WHAT DOES IT MEAN TO BE PRAGMATIC? Opportunities and Challenges for Pragmatic Approaches

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National Cancer Institute

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.

http://cancercontrol.cancer.gov/is/

Pragmatic Methods, Measures and Models

- Overview and Methods Issues:
  - Pragmatic Trials
  - Types of Evidence Needed:“2 R’s and RCT”
- Measurement Issues:
  - Criteria for Pragmatic Measures
  - Example applications
- Models:
  - Realist perspective, Evidence Integration Triangle
- Opportunities and Challenges:

Definitions of Pragmatic

Wikipedia on Pragmatism:

- "a philosophical tradition centered on the *linking of practice and theory*"

Miriam Webster adds:

- Pragmatic approaches use a process where theory is extracted from practice, and applied back to practice to form what is called *intelligent practice.*

Why is Pragmatic Research Needed?

- Not reaching those with complex problems and those most in need
- Not testing in settings and with staff that are typical to most public health or clinical situations
- Not addressing issues important to practitioners, policy makers, and citizens/families
- Many "evidence-based"; treatment not feasible in most real-world settings
- Bottom Line— *research not seen as RELEVANT*

Rothwell PM. *Lancet* 2005;365:82-93.

Most Common Type of Research?
Bench to Bookshelf

Pragmatic Methods

- A pragmatic (or practical) trial seeks to answer the question, "Does an intervention work under *usual* conditions?"

- An explanatory (or efficacy) trial seeks to answer the question, "Can an intervention work under *ideal* conditions?"

Pragmatic Studies: Key Contextual 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*

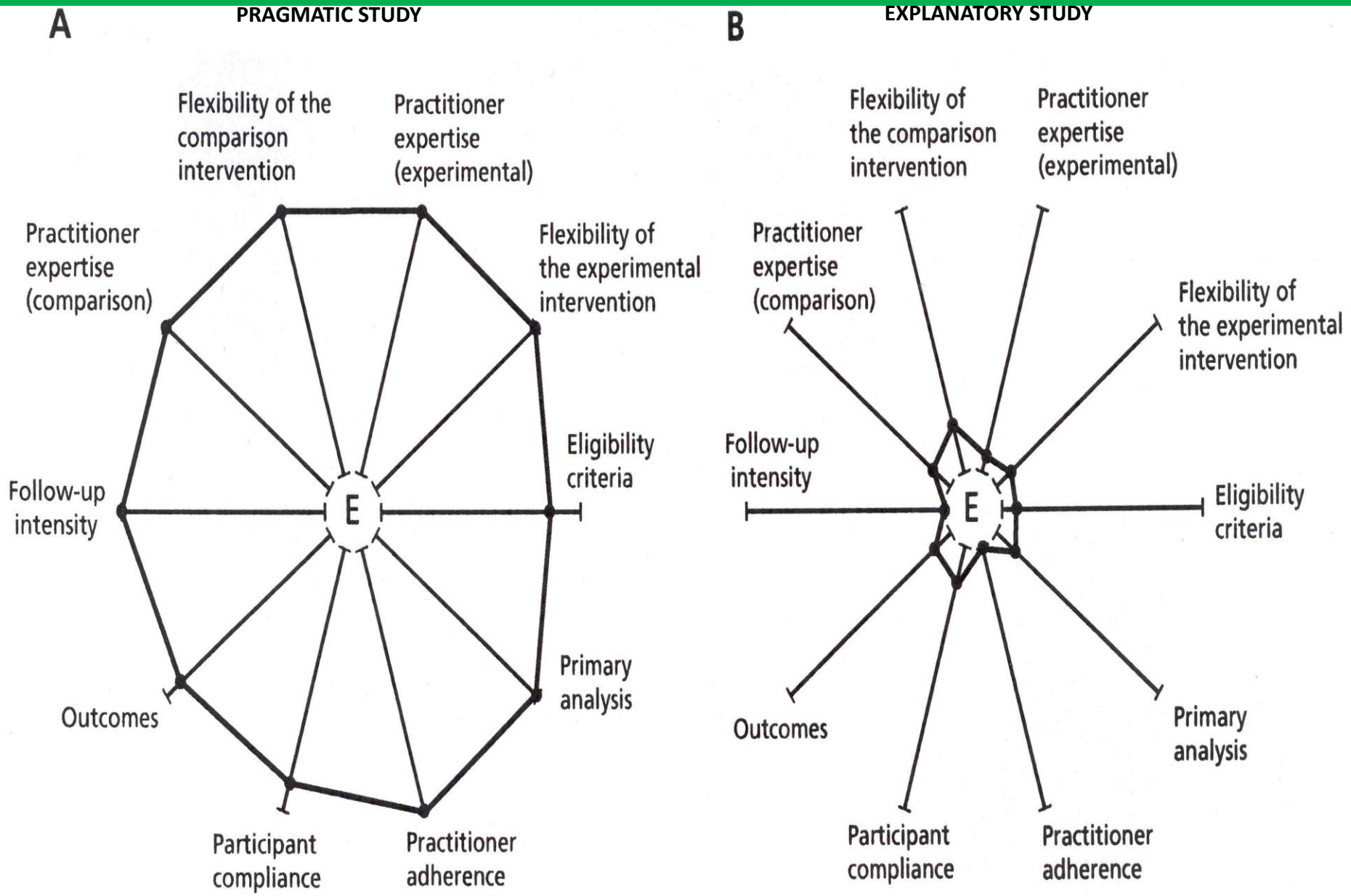
Thorpe KE et al., *Can Med Assoc J*, 2009, 180: E47-57
Tunis SR et al. Practical clinical trials…*JAMA* 2003;290:1624-1632
Glasgow RE et al. Practical clinical trials…*Med Care*2005;43(6):551-557

