National Cancer Institute

Implementation Science in 2013

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

ISRII 6th Scientific Meeting
Chicago – May 2013

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Cancer Institute

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/

National Cancer Institute

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.

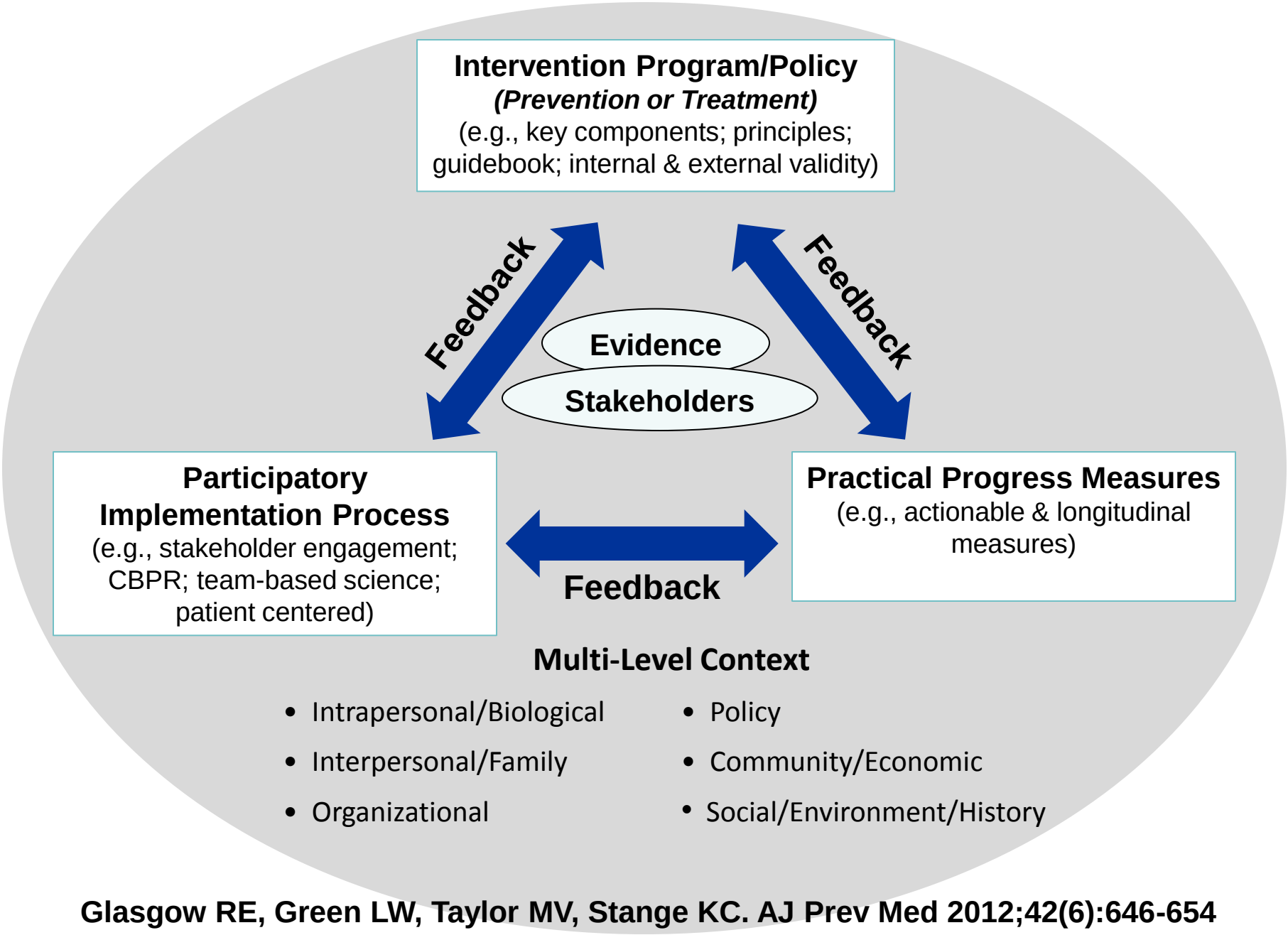
Gaglio B, Glasgow RE. Evaluation approaches…In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-356.

