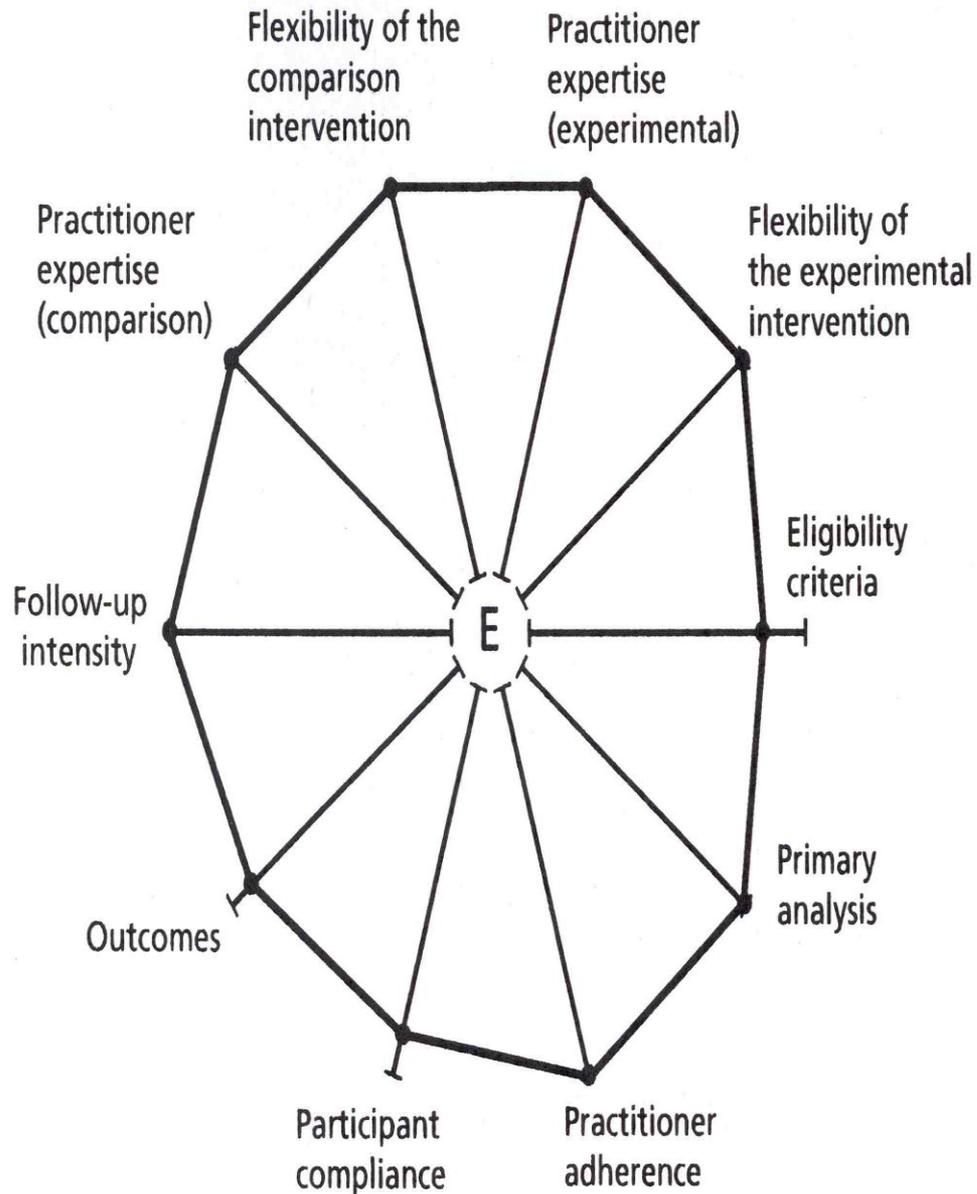
# The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