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. *Can Med Assoc J* 2009*; 180,* E47-E57.


A
PRAGMATIC 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
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

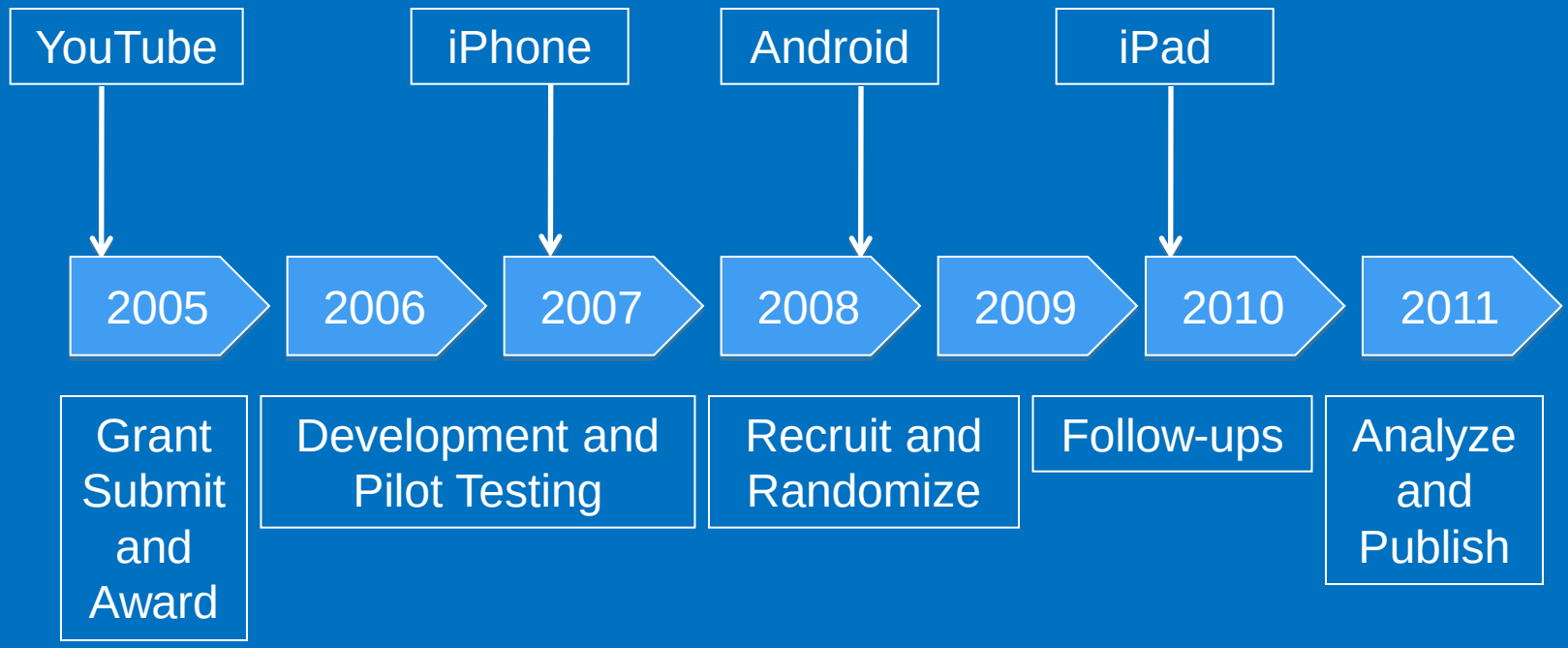
Types of Pragmatic Methods and Evidence Needed: 2R's and "RCT"