RE-AIM—Inequity Implications

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

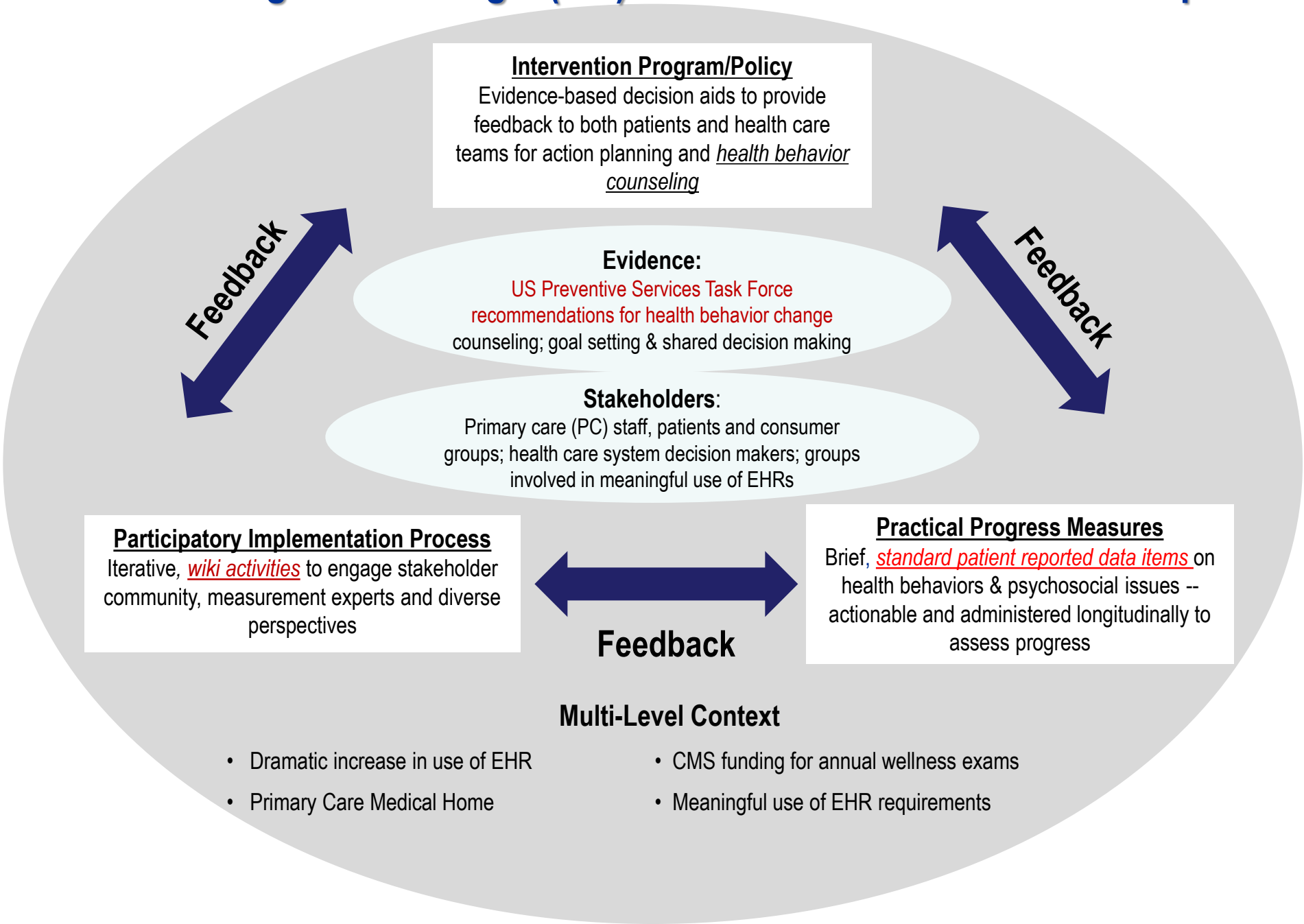
IS Team Presentation on Health Inequities: http://cancercontrol.gov/IS/presentations.html

Evidence Integration Triangle (EIT)