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

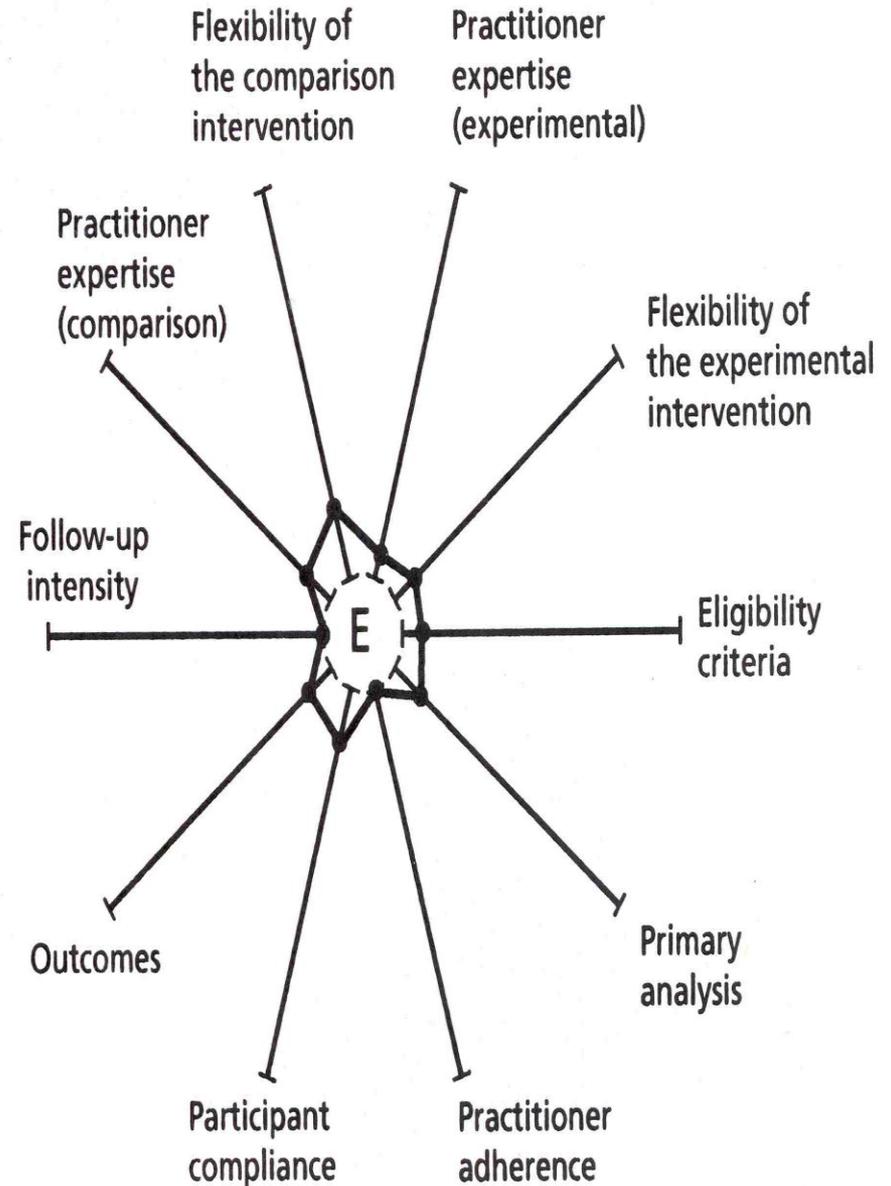
1. Participant eligibility criteria
2. Experimental intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison) outcome
6. Follow-up intensity
7. Primary trial outcome
8. Participant compliance
9. Practitioner adherence
10. Analysis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

