Pragmatic Models, Methods and Measures for Dissemination and Implementation Research (and Population Impact)

RUSSELL E. GLASGOW, PHD

Department of Family Medicine, Univ. Colorado School of Medicine

VA Eastern Colorado QUERI and Geriatric Research Centers

Dissemination and Implementation Science Program,

Adult and Child Consortium for Outcomes Research and Delivery Science

Acknowledgements and Conflicts of Interest

ACKNOWLEDGMENTS:

Cathy Battaglia, PhD, RN, Nurse Scientist
Denver-Seattle VA Center of Innovation
University of Colorado SOM- ACCORDS Dissemination and Implementation Science Program, DFM Evaluation Hub
RE-AIM colleagues

FINANCIAL DISCLOSURE:

National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Robert Wood Johnson Foundation (RWJF) funding on various projects.

UNLABELED/UNAPPROVED USES DISCLOSURE:

None

Overview

- Why do we need pragmatic science?
- How are pragmatic research and designs different from ‘research as usual’?
- Examples:
  - ✓ Pragmatic models
  - ✓ Pragmatic methods
  - ✓ Pragmatic measures
- Tools and Resources
- Conclusions, discussion; Q & A

Need for Pragmatic Research?

Usual Research is Slow

- Traditional RCTs are slow and expensive
- Most common reason for non-adoption…research not seen as relevant
- Rarely produce findings that are easily put into practice

It takes an average of 17 years before 14% of research findings lead to widespread changes in care.

Need for Pragmatic Research

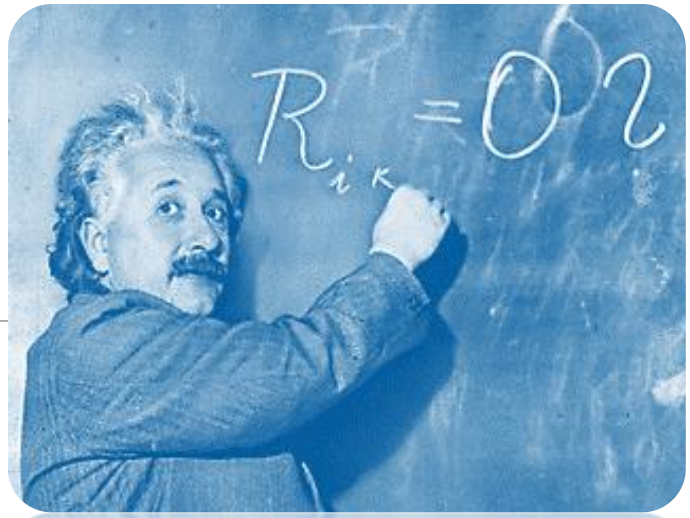
- Traditional RCTs study the effectiveness of treatments delivered to carefully selected populations under ideal conditions.
- Even when we do implement a tested intervention into everyday clinical practice, we often see a "voltage drop"… a dramatic decrease in effectiveness.

"If we want more evidence-based practice, we need more practice-based evidence."

Green LW

Am J Pub Health 2006

Rothwell PM. External validity of randomised controlled trials…Lancet 2005;365:82-93.



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

Albert Einstein

A Different Approach: Pragmatic Research for Population Health

Explanatory (Efficacy) 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.

Key Differences Between Traditional RCTs and Pragmatic Controlled Trials (PCTs)

	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
GOALS	To determine causes and effects of treatment	To improve practice and inform clinical and policy decisions
DESIGN	Tests the intervention against placebo using rigid study protocols and minimal variation	*Tests two or more real-world using flexible protocols & local customization*
PARTICIPANTS	Highly defined and carefully selected	More representative because eligibility criteria are less strict
MEASURES	Require data collection outside routine clinical care	Brief and designed so data can be easily collected in clinical settings
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

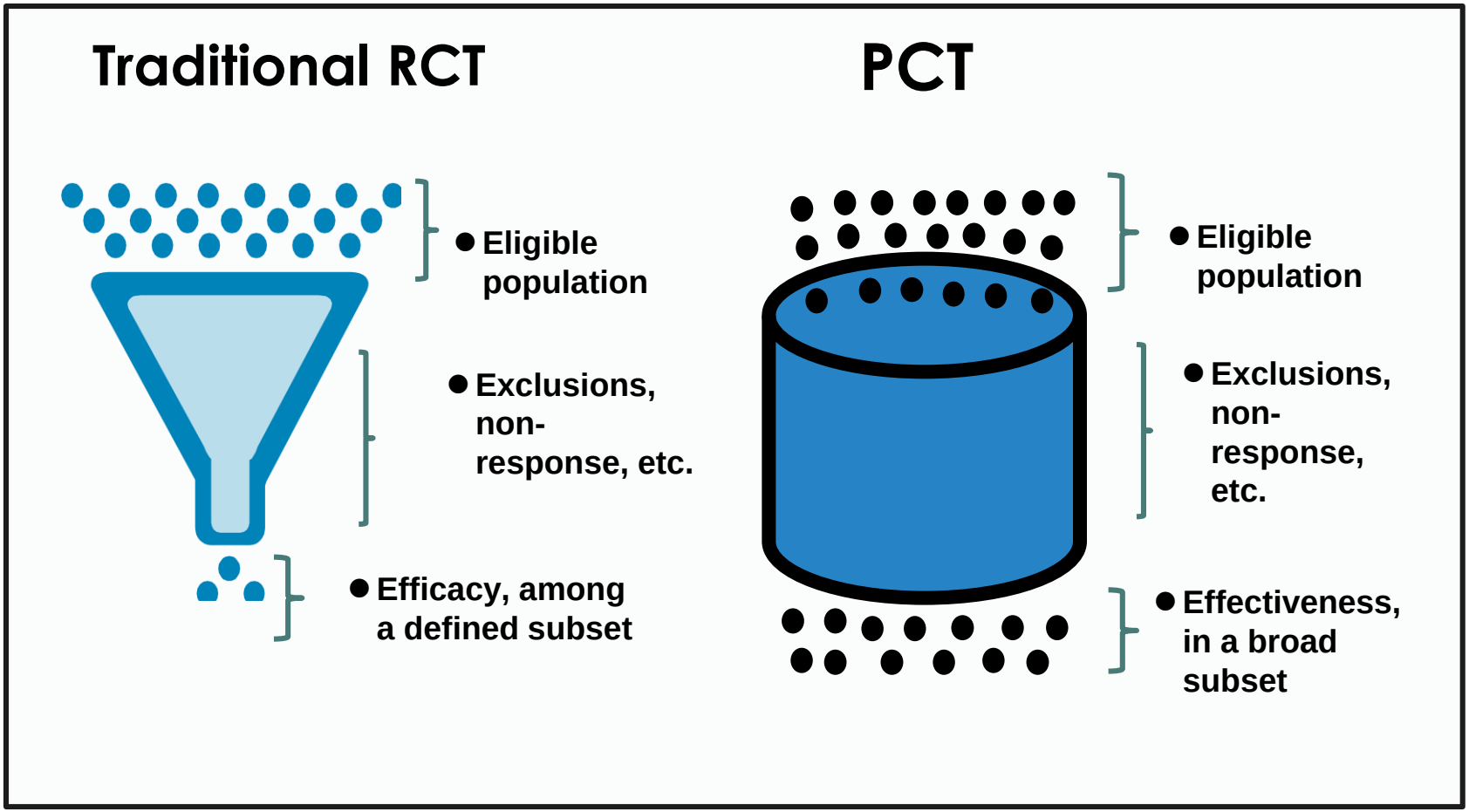
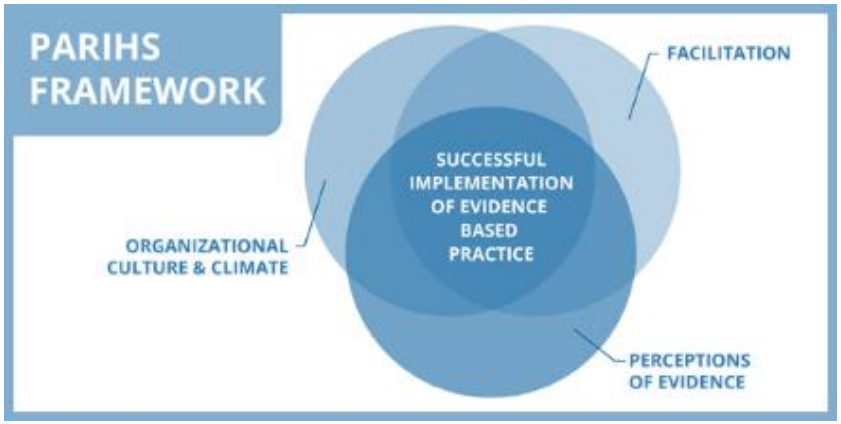
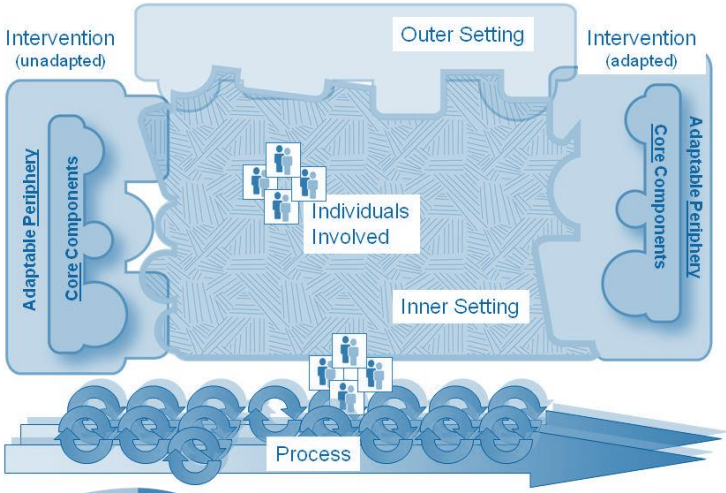