- **R**elevant
- **R**igorous and

- **R**apid
- **C**ost informative
- **T**ransparent

Glasgow R, *Annals of Behavioral Medicine, 2008, 35:* 19-25.
Glasgow R, Chambers D. *Clinical and Translational Science*, 2012, 5(1):48-55
http://cancercontrol.cancer.gov/IS/

How to Evaluate Technologies that Outpace Research?



William Riley, NHLBI and NCI

Rapid Evidence

- Need rapid learning research—especially for pressing issues such as obesity, HIV, explosion of health care spending, health inequities, and cancer survivorship

- EMRs, and their potential enhancements, make possible "rapid learning health care systems"*
  - *Real-time data on millions of real-world patients in real-world health care settings, treated under usual conditions*

– Institute of Medicine, A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care, 2010. http://www.iom.edu/Reports/2010/A-Foundation-for-Evidence-Driven-Practice-A-Rapid-Learning-System-for-Cancer-Care.aspx

– Etheredge L et al, *Health Affairs, Web Exclusive Collection,* w107-w118, doi:10.1377/hlthaff.26.2.w107)

Transparent Evidence on…

- Info needed to *replicate* or implement
- *Resources required*—costs for participants and delivery setting perspectives
- How were settings, staff, and participants selected—(who *was excluded and why*)
- *Adaptation*—changes made to protocol, to intervention, to recruitment, etc.
- *Differences across settings*

Pragmatic Measures—(proposed)