Glasgow RE, Green LW, Taylor MV, Stange KC. AJ Prev Med 2012;42(6):646-654

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



National Cancer Institute

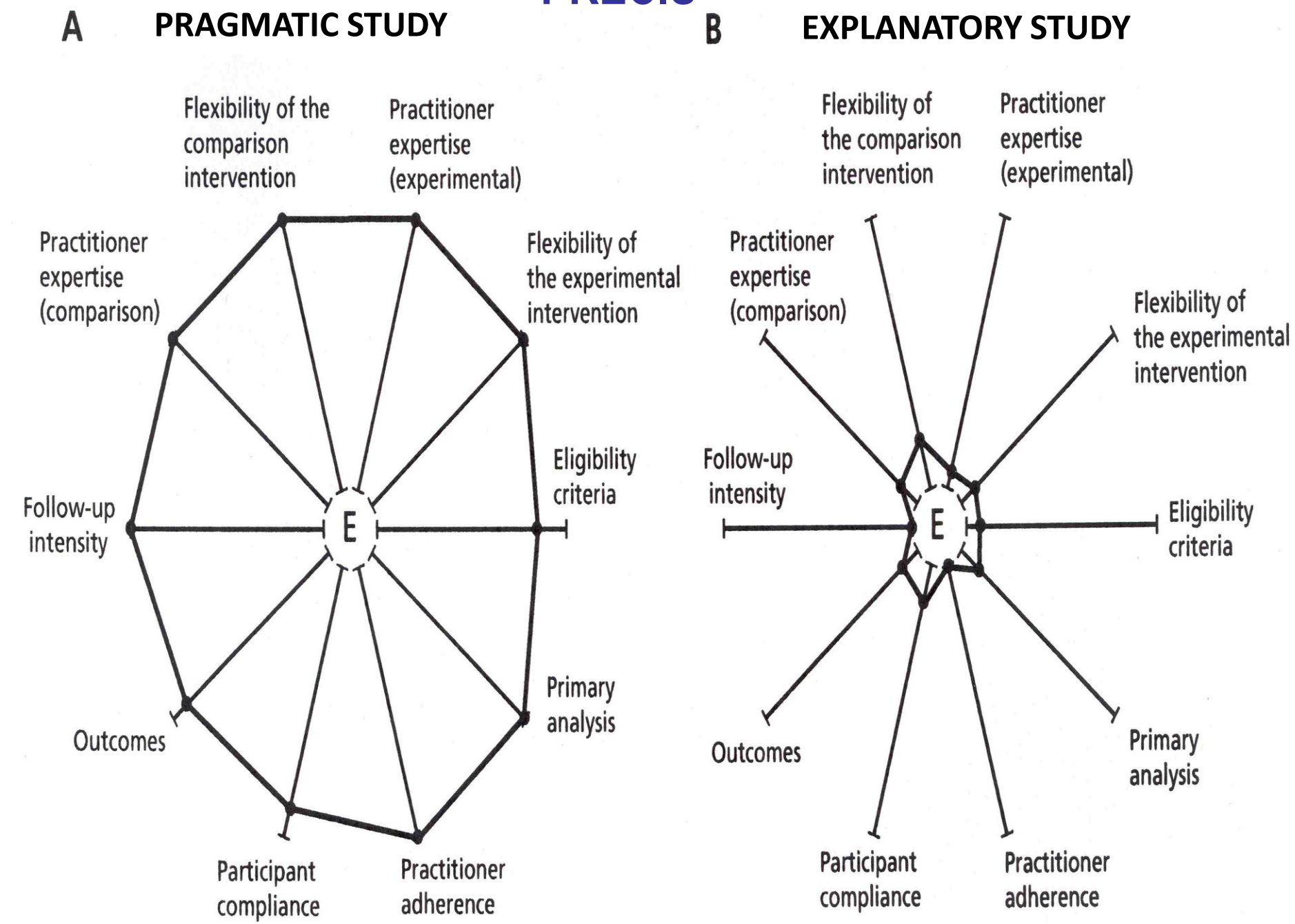
The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

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

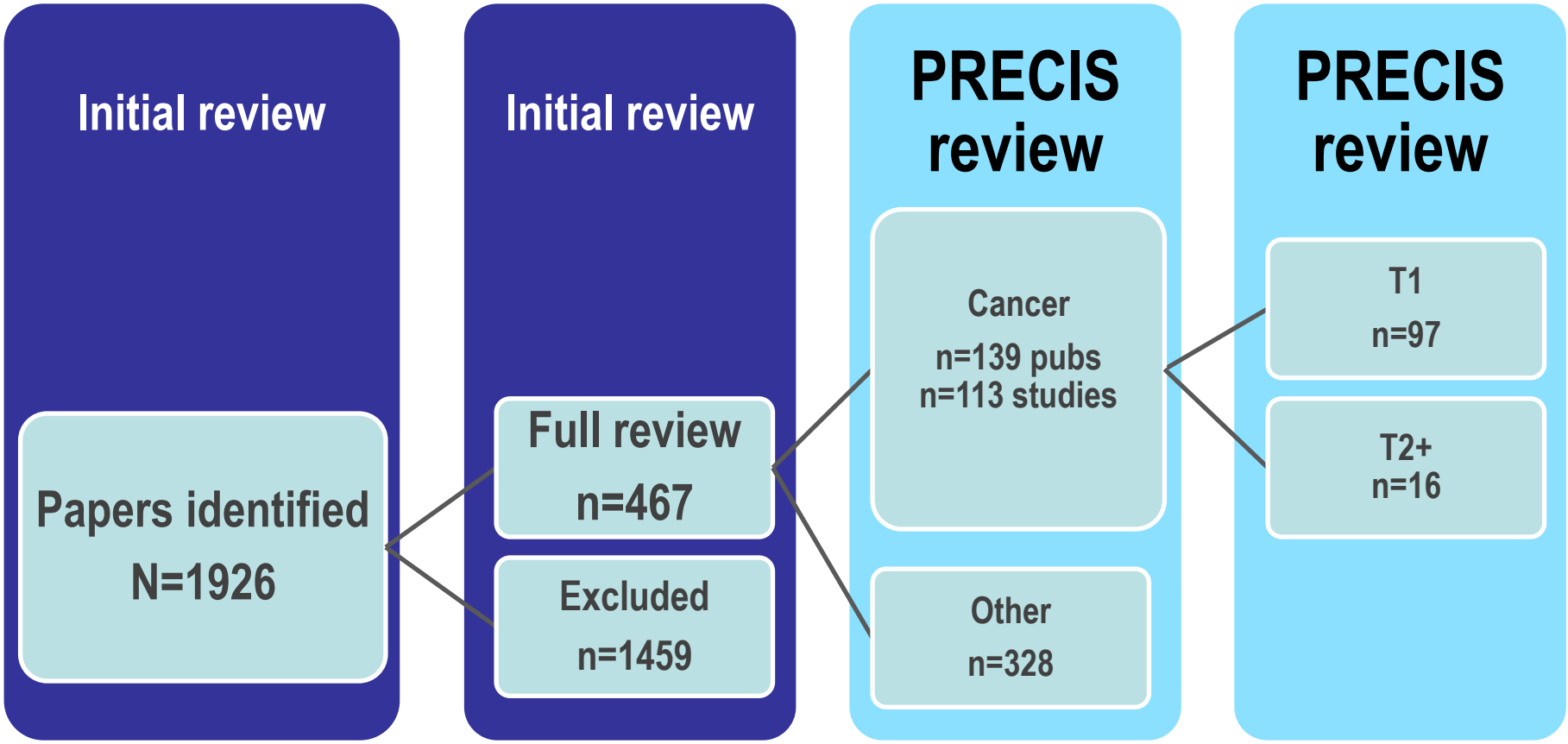
1. Participant eligibility criteria
2. Experimental intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison) outcome
6. Follow-up intensity
7. Primary trial outcome
8. Participant compliance
9. Practitioner adherence
10. Analysis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