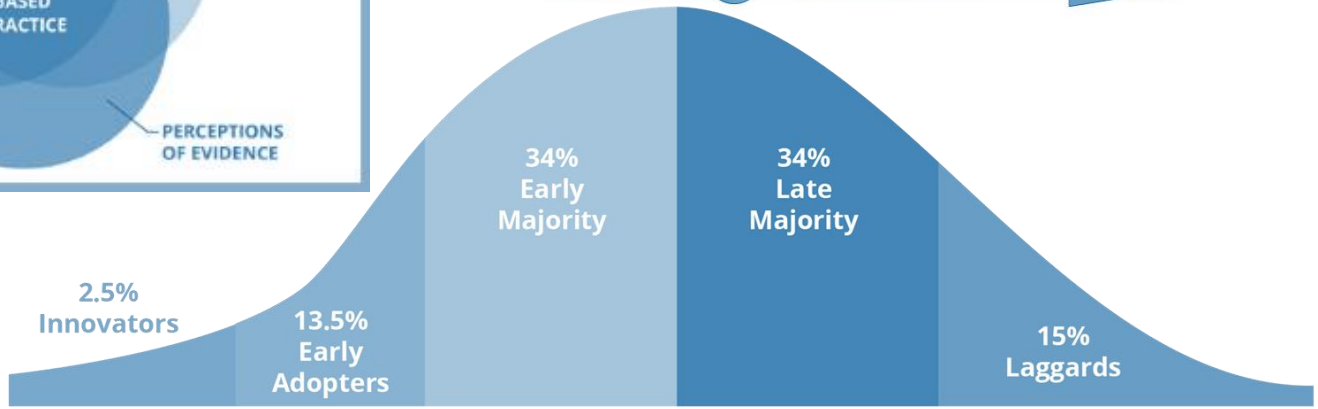
Figure provided by Gloria Coronado, PhD, Kaiser Permanente Center for Health Research

Pragmatic Models- RE-AIM

Other Models







91 Frameworks: http://dissemination-implementation.org/index.aspx

Most Common at NIH: RE-AIM and DOI (now also CFIR)

Many commonalities across models and theories

Pragmatic Use of RE-AIM

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 benefits you are trying to achieve and what is (was) the likelihood of negative outcomes?
Adoption	**WHERE** is (was) the program or policy applied and WHO applied it?
Implementation	**HOW** consistently is (was) the program or policy delivered, HOW will (was) it be adapted, HOW much will (did) it cost, and 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)?

Glasgow R and Estabrooks P, Preventing Chronic Disease, 2017

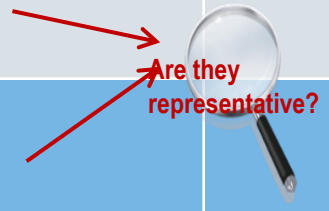
Why Is This Important?
Impact Loss at Each RE-AIM Step

Re-aim.org

Example of Translation of Interventions into Practice		
Dissemination Step	**RE-AIM Concept**	**% Impact**
50% of clinics use intervention	Adoption	50.0%
50% of clinicians/staff take part	Adoption	25.0%
50% of patients identified accept	Reach	12.5%
50% follow regimen correctly	Implementation	6.2%
50% benefit from the intervention	Effectiveness	3.2%
50% continue to benefit after 6 months	Maintenance	1.6%

Ultimate Impact of a Weight Management Program

Dissemination Step	Concept	% Impacted
8.8% of weight management sites participated	Adoption	8.80%
5.9% of members participated	Reach	0.52%
91.4% program components implemented	Implementation	0.47%
43.8% of participants showed weight loss	Effectiveness	0.21%
21.2% individuals maintained benefit (individual)	Maintenance	0.04%



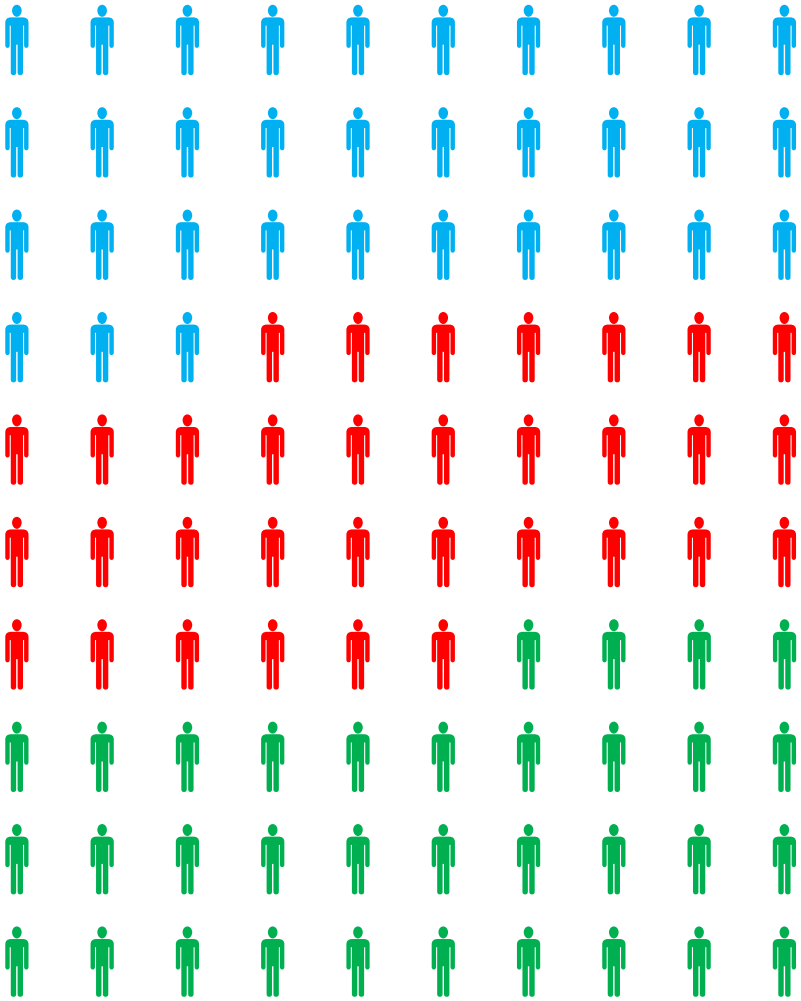
Abildso CG, Zizzi SJ, Reger-Nash B. *Prev Chronic Dis* 2010 May;7(3):A46

Moral of this Story?

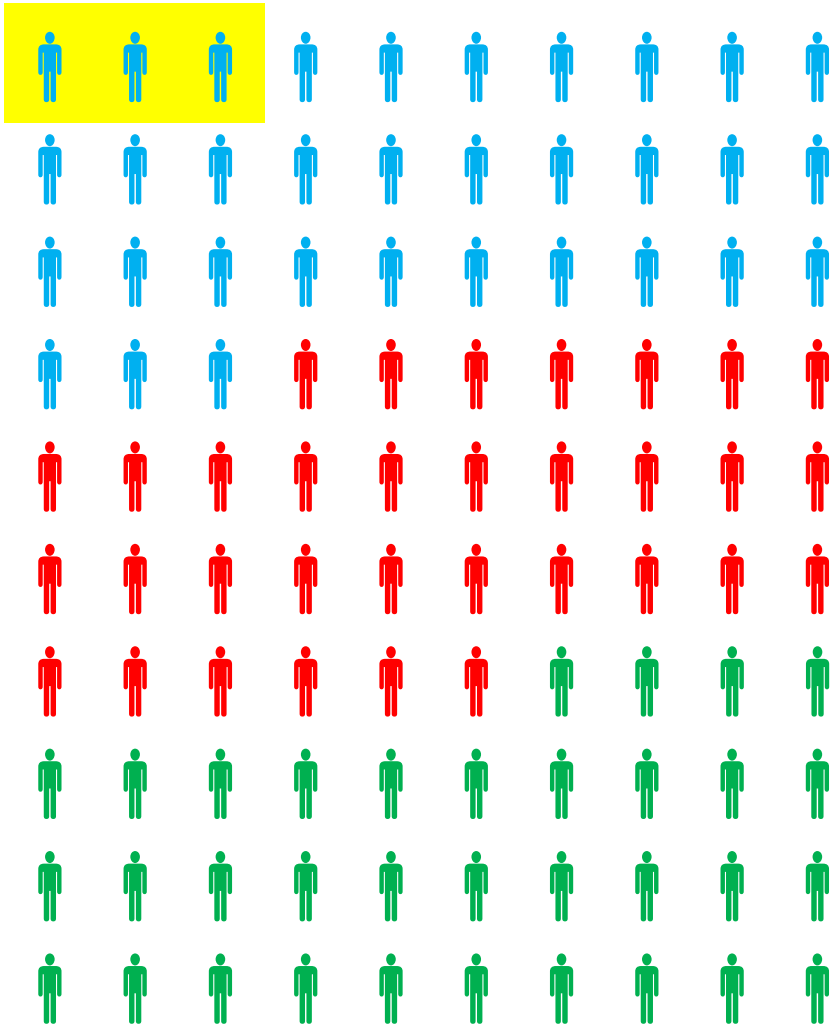
- All steps or phases in translation are important and provide opportunities to improve population health