1. Required Criteria

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

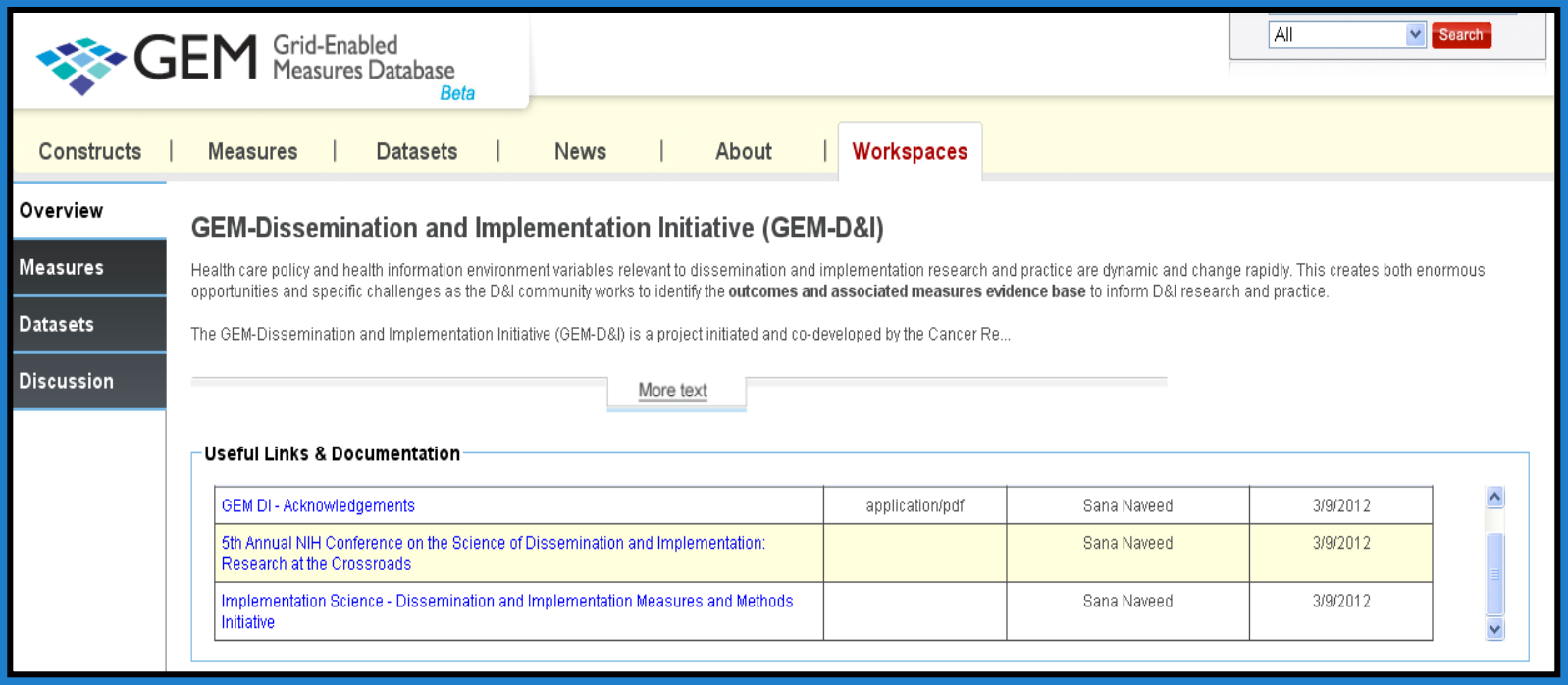
2. Additional Criteria

- Causes no harm
- Addresses public health goal
- Related to theory or model
- “Maps” to “gold standard” metric or measure

Need for Better and Harmonized Measures

- Most studies use their own measures, often unknown characteristics, and quite different measures of same construct
- Without more standardized measures, difficult to do reviews, syntheses, compare across studies
- Are different purposes of measurement—e.g.:
  - **"Gold standard"**—when this is primary focus for grant, need "best possible measure", have staff to ensure quality
  - **"Practical measure"**—for use in busy, low-resource settings; when one of a large set of measures; has to be brief and feasible

D&I and Patient-Reported Measures Initiatives



https:www.gem-beta.org/GEM-DI (Grid Enabled Measures)

http://cancercontrol.cancer.gov/IS/resources.html (IS Team Website)

Cancer Communication Research Center

National Institutes of Health | National Cancer Institute

EHR Measures for Primary Care

- In the billions of dollars spent on EHRs in last several years, one thing is missing: Patient-Reported Measures
- Advent of patient-centered medical home and "meaningful use" of EHRs
- *Impossible to provide patient-centered care if no patient measures*, goals, preferences, concerns collected
- With recent advances in measurement, meaningful use incentives, time is right

PATIENT REPORT EHR MEASURES

- Content experts identify 2-3 candidate measures in each of 13 key domains
- Widespread web-based wiki activity: **https://www.gem-beta.org/GEM-DI**
- "Town Hall" Meeting at NIH: Day 1: town hall; Day 2: invited stakeholder decision makers
- Post Meeting and Beyond: Pilot study followed by pragmatic trial of actual implementation

Estabrooks PA, et al. *J Am Med Inform Assoc* 2012 Jul 1;19(4):575-82.