# PRECIS

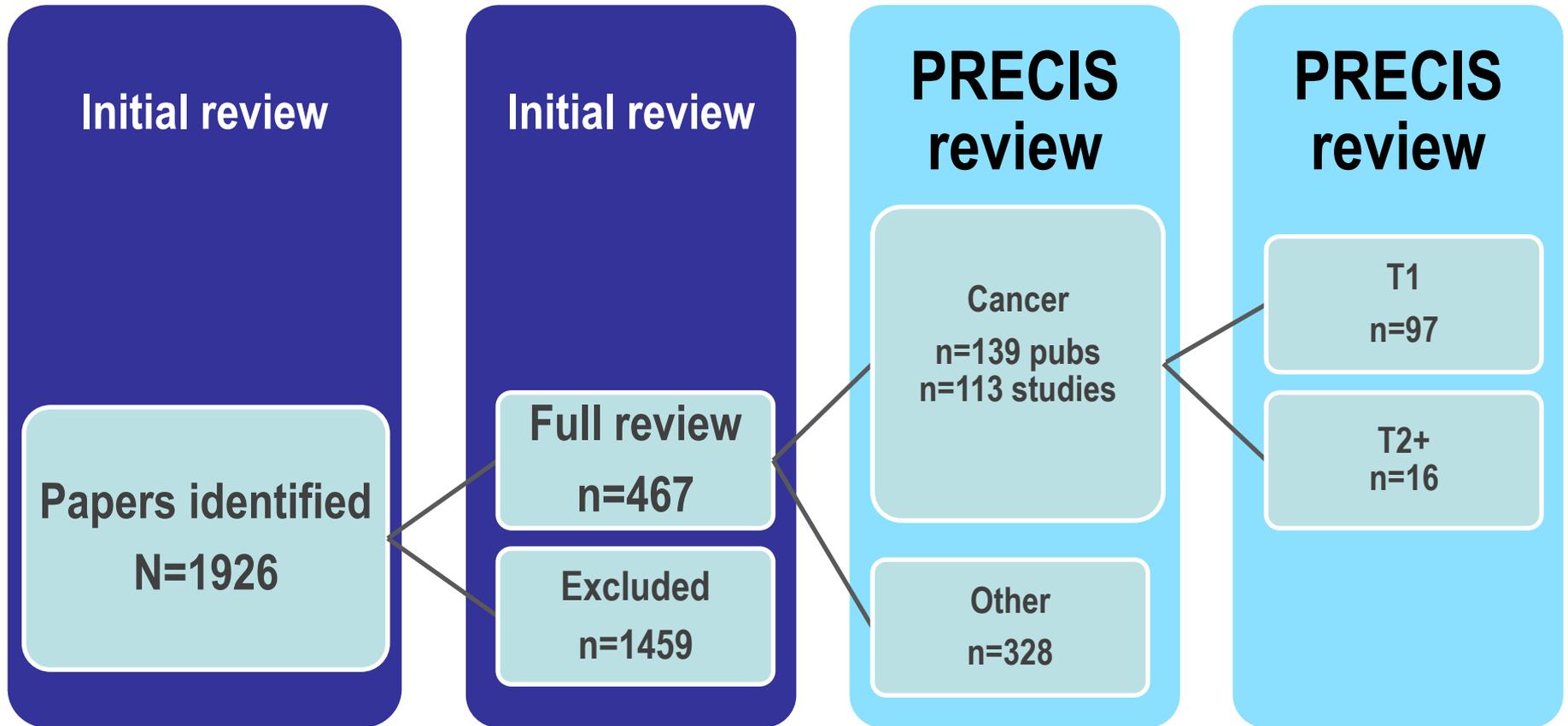
## A PRAGMATIC STUDY



## B EXPLANATORY STUDY



# eHEALTH REVIEW



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