- It is about the DENOMINATOR

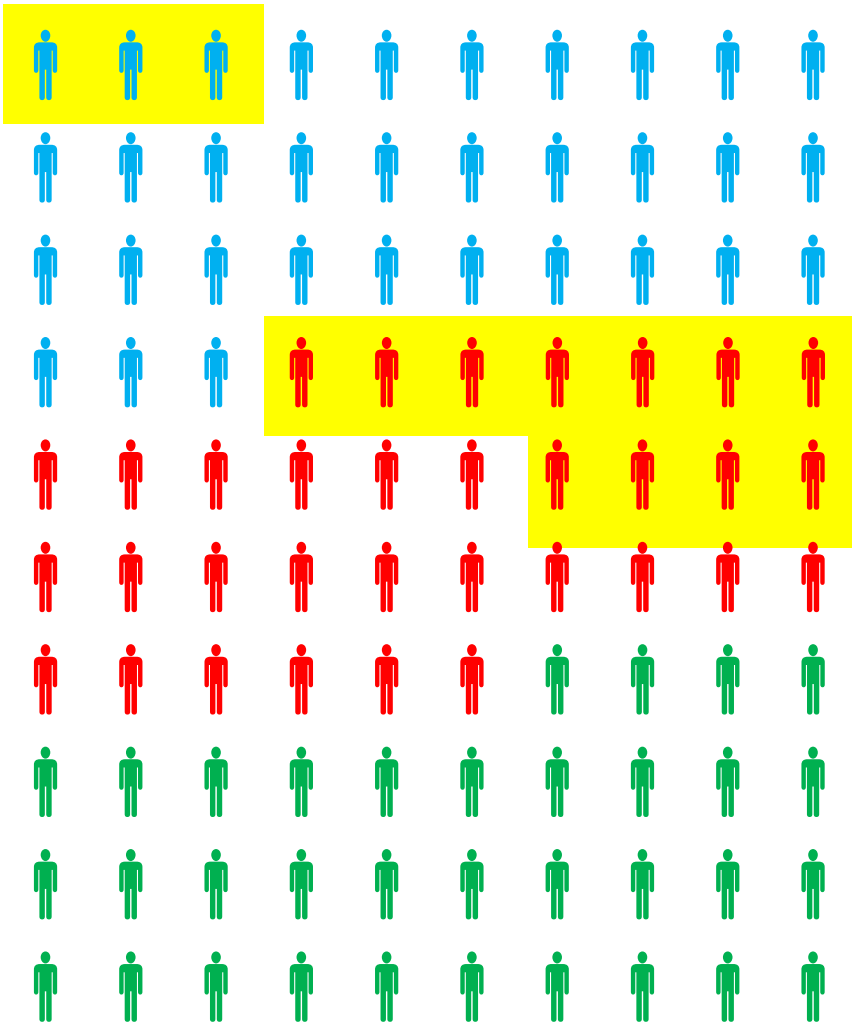
Population Health



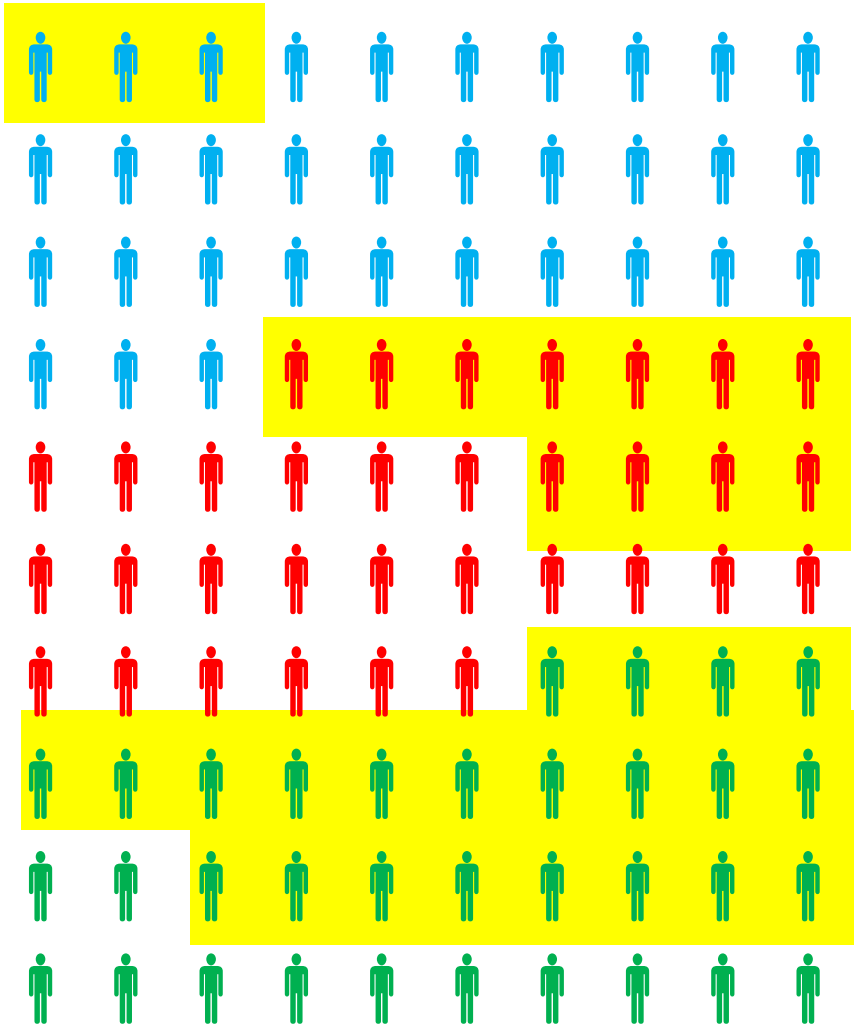
Population Health-



Population Health-Its about the denominator



Population Health- Its about equity



Pragmatic RE-AIM Precision Science and Health Questions

Determine:

- What percentage and what types of patients are Reached;
- For whom is the intervention Effective, in improving what outcomes, with what unanticipated consequences;
- In what percentage and in what 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?

Gaglio B, Glasgow RE. Evaluation approaches…In: Brownson R, Colditz G, Procter E, (Eds). *Dissemination and implantation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-56

Pragmatic Considerations for RE-AIM Framework

- Intended to facilitate translation of research to practice
- Internal and external validity, and emphasizes representativeness
- Individual and organizational factors - experimental and observational
- Public health impact depends on all elements (reach x effectiveness, etc.)