Thorpe KE, et al. *J Clin Epidemiol* 2009; 62: 464–475, *Can Med Assoc J* 2009; 180(10)

PRECIS


A
PRAGMATIC STUDY
Flexibility of the comparison intervention
Practitioner expertise (experimental)
Practitioner expertise (comparison)
Flexibility of the experimental intervention
Eligibility criteria
Follow-up intensity
E
Primary analysis
Outcomes
Participant compliance
Practitioner adherence
B
EXPLANATORY STUDY
Flexibility of the comparison intervention
Practitioner expertise (experimental)
Practitioner expertise (comparison)
Flexibility of the experimental intervention
Follow-up intensity
E
Eligibility criteria
Outcomes
Primary analysis
Participant compliance
Practitioner adherence

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.

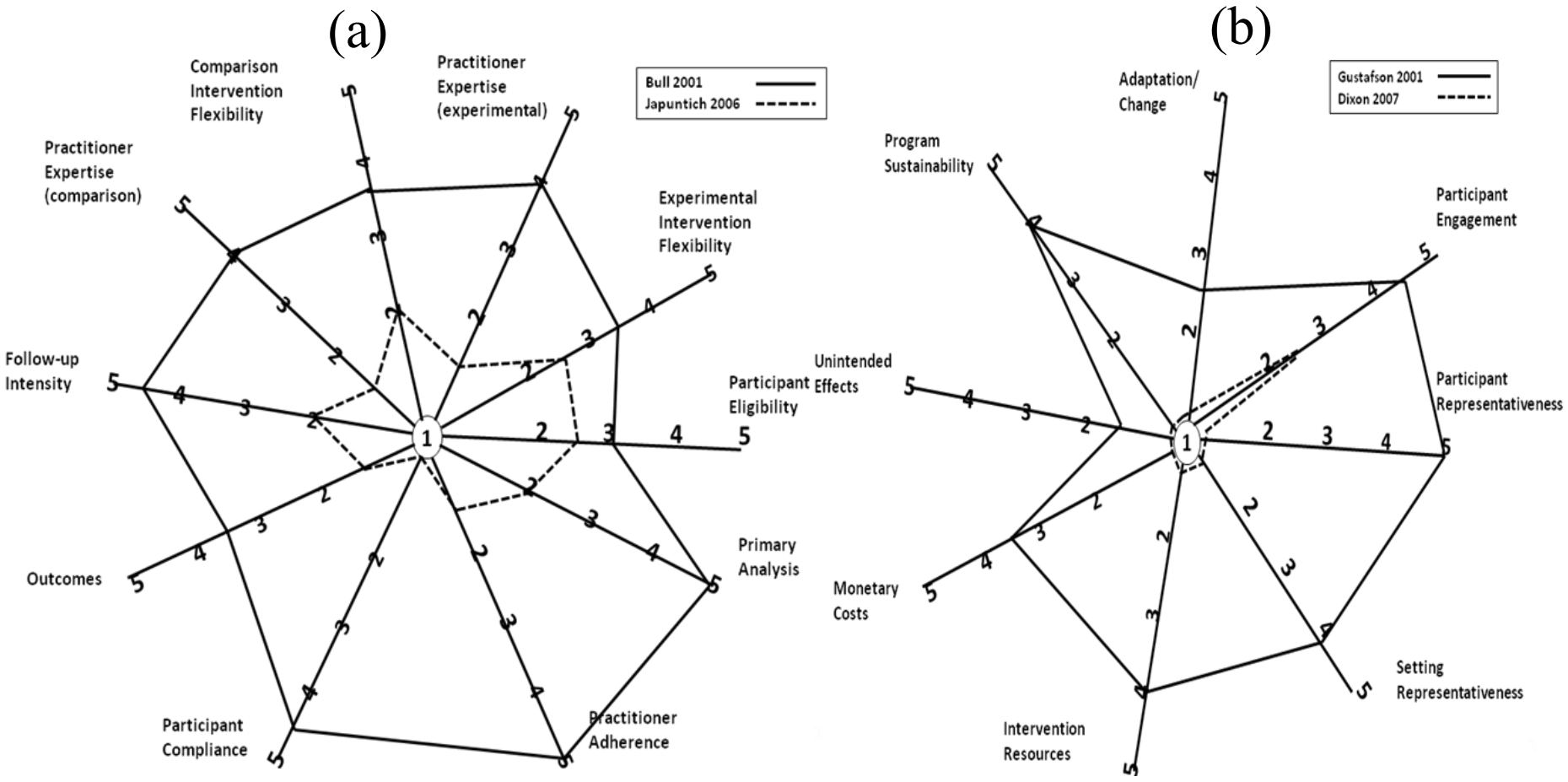
National Cancer Institute

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.

National Cancer Institute

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

