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Agency for Healthcare Research and Quality

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How pragmatic is it?

Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research

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Sponsored by the AHRQ PBRN Resource Center

May 1, 2015



Agenda

- Welcome and introduction
- Presentation
- Q&A session
- Instructions for obtaining your CME Certificate of Participation

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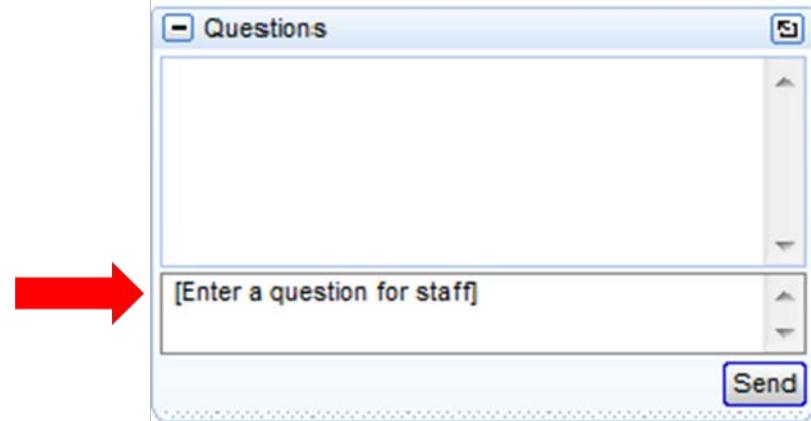
Disclosures

- Dr. Gaglio is a current employee of the Patient-Centered Outcomes Research Institute (PCORI) and former employee of Kaiser Permanente.
- Dr. Gaglio will not discuss off label use and/or investigational use of medications in the presentation.



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Today's Presenter

How pragmatic is it?
Determining pragmatic characteristics of research



Bridget Gaglio, PhD

Program Officer, Communication and Dissemination Research at the Patient-Centered Outcomes Research Institute (PCORI)



How pragmatic is it? Determining pragmatic characteristics of research

Bridget Gaglio, PhD

Communication and Dissemination Research

Patient-Centered Outcomes Research Institute (PCORI)

May 1, 2015

Today's session

- Introduction
- RE-AIM
- PRECIS refresher
- Using both frameworks
- Discussion
- References
- Questions

Definitions

- Pragmatic trial – seeks to answer the question, “Does an intervention work under usual/ real-world conditions?”
- Explanatory trial – seeks to answer the question, “Can an intervention work under ideal conditions?”

Differences between explanatory and pragmatic trials

Question	Can the intervention work? (efficacy)	Does the intervention work in real-world practice/settings? (effectiveness)
Setting	Ideal setting – well resourced	Normal, everyday practice
Participants	Highly selected – variety of inclusion/exclusion criteria	All individuals with the condition of interest
Intervention	Highly controlled and strict instructions for every intervention element	Flexible – normal practice
Outcomes	Known to be a direct and immediate relation to the intervention	Clinical significance and directly relevant to patients, stakeholders, providers, and payers
Relevance to practice	Indirect	Direct

Key Challenges

- Traditional RCTs study the effectiveness of treatments delivered to carefully selected populations under ideal conditions.
- This makes it difficult to translate results to the real world.
- 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

Why is it important?

Conducting pragmatic trials allows for:

- the comparison of a new intervention with the existing/previous standard of care,
- assessing process, clinical and population outcomes, and
- it provides practical information about the impact on time, resources, the training requirements and workplace implications of implementing the intervention into routine care/practice.

Key features of a pragmatic study

- The questions, perspectives taken, and outcomes studied are those that are important to stakeholders such as policy makers, practitioners, and patients.
- The research is conducted in multiple, heterogeneous settings similar to those in practice.
- There are few exclusion criteria and characteristics of participants resemble those seen in typical practice.
- Comparison conditions are real-world alternatives (i.e., current standard of care, rather than no treatment or placebo).