www.re-aim.org

Evolution of RE-AIM

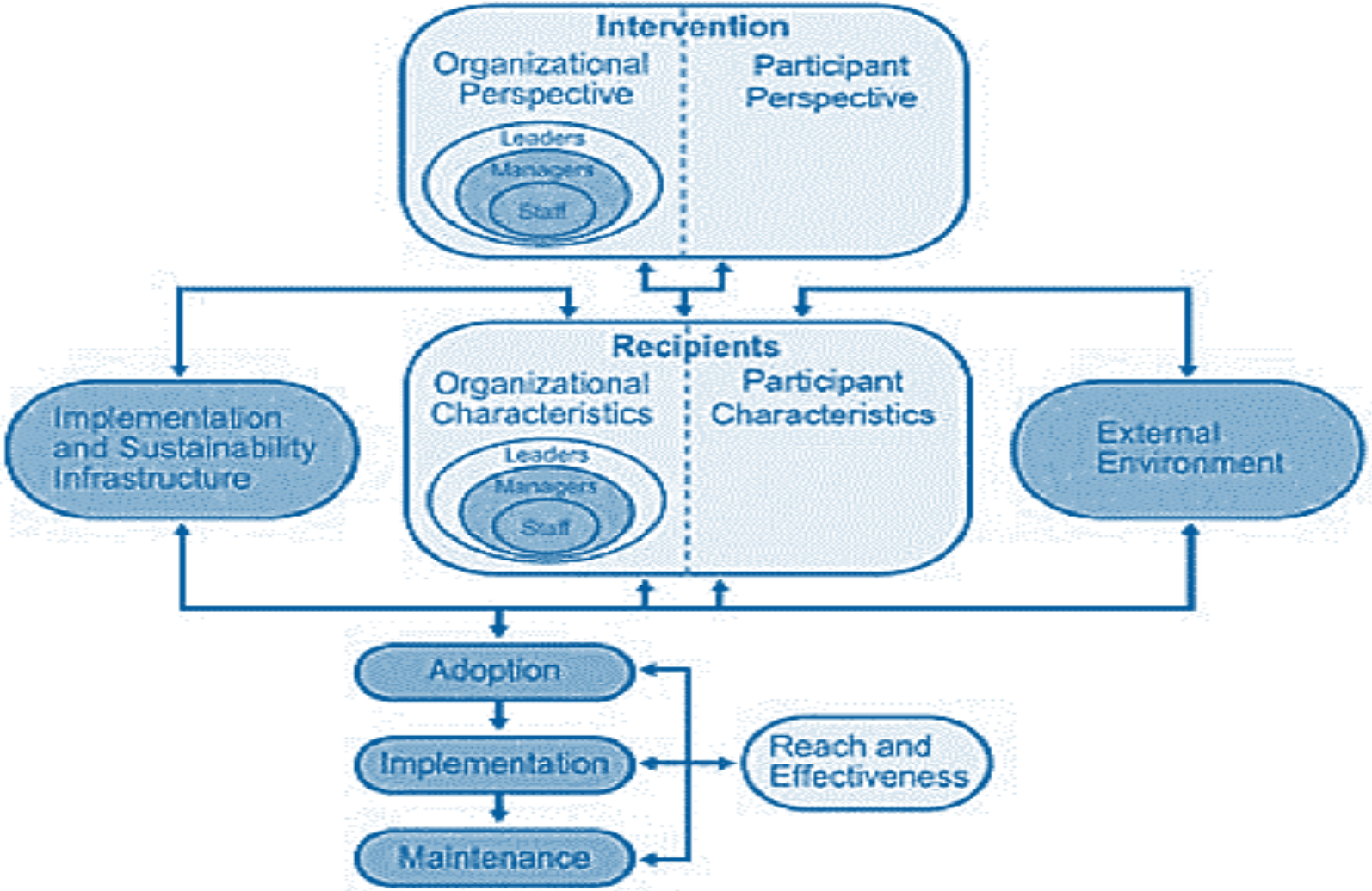
- Reviews documenting use over time
- Applicability to many different content areas- over 350 articles
- Used for both planning and evaluation
- Underreporting of key components
- Setting level factors reported much less often (e.g., adoption)
- Maintenance (sustainability) reported least often

NEW AREAS

- Costs and resources
- Adaptations
- Patient centered outcomes research
- Qualitative RE-AIM assessments

Gaglio et al. The RE-AIM framework….AJPH 2013; 103: 38-46.

Practical, Robust Implementation and Sustainability Model



Feldstein and Glasgow, *The Joint Commission Journal on Quality and Patient Safety* 2008;34(4):228-243.

RE-AIM Summary Points

- RE-AIM is an outcomes framework that can be used for planning and evaluation
- Each dimension is an opportunity for intervention
- RE-AIM can be used for observational, efficacy, effectiveness, and implementation science projects
- All dimensions can be addressed within a given study (though likely not all intervened upon)
- Methods exist to combine and summarize RE-AIM outcomes

All Models (and methods) are Wrong… Some are useful

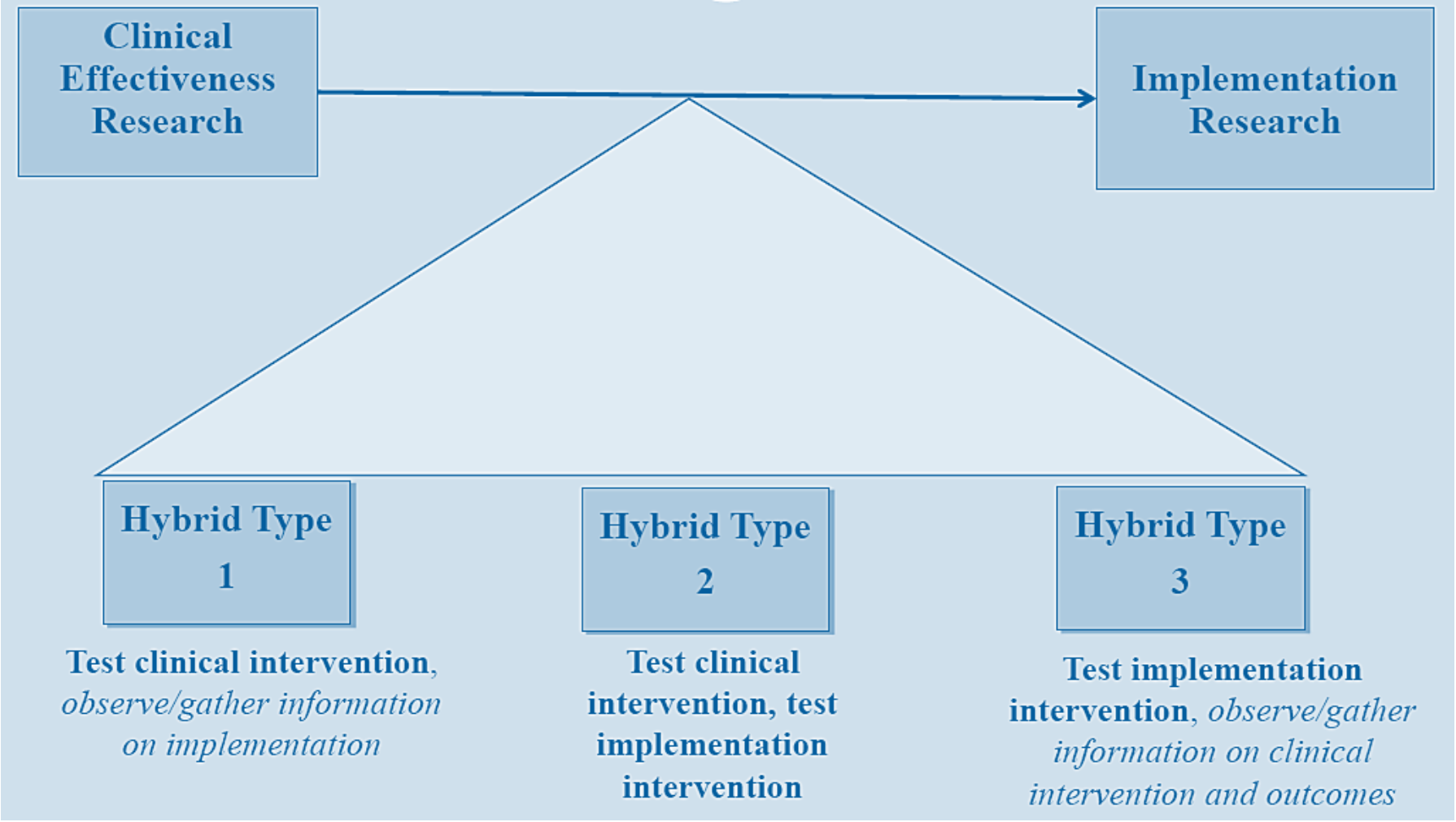
"To every complex question, there is a simple answer… and it is wrong."

~H. L. Mencken

RE-AIM and Pragmatic Science and Models Q & A

Pragmatic Design Issues

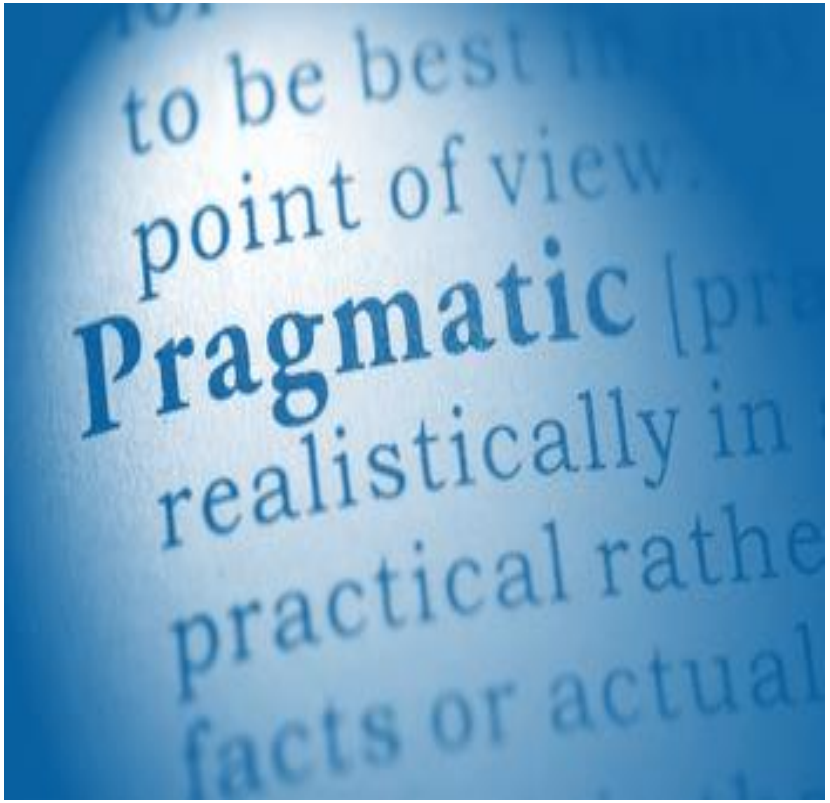
Effectiveness/Implementation Hybrids



Curran, et al. Medical Care. 2012

Pragmatic Experimental Designs

- Individual RCT
- Cluster randomized RCT
- Natural experiment
- Stepped wedge
- Preference design



What Types of Observational Research are Related to Pragmatic Research?