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: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. Am J Prev Med 2011;40(1):67-71]**
3. Physical Activity	**2 items: The Exercise Vital Sign [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: Tobacco Use Screener [Adapted from YRBSS Questionnaire]**
8. Risky Drinking	**1 item: Alcohol Use Screener [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)

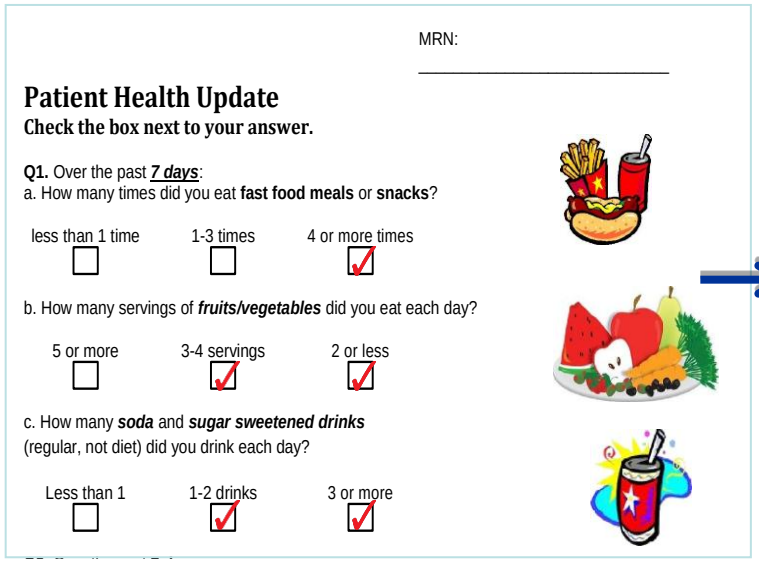
National Cancer Institute

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 ☑

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

MOHR Project—Key Points

http://www.myownhealthreport.org/

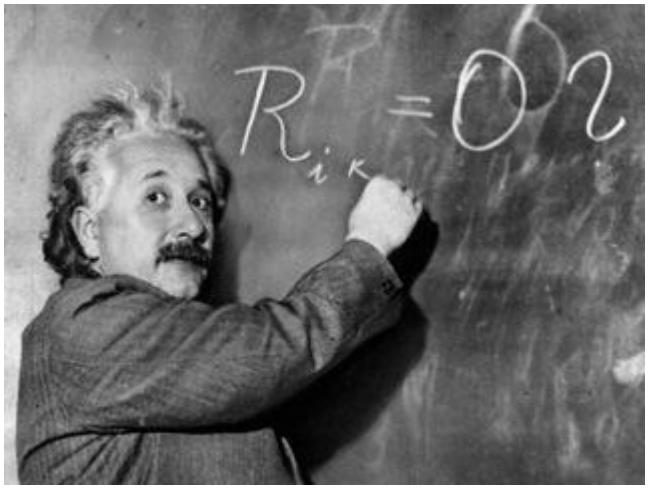
- Cluster randomized trial of 9 pairs of clinics. Approximately half of clinics community health centers, others AHRQ-type PBRN clinics
- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- **WHAT is delivered** - 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

Fact Sheet Available at: http://cancercontrol.cancer.gov/IS/pdfs/MOHR_Executive_Summary_2-22-2013.pdf