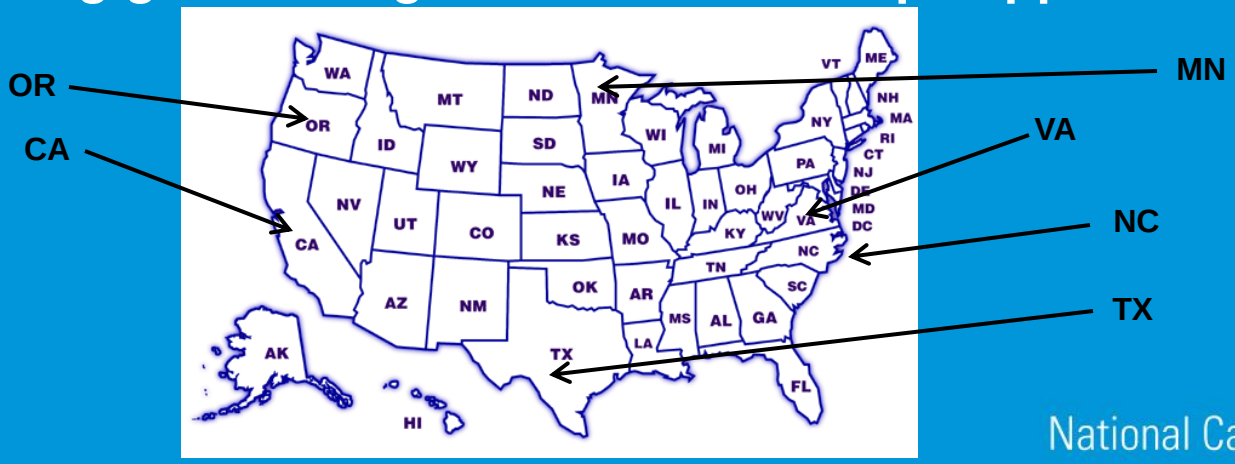
Domain	Final Measure (Source)
1. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, IOM, and *National Health Interview Survey (NHIS)*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

Pragmatic Implementation Trial (Fall 2012 - Summer 2013)