- Natural experiments
- Multiple case studies
- Contextual impact on process and outcomes
  - ✓ especially at multiple levels
- Assess multiple stakeholders and perspectives
- Multiple methods
- Theory guided prospective studies

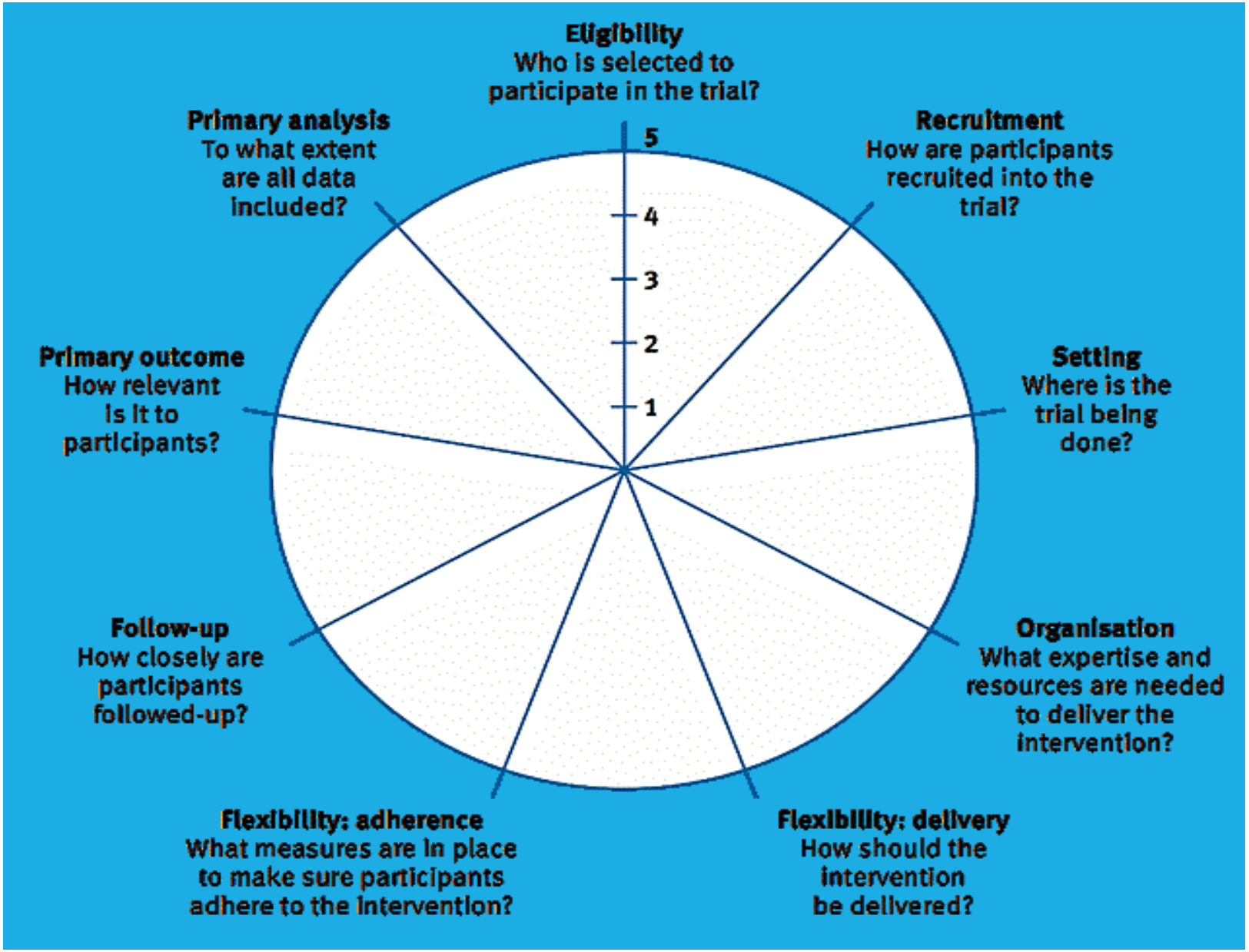
The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) Planning Tool

- How pragmatic is your study?
- 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.

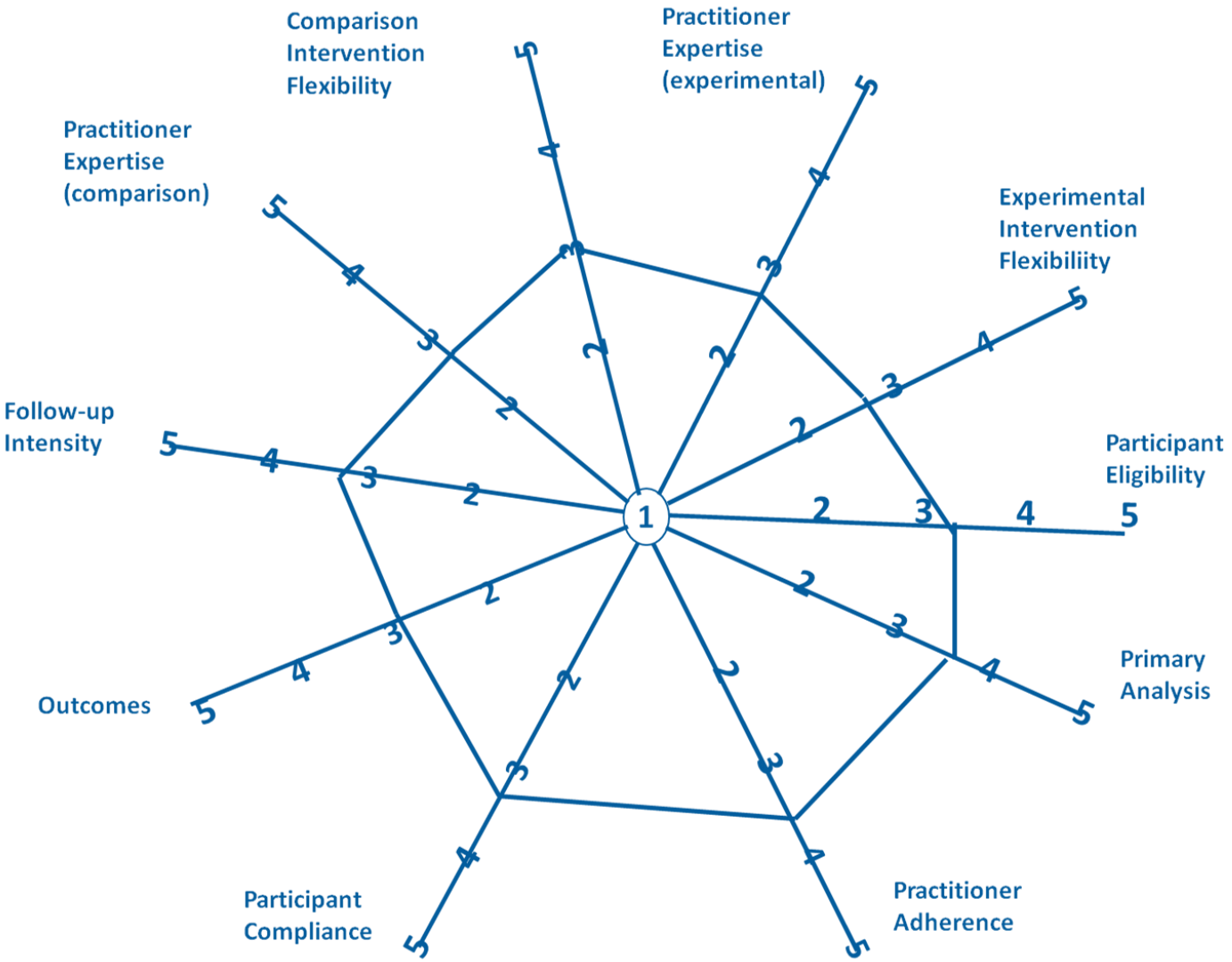
Thorpe KE, et al. A pragmatic-explanatory continuum indicator summary (PRECIS)…CMAJ 2009;180(10):E47-57.