Several models and frameworks are available to facilitate translation of research into practice

- Continuum – development to evaluation of an intervention
- Pragmatic models are concerned with application to practice and emphasize key issues that are important to address for successful implementation or evaluation.
- Guide the types of questions that should be asked to assess how successful intervention efforts have been - *how useful they are in guiding action in real-world settings.*
- Today I will focus on one evaluation framework and one tool designed to help investigators to ensure their design decision care consistent with the stated purpose of the trail.

RE-AIM

An overview of the RE-AIM Framework for planning and evaluating health interventions.

- REACH
- EFFECTIVENESS
- ADOPTION
- IMPLEMENTATION
- MAINTENANCE

REACH

- The absolute number and proportion of individuals who are willing to participate in a given initiative, intervention, or program and the representativeness of the participants.
- REACH is always measured at the individual level.
- Focused on WHO

REACH

- How many people are eligible to participate? (the denominator)
- How many people actually participate and to what extent? (the numerator)

$$\frac{\text{\# people who participate}}{\text{\# people who are eligible}} = \text{REACH}$$

- Are they representative of the population?
- Are the individuals most at risk the ones that are reached?

Assessing representativeness

- Representativeness of those who participate
 - Characteristics of participants versus general population in that area
 - Characteristics of participants versus those who declined to participate

EFFECTIVENESS

- Effectiveness refers to how well an intervention affects a change in the primary outcome of interest, how it impacts quality of life and whether or not there are any unanticipated outcomes, positive or negative.
- Outcomes may be interim or long term.
- An often over-looked aspect of effectiveness is the impact of an intervention on quality of life, the “costs” of behavior change to participants, and potential negative outcomes that are a result of the intervention.
- Generally measured at the individual level.
- Focused on WHAT

EFFECTIVENESS

- Measure of primary outcome
- Measure of primary outcome relative to public health goal
- Measure of broader outcomes or use of multiple criteria (i.e., quality of life or potential negative outcome)
- Measure of robustness across subgroups
- Measure of short-term attrition and differential rates by patient characteristics or treatment group

ADOPTION

- The absolute number or proportion of settings and/or staff that are willing to initiate a program or intervention, and the representativeness of participating settings and staff.
- Includes number and types of staff responsible for implementation.
- Focused on **WHERE**

ADOPTION

- How many settings are eligible to participate?
 - The number of settings that are eligible and invited to participate is the denominator for adoption.
- How many settings actually participate? (the numerator)

$$\frac{\text{\# settings who participate}}{\text{\# settings who are eligible}} = \text{ADOPTION}$$

- What are the requirements to deliver a program or intervention?
- How many staff were approached and how many participated?
- Are there differences between settings and staff that adopt the intervention and those that do not?

Lesson Learned

- Most prevalent problem identified – confusing the definitions of REACH and ADOPTION

- Reach – Who
- Adoption – Where

IMPLEMENTATION

- The extent to which the intervention is delivered as it was intended, or with fidelity and includes the time and cost of the intervention.
- Consistency of intervention delivery across different settings and different staff - over time.
- Focused on HOW

IMPLEMENTATION

- Which elements of the intervention are most critical?
- What are the costs of implementing the intervention?
- How complex is the implementation protocol?
- Can different types of staff implement the program?

MAINTENANCE

- Measured at both the individual and setting level.
- Individual level – maintenance refers to the long-term effects for the participants that occur as a result of the intervention.
- Setting level – maintenance is defined as the extent of continuation or modification of the intervention.
- Focused on HOW LONG

MAINTENANCE

- Individual level – How can participants stay engaged and sustain positive behavior changes over time?
- Setting level – How can the intervention be incorporated into an organization so that it is sustained over time?