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

National Cancer Institute

Russ' Observations and Reflections

On Evidence

National Cancer Institute

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

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

National Cancer Institute

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

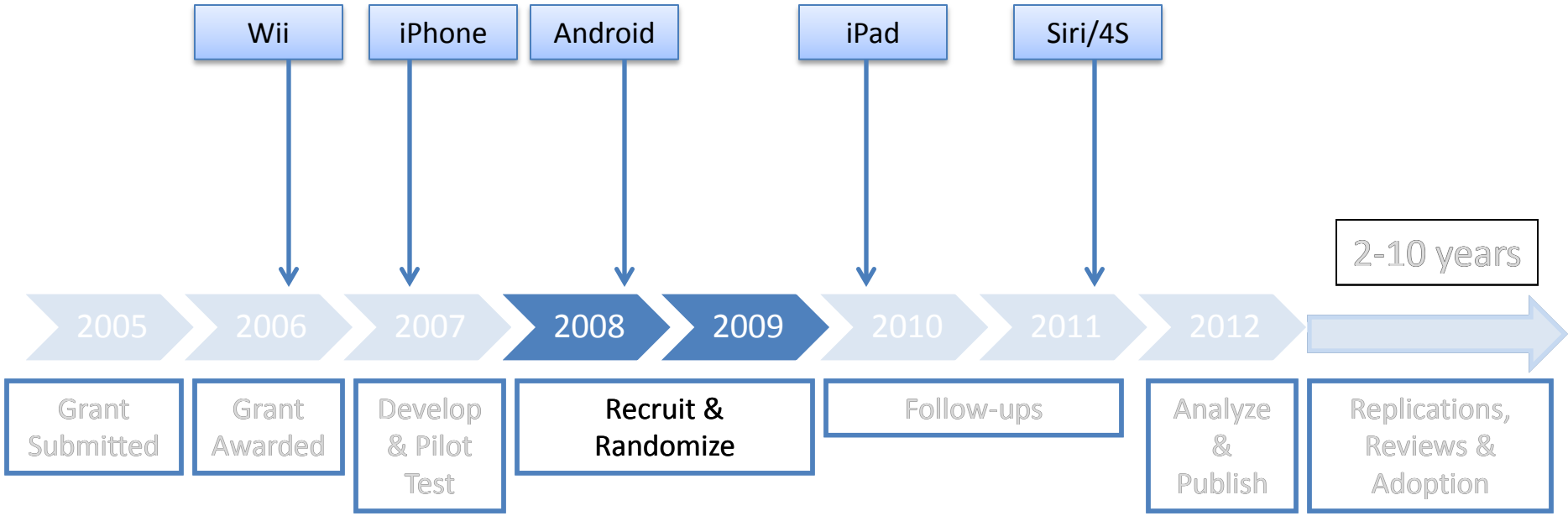
National Cancer Institute

Rapid* and Recursive

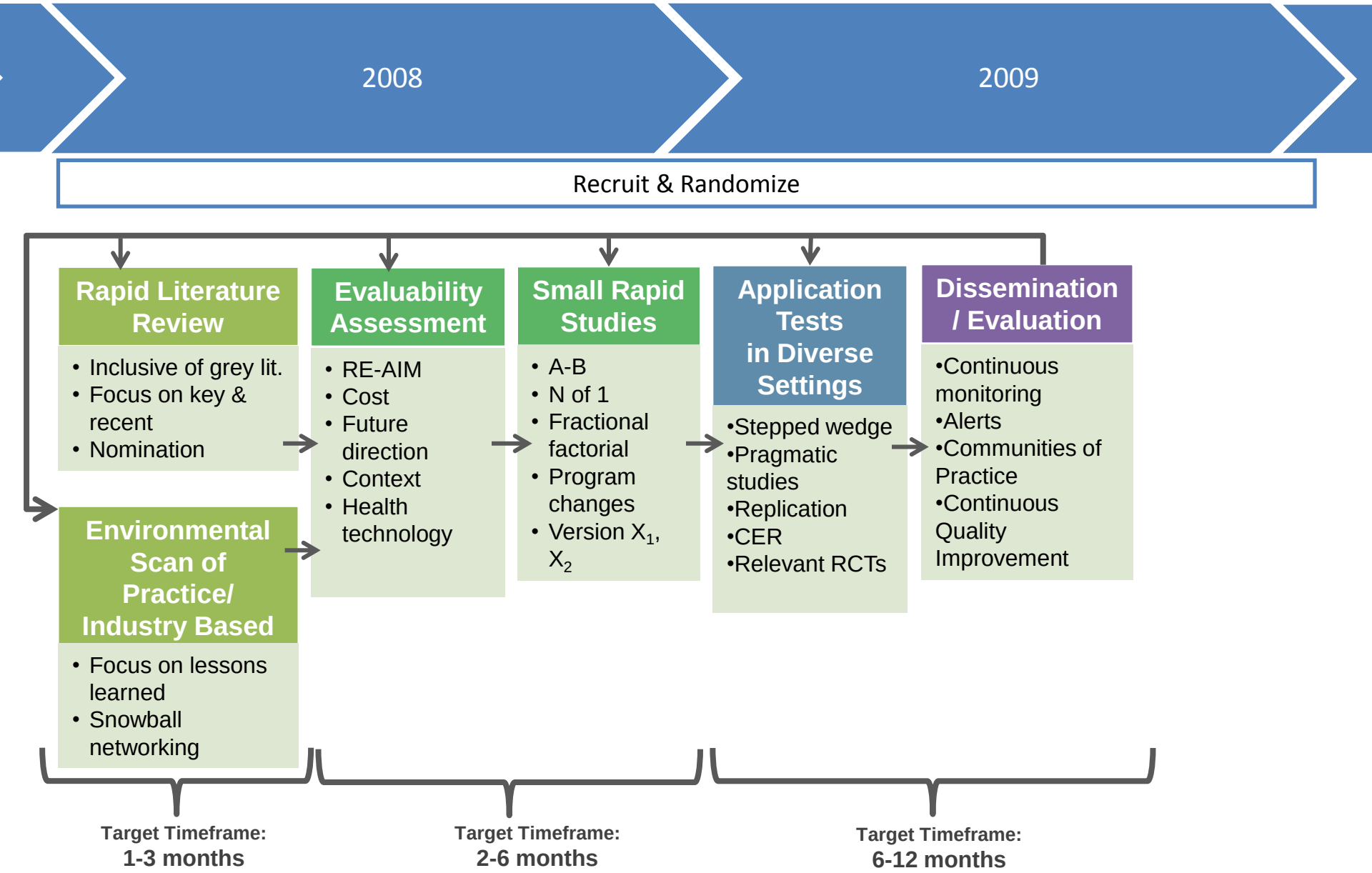
- Pace of research (17 years for 14% of data to translate) is way too slow
- Need changes in design, review, measures, publication, and culture
- Many evolving, adaptive designs; several from different fields
- Across the T1-T4 cycle
- In Quality Improvement (QI) sense of continuous improvement
- Programs 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