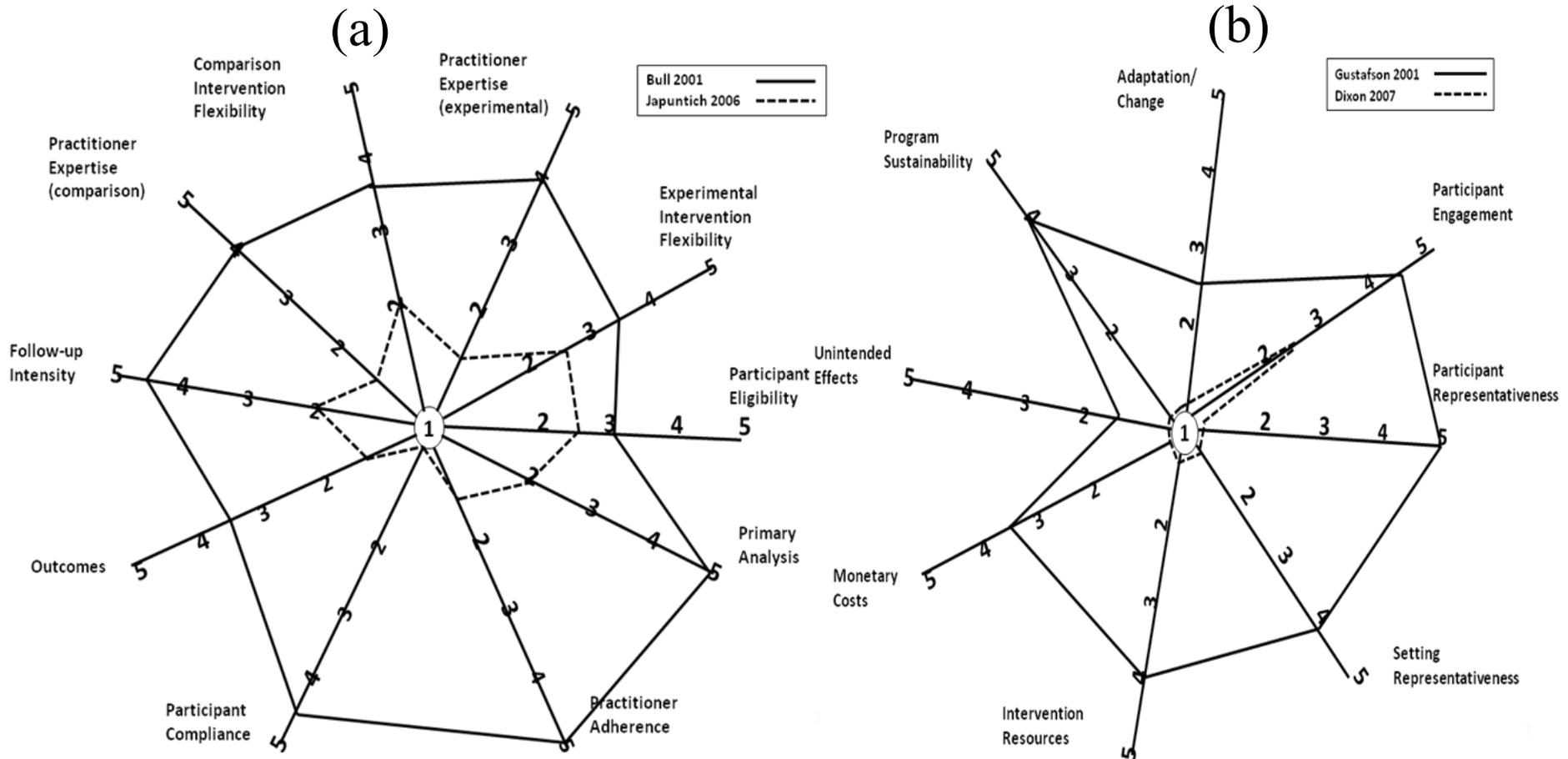
Sanchez et al. A Systematic Review of eHealth Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Under Review.