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



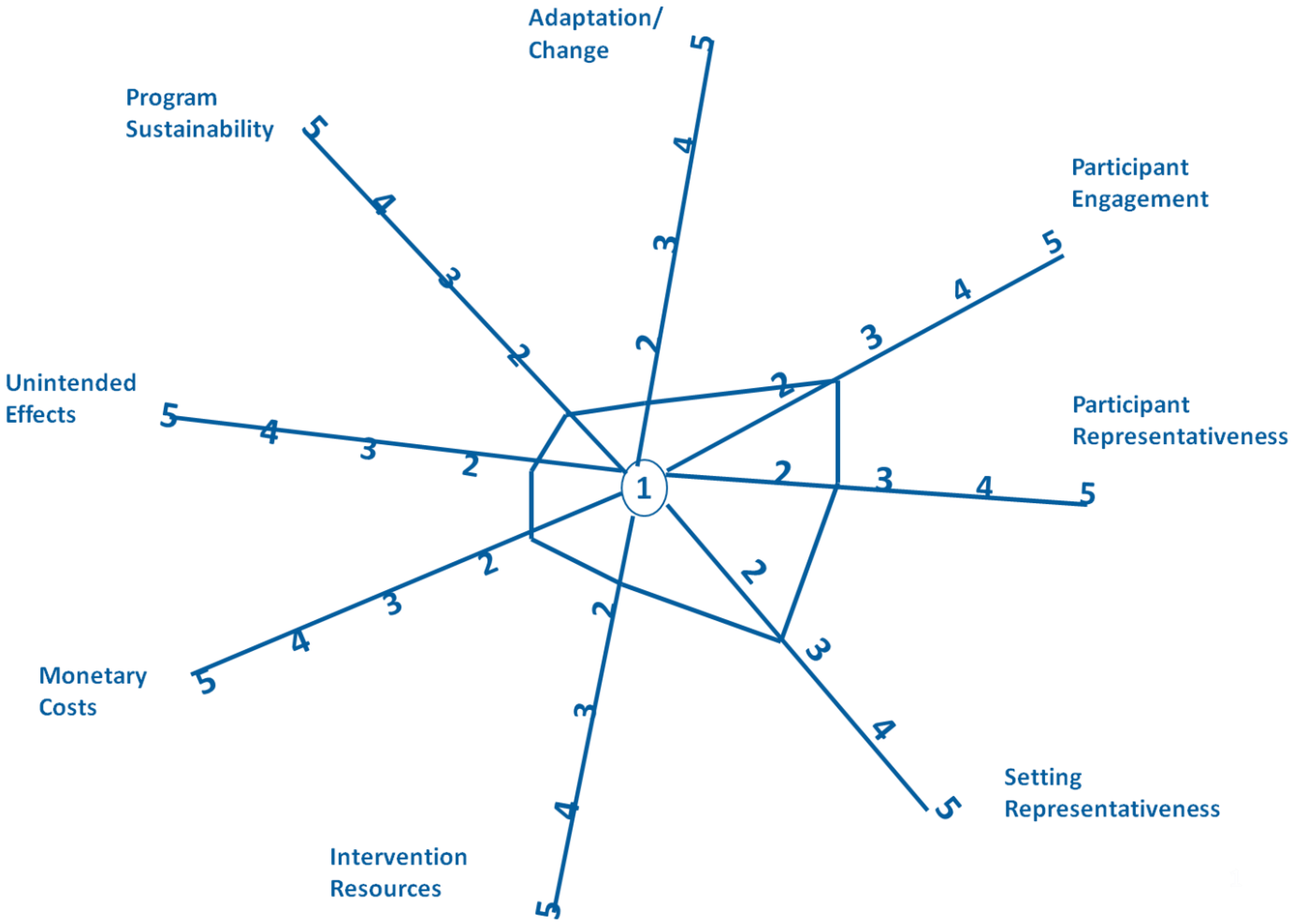
https://www.precis-2.org/

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.

The 5 Rs to Enhance Pragmatism and Likelihood of Translation

Research that is:

- Relevant
- Rapid and Recursive
- Redefines Rigor
- Reports Resources Required
- Replicable

Peek, C.J, et al. (2014). The 5 Rs: An Emerging Bold Standard for Conducting Relevant Research in a Changing World. *Annals Of Family Medicine*, *12*(5), 447-55. doi:10.1370/afm.1688

deGruy, F.V, et al. (2015). A plan for useful and timely family medicine and primary care research. *Family Medicine*, *47*(8), 636-42.

Reporting Resources Required

- Reporting on cost and other resources in a standardized manner is useful in:
  - ✓ Demonstrating *value*
  - ✓ Promoting rigor, transparency and relevance to stakeholders
- Present *from perspective of stakeholders* and decision makers
- Simple is fine – sophisticated economic analyses are not needed
  - ✓ Report costs of conducting or replicating interventions
  - ✓ Beyond money, costs can include clinician and staff time, training, infrastructure, startup costs, opportunity costs

Ritzwoller, D P, et al. (2009). Costing behavioral interventions: A practical guide to enhance translation. *Annals of Behavioral Medicine*, *37*(2), 218-27.

EXAMPLE PRAGMATIC STUDY: My Own Health Report (MOHR) Study

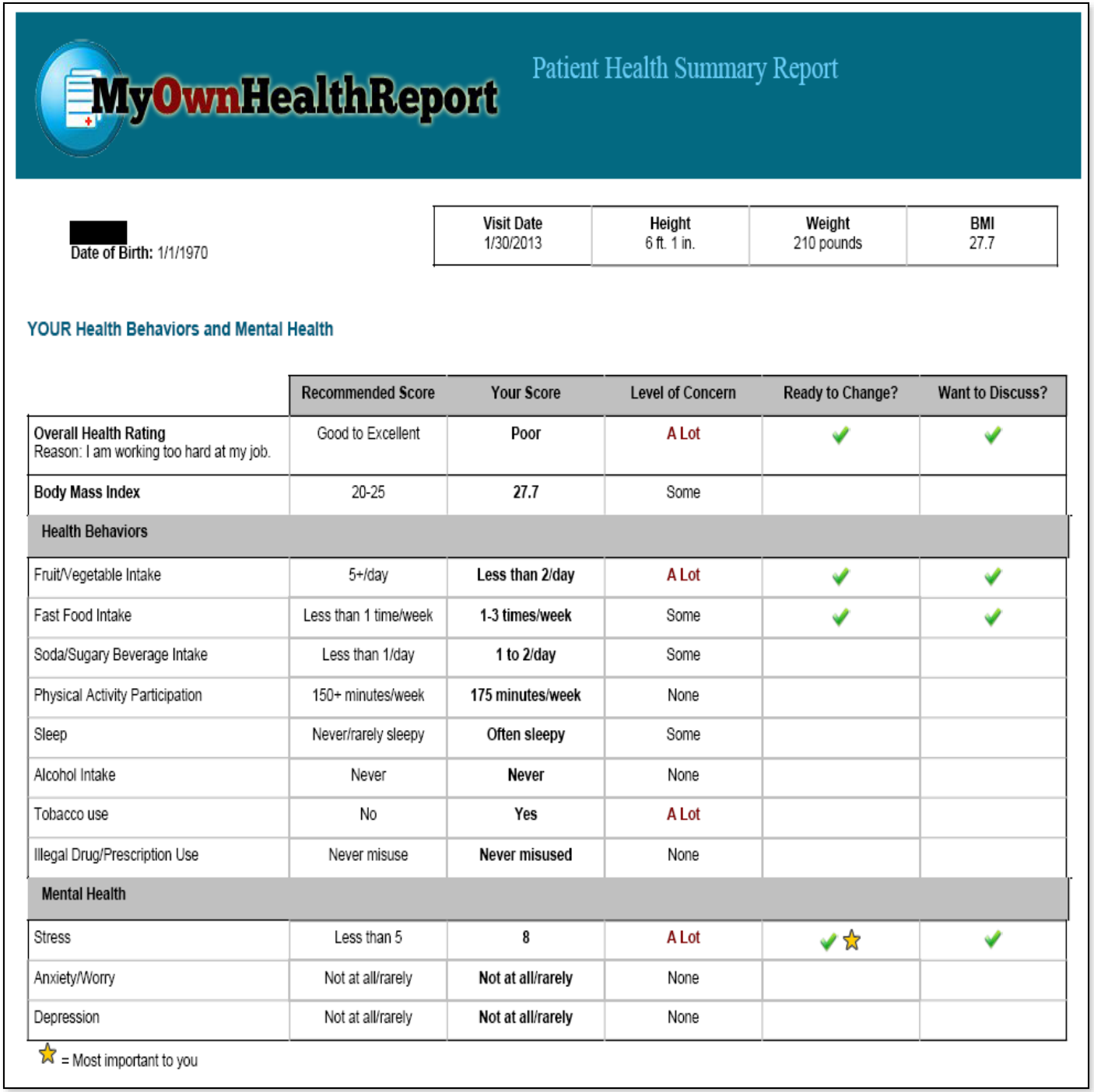
Cluster randomized pragmatic trial of web-based, brief health behavior and mental health assessment and intervention in nine diverse pairs of primary care practices to test whether they could implement My Own Health Report (MOHR).

Outcomes included:

- *Reach* of the MOHR program across patients
- Whether practices would *adopt* MOHR
- How practices would *implement* MOHR
- *Effectiveness* of the MOHR program

Glasgow, et al. (2014). Conducting rapid, relevant, research American Journal of Preventive Medicine, August;47(2):212-9.

Krist, et al. (2016). Translational Behavioral Medicine, Jun; 6(2):212-9.