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

National Cancer Institute

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

National Cancer Institute

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.

National Cancer Institute

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.

National Cancer Institute

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

National Cancer Institute

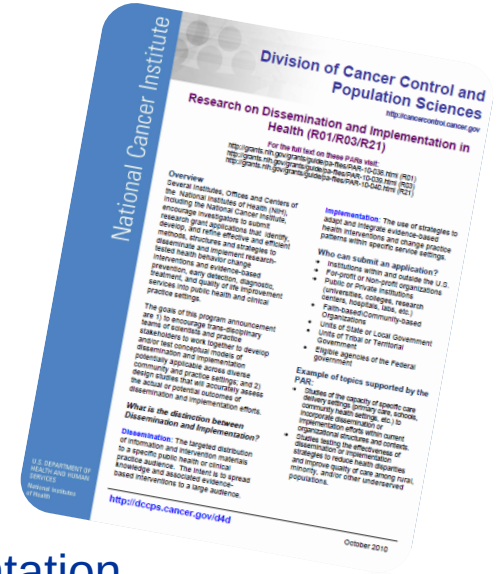
Types of Evidence Needed: A New "Bold Standard"? The 5 R's

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

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

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

National Cancer Institute

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

COMING SOON

Criteria for Inclusion on RTIPs

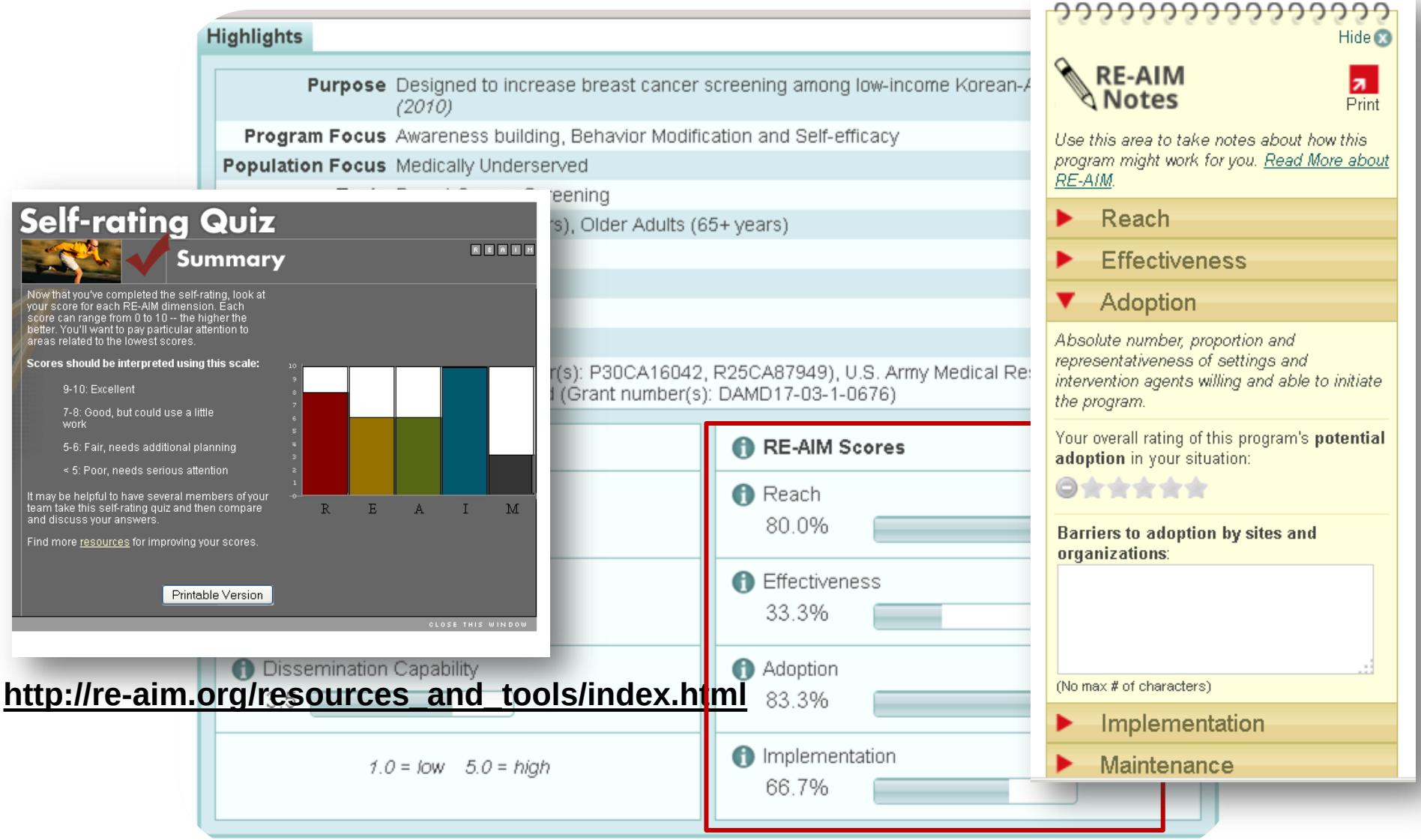
- Intervention outcome finding(s) must be published in a peer-reviewed journal.
- The study must have produced one or more positive behavioral and/or psychosocial outcomes ($p \leq .05$) among individuals, communities, or populations.