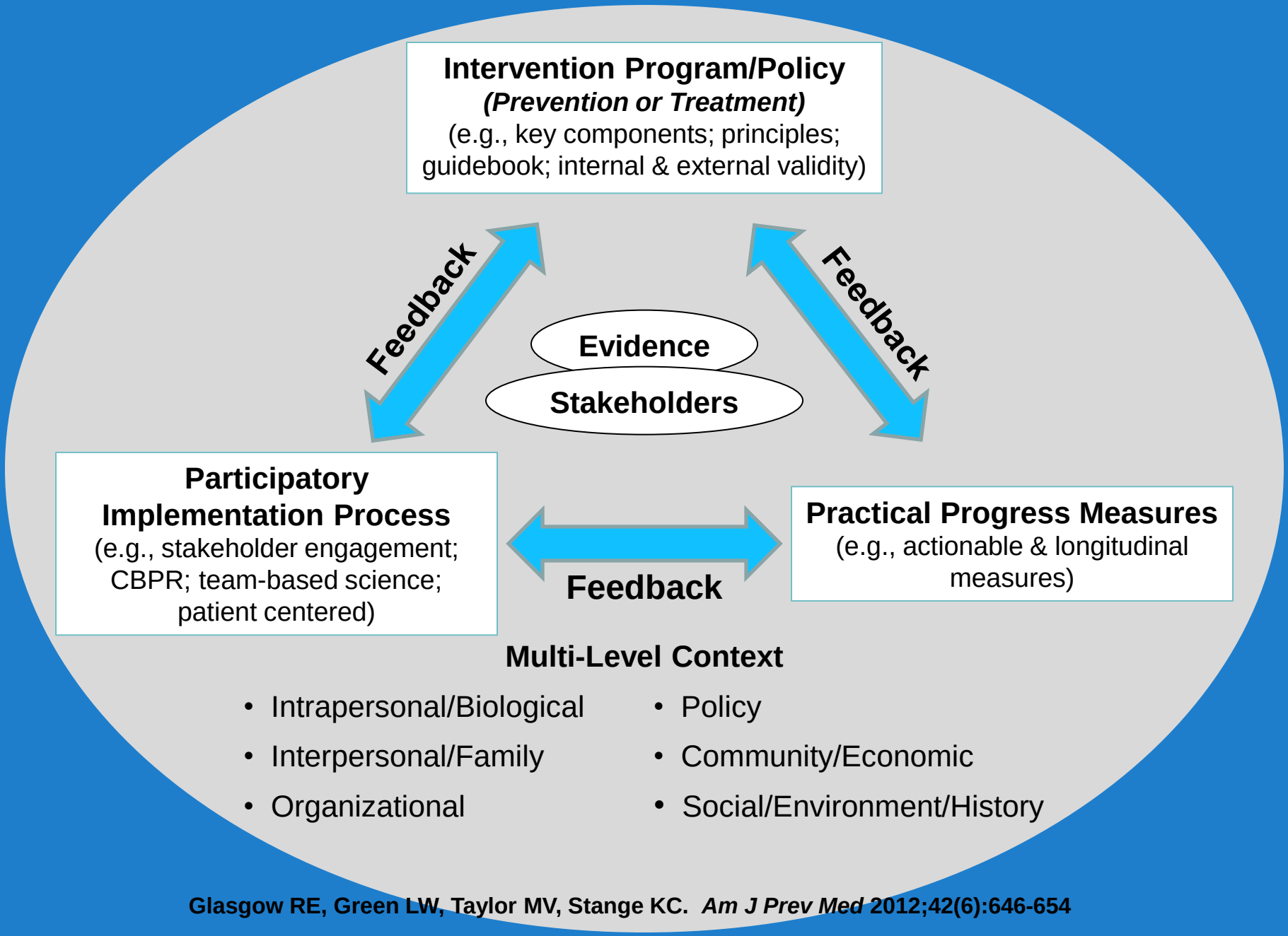
- Nine pairs of primary care clinics (18 total): Half FQHC community health centers (NCI), half other PBRN primary care clinics (AHRQ)
  - Each clinic contributes approximately 200 patients
  - Cluster Randomized *pragmatic study*—delayed intervention control—assess at 4 and 8 months
  - Clinics elected to be diverse and at different stages of EHR implementation
  - *Key outcomes are implementation*; creation of action plans; patient behavior change is secondary
  - Final protocol designed collaboratively

Key Points of Collaborative Implementation Trial

- 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., survey, feedback, goal setting, follow-up is STANDARD
- HOW this is delivered is CUSTOMIZED to setting
- Study goal = routine use of survey items, feedback, action planning/goal setting tools and follow-up support



Evidence Integration Triangle (EIT)



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

Realist Perspective

- Answers "contextual" questions, such as "*which intervention components are effective for what outcomes under what conditions when delivered by what staff for what groups*?"
- Contrast with "average effects" approaches

RE-AIM Realist *Evaluability* Questions

- What percent and what types of participants 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 participant subgroups…and at what cost;
- And how well is the program and its effects likely to be ***Maintained***?

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

Pragmatic Science Funding Opportunities

- Dissemination and Implementation Research in Health PAR 10-040
- Small Business Initiative (SBIR and STTR) grants
- NIH Health Care System Collaboratory grants, other NHLBI and NIDDK R18 grants
- NIH research networks—CRN, CVRN, MHRN etc.
- PCORI, CDC and AHRQ grants and networks
- VA Health Services Research grants

Take-Home Points

- There is a pressing need for a DIFFERENT type of research and evaluation—on pragmatic methods, measures and models that produce results more rapidly, and are more relevant to stakeholders
- This field is still emerging, but there is agreement on key common points and goals
- There are many opportunities for this type of research, especially among research networks and for academic-community coalitions to study context