Assessing MAINTENANCE

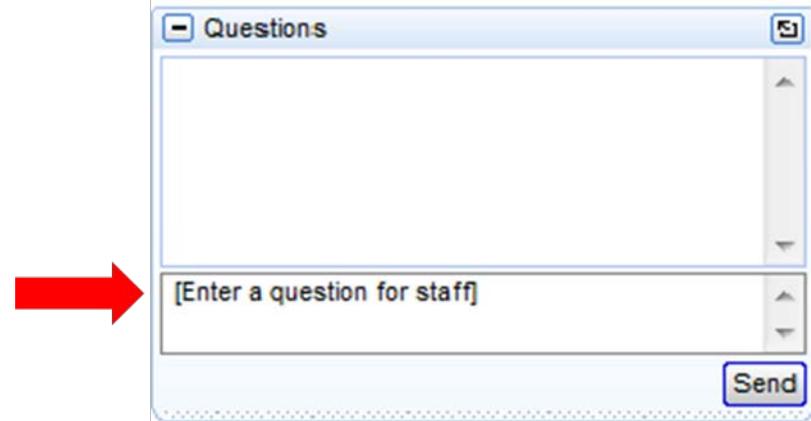
- **Individual level –**
 - Measure of primary outcome at ≥ 6 months follow-up after final treatment contact
 - Measure of long-term attrition and differential rates by patient characteristics or treatment
- **Setting level –**
 - Is program still ongoing ≥ 6 months post-treatment follow-up?
 - If and how program was adapted long-term (which elements were retained)?
 - Some measure/discussion of alignment to organization mission or sustainability

Questions about RE-AIM



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Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

- Quick overview
- For more in-depth information on PRECIS please see:

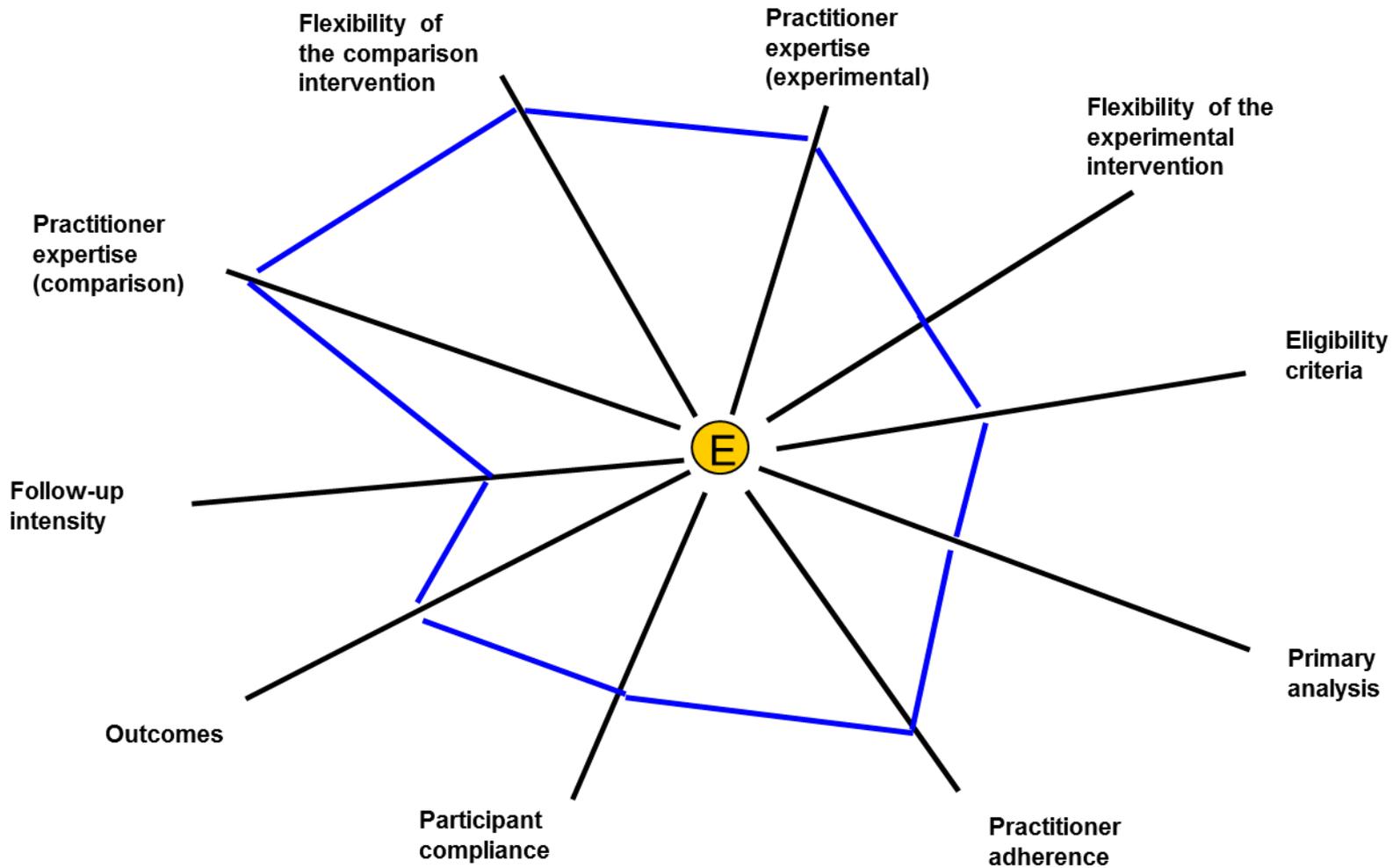
Kevin Thorpe's presentation on December 11, 2014