- Evidence of these outcomes has been demonstrated in at least one 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.

WE WANT YOU!

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.

EVIDENCE-BASED PROGRAM AND RE-AIM RESOURCES



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

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

National Cancer Institute

Key Take Home Points

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

We need:

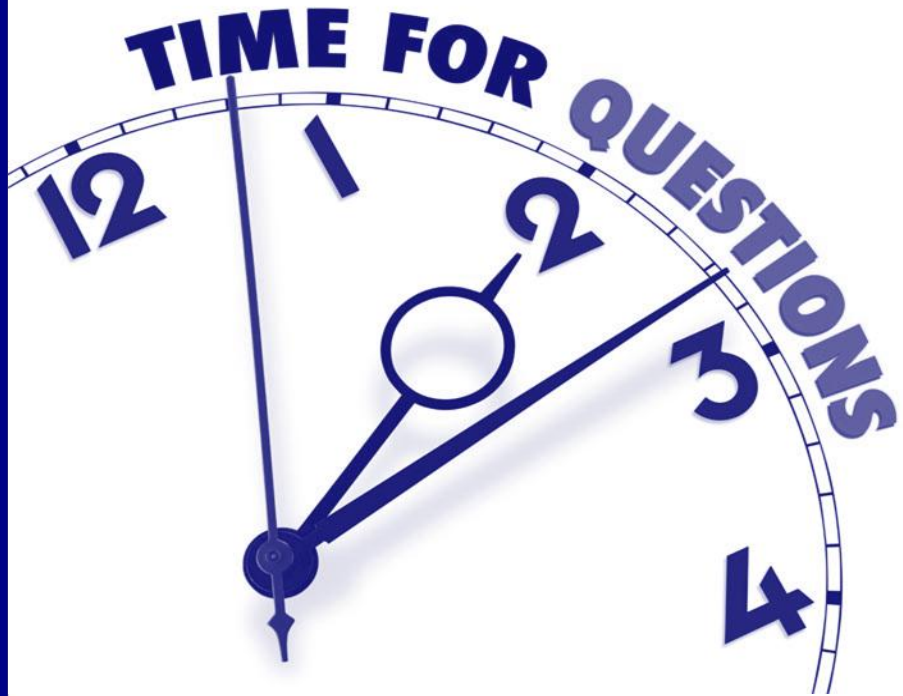
- Balance and respect for different types of evidence
- To think and evaluate broadly
- To consider evidence from multiple perspectives, and especially of potential target audience

National Cancer Institute

Contact me: glasgowre@mail.nih.gov

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

IS Team Email: NCIdccpsISteam@mail.nih.gov



Additional Slides

National Cancer Institute

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***?

Leviton LC, et al. Evaluability assessment…*Annu Rev Public Health* 2010;31:213-233.

National Cancer Institute

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

National Cancer Institute

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