# eHEALTH REVIEW 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

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

# Pragmatic Explanatory Continuum Indicator Summary (PRECIS) and Practical Feasibility “Spoke and Wheel” Diagrams: (a) PRECIS lowest versus highest scored studies\*; (b) Practical feasibility lowest versus highest scored studies



\* Maximum and minimum PRECIS scores based on only studies for which all domains were scored.

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

# 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

Riley, W. T. & Glasgow, R. E. Pragmatic measures... *Am J Prev Med.* 2013.

# Dissemination and Implementation Measures Initiative



GEM-D&I Homepage:  
[www.gem-beta.org/GEM-DI](http://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



# EHR Measures for Primary Care

Domain	Final Measure (Source)
1. Overall Health Status	1 item: BRFSS Questionnaire
2. Eating Patterns	3 items: <b>Modified from Starting the Conversation (STC)</b> [Adapted from Paxton AE et al. Am J Prev Med 2011;40(1):67-71]
3. Physical Activity	2 items: <b>The Exercise Vital Sign</b> [Sallis R. Br J Sports Med 2011;45(6):473-474]
4. Stress	1 item: Distress Thermometer [Roth AJ, et al. Cancer 1998;15(82):1904-1908]
5. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. Psychosomatics 2009;50(6):613-621]
6. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL [Item PQSLP04]
7. Smoking/Tobacco Use	2 items: <b>Tobacco Use Screener</b> [Adapted from YRBSS Questionnaire]
8. Risky Drinking	1 item: <b>Alcohol Use Screener</b> [Smith et al. J Gen Int Med 2009;24(7):783-788]
9. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. Arch Int Med 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 National Health Interview Survey (NHIS)

# 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

MRN: \_\_\_\_\_

**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
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

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

5 or more	3-4 servings	2 or less
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



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

# MOHR Project—Key Points

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

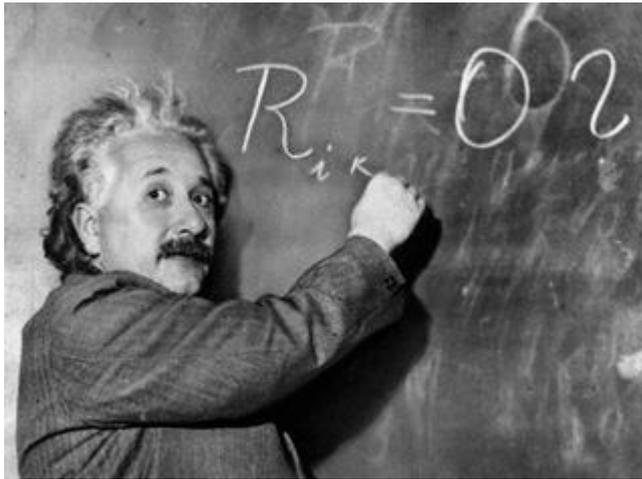
- Cluster randomized trial of 9 pairs of clinics. Approximately half of clinics community health centers, others AHRQ-type PBRN clinics
- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- **WHAT is delivered** - e.g., automated assessment tool, feedback, goal setting materials, follow-up are **STANDARD**
- **HOW this is delivered is customized** to setting
- Study goal = Sustainable, routine use of intervention



# Pragmatic Features

<b>Relevant</b>	Diverse, real-world primary care settings; and staff who do all the intervention
<b>Rigorous</b>	Cluster randomized, delayed intervention design
<b>Rapid</b>	One year from concept, planning, and execution, low cost, and cost informative
<b>Resource Informative</b>	Low cost; studying costs and cost-effectiveness under different delivery conditions
<b>Transparent</b>	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***

# Russ' Observations and Reflections

## On Evidence



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

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

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**

Thorpe KE, Zwarenstein M, Oxman AD et al. Journal Clin Epidemiol. 2009; 62: 464–475