MyOwnHealthReport

Patient Health Summary Report

[redacted]
Date of Birth: 1/1/1970

Visit Date	Height	Weight	BMI
1/30/2013	6 ft. 1 in.	210 pounds	27.7

YOUR Health Behaviors and Mental Health

	Recommended Score	Your Score	Level of Concern	Ready to Change?	Want to Discuss?
Overall Health Rating Reason: I am working too hard at my job.	Good to Excellent	**Poor**	A Lot	✓	✓
Body Mass Index	20-25	**27.7**	Some		
Health Behaviors					
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		
Mental Health					
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)

Adoption

18 practices agreed to adopt MOHR

- 30 practices approached (adoption 60%)
- 7 of 9 sites recruited, first practices approached
  - ✓ Decliners were doing other studies, worries about workload, or doing HRAs
- Participating practices represented a diverse spectrum of primary care

Overall **Reach**
1768 of 3591 patients (49.2%)

Mailed (patient complete)

Site 1: 100 of 344 (29.1%)
Site 3: 11 of 420 (2.6%)
Site 4: 138 of 444 (31.3%)
Site 5: 115 of 248 (46.4%)

Phone (nurse complete)

Site 3: 291 of 453 (64.2%)

Lobby (patient + MD complete)

Site 2: 192 of 437 (43.9%)

Lobby (MA or coordinator)

Site 6: 265 of 287 (92.3%)
Site 7: 211 of 306 (69.0%)
Site 8: 247 of 323 (76.5%)
Site 9: 198 of 329 (60.2%)

Implementation

Practices used four main implementation strategies:

- Web at home (n=3), called patients (n=1), completed in office on paper (n=1) or electronically in office (n=4)
- 4 asked patients and 5 asked staff to complete MOHR with patients
- 8 needed research team or health systems help
- 8 asked clinicians to counsel patients, 4 had some follow-up, 1 had no counseling or follow-up

Delivery of MOHR took 28 minutes (16-31), including assessment and feedback

Effectiveness:
Did anyone help you set a goal?

Topics	% Yes		p-value
	Intervention	Control	
Eating/Diet	51.7	34.1	**<.0001**
Physical Activity/Exercise	49.5	37.9	**<.0001**
Tobacco/Smoking	22.6	19.7	0.0769
Alcohol Use	17.1	13.1	**0.0055**
Drug Use	13.5	11.4	0.1012
Stress Level	31.2	22.2	**<.0001**
Anxiety/Depression	32.1	23.1	**<.0001**
Sleep	29.6	24.4	**0.003**

Effectiveness:
Have you made any positive changes?

Topics	% Yes		p-value
	Intervention	Control	
Eating/Diet	62.9	49.9	**<.0001**
Physical Activity/Exercise	55.1	48.2	**0.0004**
Tobacco/Smoking	17.3	16.6	0.5501
Alcohol Use	15.2	14	0.4334
Drug Use	11.5	11.2	0.7848
Stress Level	31.2	25.1	**0.0008**
Anxiety/Depression	29.2	24.6	**0.0092**
Sleep	30.2	24.4	**0.0011**

Pragmatic Features of MOHR

Relevant	Diverse, real-world primary care settings, and staff who do all the interventions
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

Moral of this Example?

- Success demands tailoring and customization at the levels of:
  - ✓ Patient
  - ✓ Clinician
  - ✓ Setting

- Opportunity to contribute to big data elements not usually present, currently adding in social determinants of health

AND NOBODY CAN USE IT…..

DOES IT STILL MAKE AN IMPACT?

Pragmatic Research Designs Q & A

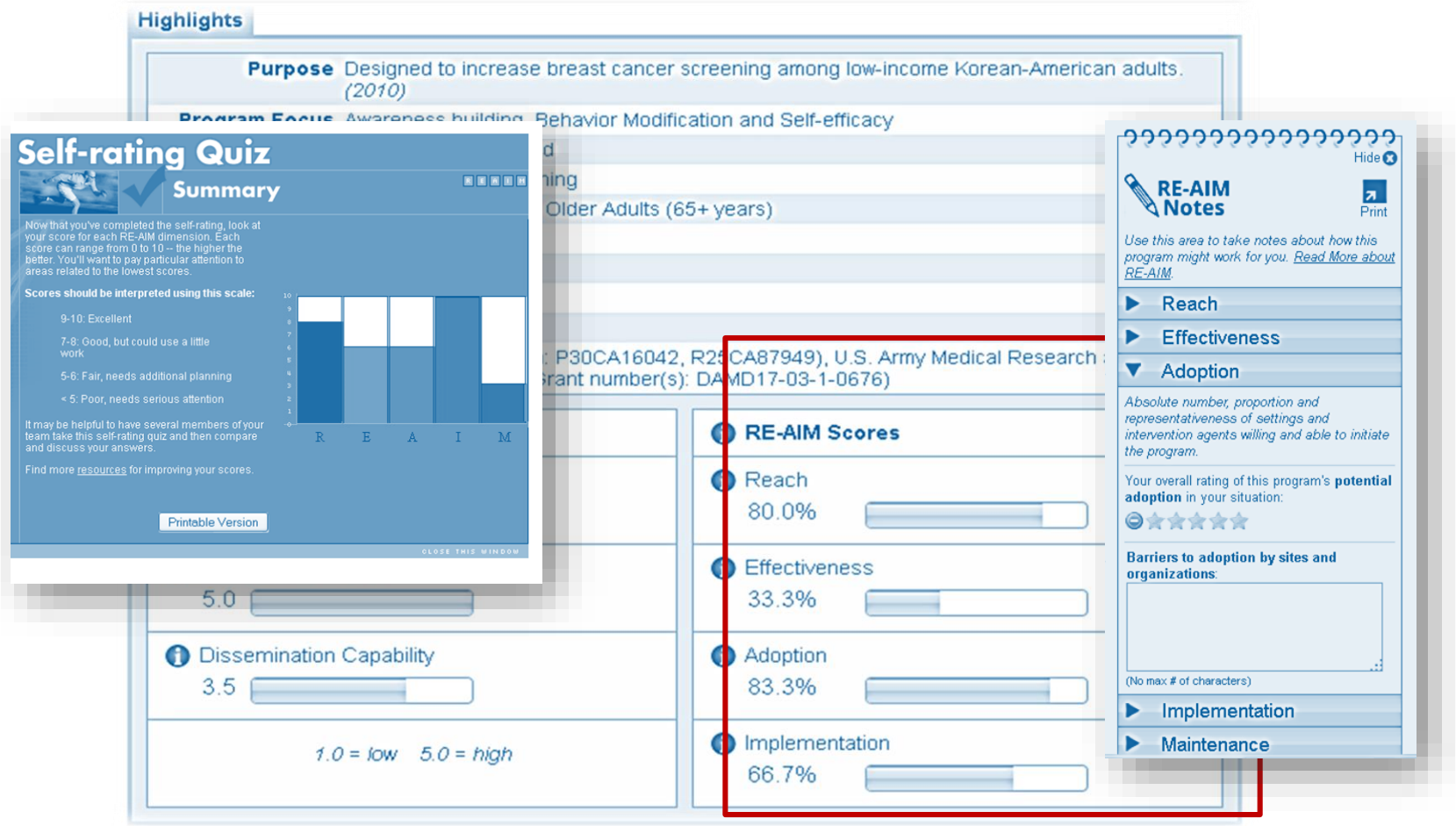
Pragmatic Outcomes and Measures

Evidence-Based...on what?