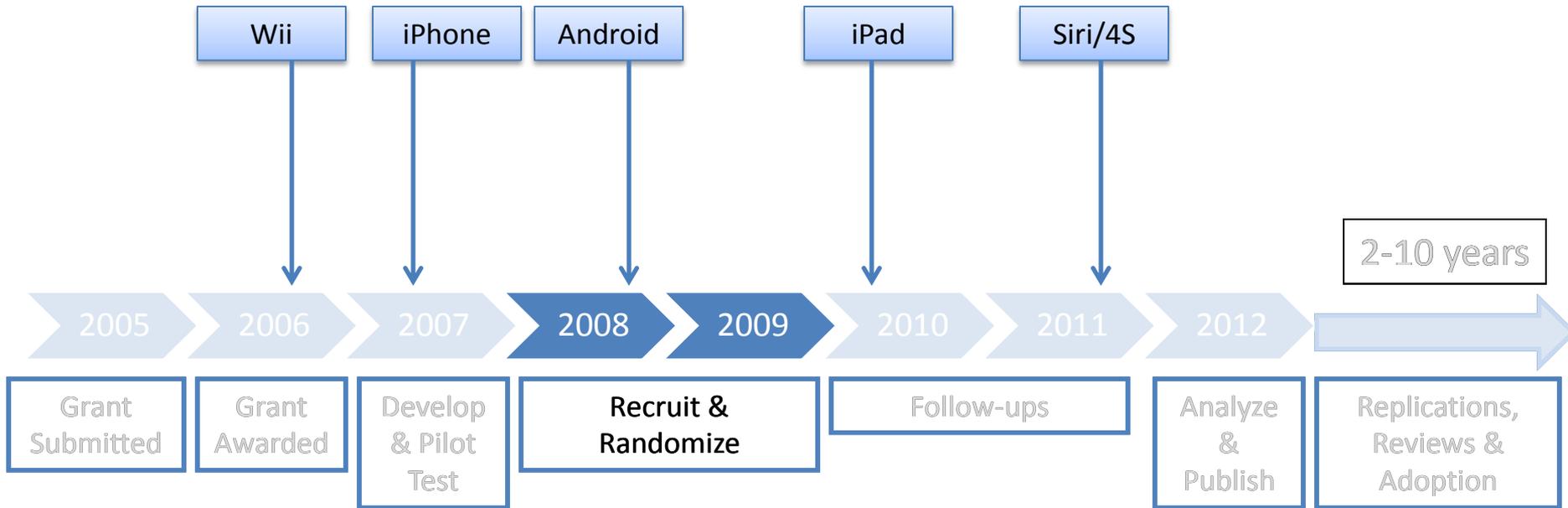


# Rapid\* and Recursive

- 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
- 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

\*Riley, Glasgow, Etheredge, Abernethy. Pragmatic measures... *Am J Prev Med.* 2013

# Traditional Timeframe for Research in Comparison to Technology

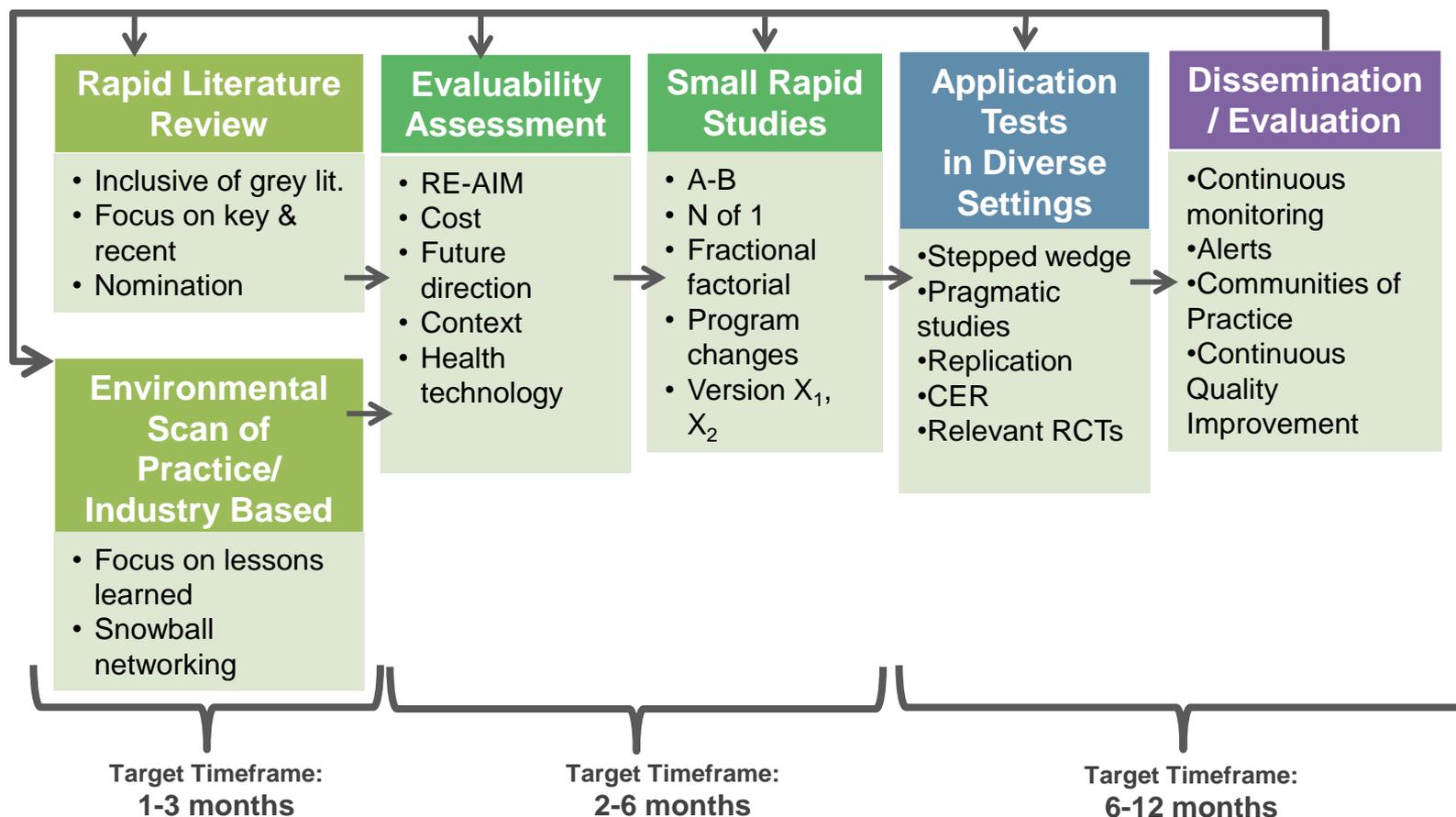


# Development/Validation Steps Involving Rapid eHealth Learning Networks

2008

2009

Recruit & Randomize



**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 *sina 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.

# What Else Do We Need?

- Harmonized measures: Common measures would help cross-study comparisons, reviews, etc.
- Convergence of results across diverse methods: e.g., RCTs, observational data, simulation modeling, natural experiments, practice-based evidence, quantitative and qualitative, etc.

# All Models (and Methods) are Wrong... ....Some are useful



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

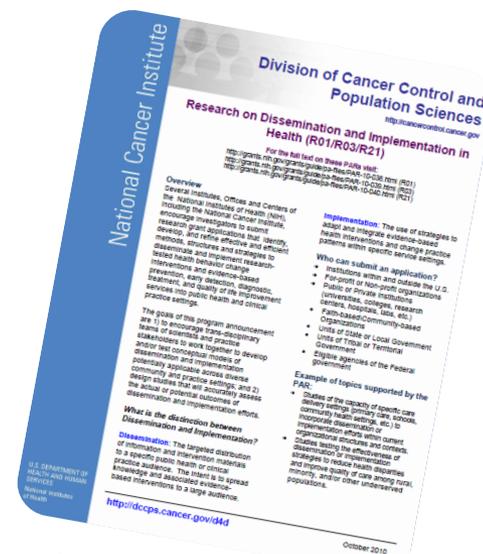
**~H. L. Mencken**

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

- Relevant (to stakeholders)
- Rapid and Recursive—iterative; ongoing learning
- Rigorous (redefined to include robustness and replication)
- Resources Reported
- Replication