External Validity/ Pragmatic Criteria, Often Ignored

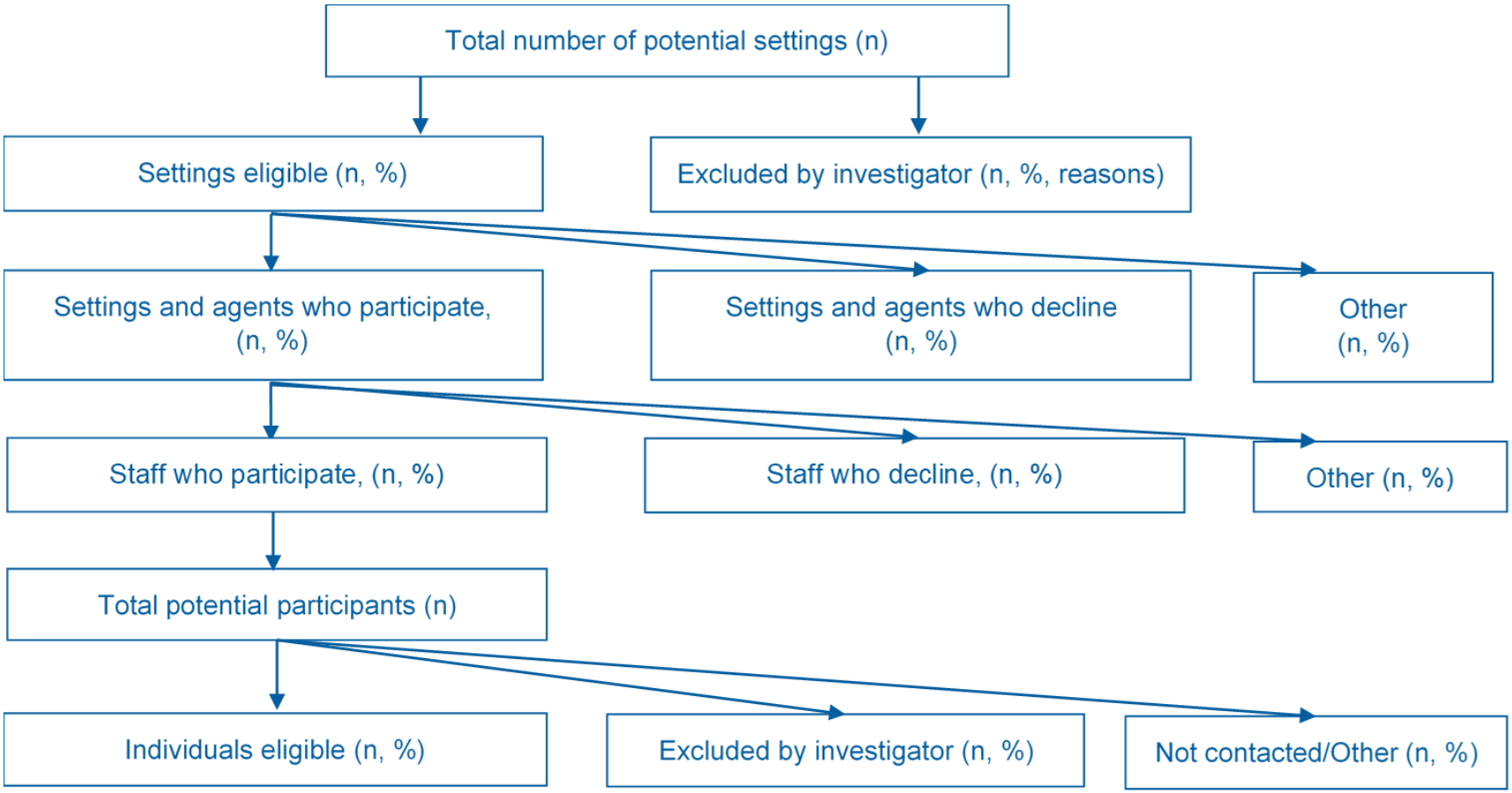
- Participant **Representativeness**
- **Setting** Representativeness
- **Context** and Setting
- Community/Setting Engagement
- **Adaptation/**Change
- Sustainability
- **Costs/Feasibility** of Treatment
- Comparison Conditions

Evidence-Based Program and RE-AIM Resources



http://re-aim.org/resources_and_tools/index.html http://rtips.cancer.gov/rtips/index.do

Expanded CONSORT Diagram



re-aim.org: https://www.re-aim.hnfe.vt.edu/resources_and_tools/figures_and_tables/consort.pdf

Types of Outcomes in Implementation Research (Proctor, et al., 2010)

Implementation Outcomes

- Acceptability
- Adoption
- Appropriateness
- Costs
- Feasibility
- Fidelity
- Penetration
- Sustainability

Service Outcomes

- Efficiency
  Safety
- Effectiveness
- Equity
- Patient centeredness
- Timeliness

Client Outcomes

- Satisfaction
- Function
- Symptoms

Proctor E, Silmere H, Hensley M, et al. Outcomes for implementation research: *Administration And Policy In Mental Health* [serial online]. March 2011;38(2):65-76.

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

Glasgow, RE & Riley, WT. Pragmatic measures… *Am J Prev Med* (in press)

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. *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)*

Replicability (and generalizability)

Important to report conditions under which program was delivered

---

- To what extent is the program replicable:
  - ✓ In similar settings?
  - ✓ In different settings?

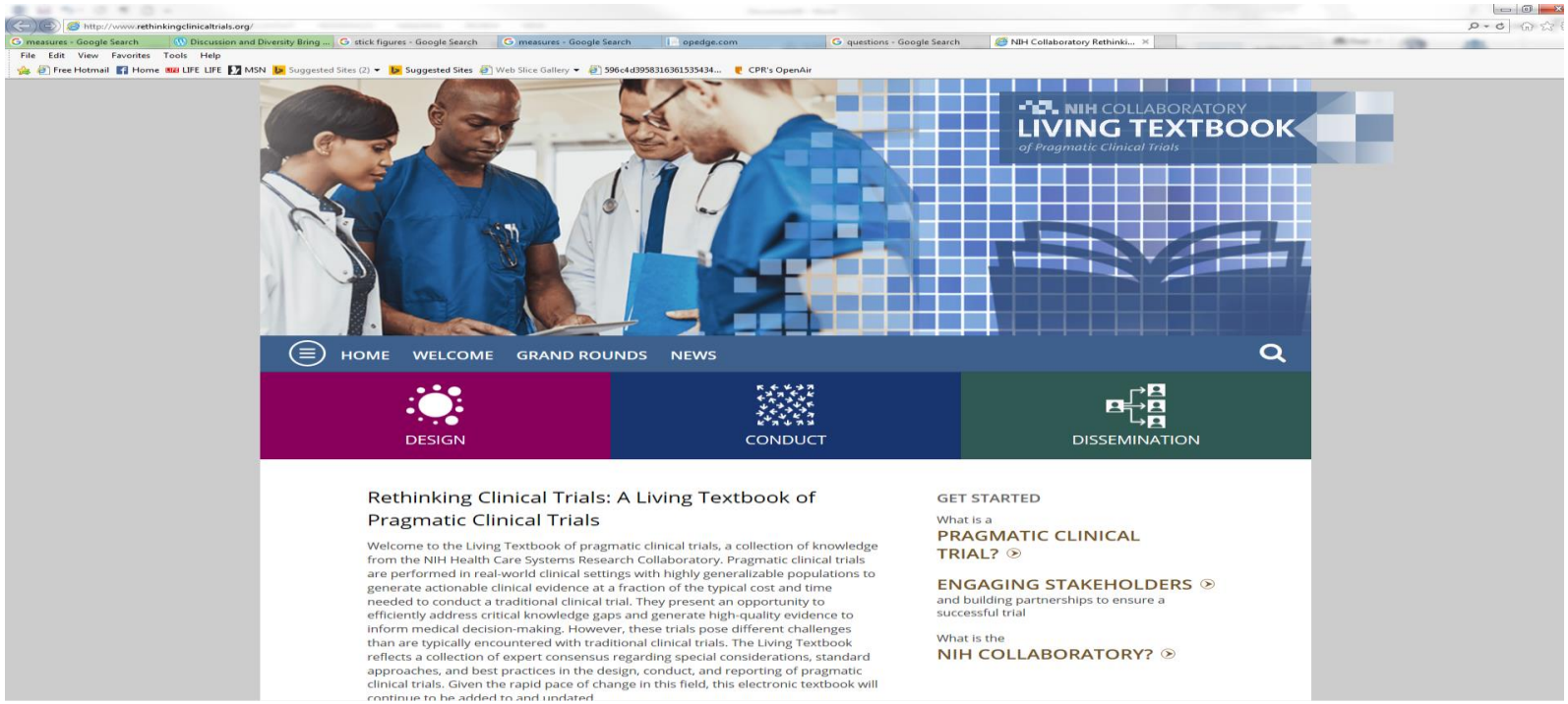
Goal: what intervention do you compare it to (real world alternative)?

Bottom Line and **ULTIMATE USE QUESTION**: "***What program/policy components*** *are most effective* for producing ***what outcomes*** for ***which populations/recipients*** when implemented by ***what type of persons*** under ***what conditions,*** with ***how many resources*** and ***how/why*** do these results come about?"

QUESTIONS, COMMENTS

Resources on Pragmatic Research

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



http://www.rethinkingclinicaltrials.org/

Where do I find pragmatic measures? Sample sites to visit!

PROMIS website http://www.healthmeasures.net/explore-measurement-systems/promis

National Institute of Nursing Research
https://cde.nlm.nih.gov/form/search?selectedOrg=NINR

GEMS- NCI website
https://www.gem-beta.org/public/MeasureList.aspx?cat=2

My own health report (MOHR) project.
http://myownhealthreport.org/

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.

General Resources

Brownson, RC, Colditz, GA, & Proctor, EK (2012 and in press). *Dissemination and implementation research in health: translating science to practice*. Oxford University Press.

re-aim.org

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

www.ucdenver.edu/accords/implementation

www.Dissemination-Implementation.org

ACCORDS D&I Program, University Colorado School of Medicine

- **Collaborative learning partnerships** to translate research into practice more quickly and successfully
- **Interactive resources and support** for patients, medical and public health students, and faculty researchers
-**Frequently updated information** on D&I related articles, grant opportunities, events, webinars, talks, and training
- **Local consultation** on D&I related research to increase funding and publication success
-**Cutting edge research** on: adaptation of interventions, self-management, pragmatic research and measures, shared decision making, planning for and evaluation of reach, implementation and dissemination

www.ucdenver.edu/accords/implementation

Questions? Comments?

I’m all ears!

Common Questions

- How does ‘adaptation’ fit with fidelity to protocol?
- How can Implementation Science help with observational studies? (natural experiments, multiple case studies, multiple levels, multiple stakeholders, theory guided prospective studies)
- How do I plan or design for ‘dissemination’?