# 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



NIH D&I Funding Announcements: [http://cancercontrol.cancer.gov/funding\\_apply.html#is](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](http://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](#)

### RTIPs News:

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

## New Moves

an alternative physical education program just for girls

RTIPs Community.

**Sun Safe**

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, call the Cancer Information Service at 1-800-4-CANCER for general information.

## Research-tested Intervention Programs

RTIPs- Moving Science into Programs for People

### Worksite Internet Nutrition (WIN)

Call the Cancer Information Service at 1-800-4-CANCER for general information. Modified: 04/23/2013



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 P.L.A.N.E.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

#### 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)

#### 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

**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.

# RESEARCH TESTED INTERVENTION PROGRAMS (RTIPS)

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

## 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

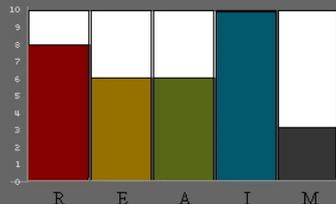
5-6: Fair, needs additional planning

< 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

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

### Dissemination Capability

1.0 = low 5.0 = high

[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>

# Key Take Home Points

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

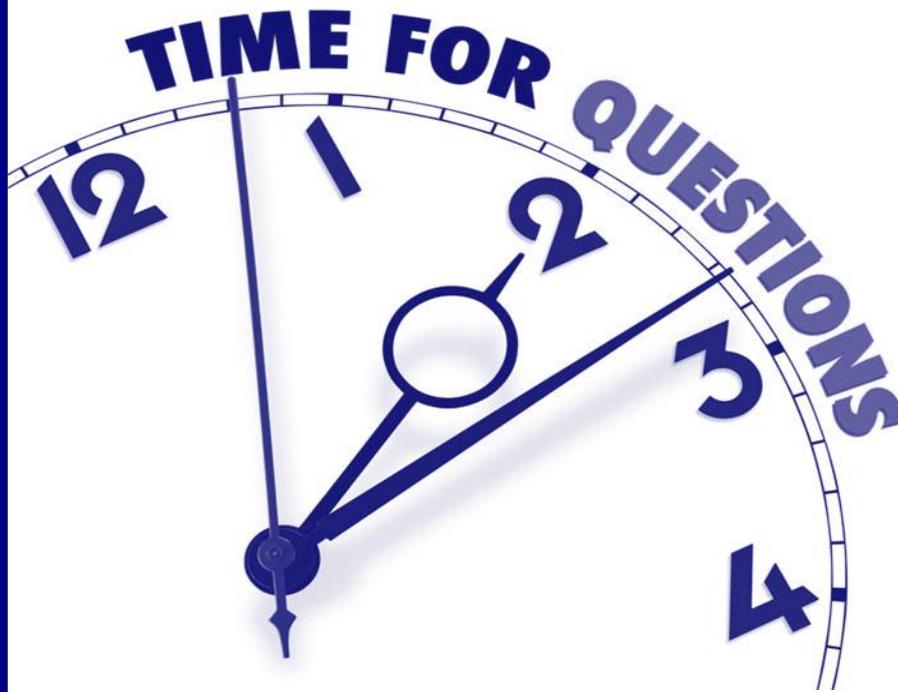
**We need:**

- 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](mailto:glasgowre@mail.nih.gov)

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

IS Team Email: [NCIdccpsISteam@mail.nih.gov](mailto: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