http://pbrn.ahrq.gov/sites/default/files/docs/AHRO%20PBRN%20Webinar_PRECIS%20Tool_12%2011%2014_FINAL.pdf

Thorpe KE, Zwarenstein M, Oxman AD, Treweek S, Furberg CD, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): A tool to help trial designers. *J Clin Epidemiol* 2009, 62(5):464-475.

Pragmatic-Explanatory Continuum Indicator Summary - PRECIS

- Participant eligibility criteria
- Experimental intervention flexibility
- Practitioner expertise (experimental)
- Comparison intervention
- Practitioner expertise (comparison)
- Follow-up intensity
- Primary trial outcome
- Participant compliance
- Practitioner adherence
- Analysis of primary outcome

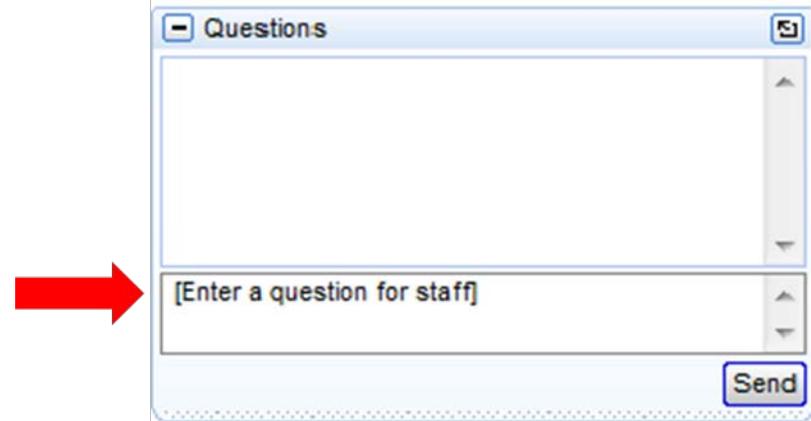


Questions related to PRECIS



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Understanding context – use of qualitative methods



Combining frameworks

- Combining frameworks can provide a more robust and comprehensive assessment of issues related to translation of research.
- Can be done during the planning, implementation, and/or evaluation phases of a study.

Examples of combining RE-AIM and PRECIS



Participant Eligibility

R
E
A
C
H

Who is the target population for this intervention? Whose health and health behaviors are you hoping to improve once the intervention is implemented?

What proportion of patients were 21 years of age or older, obese, and had at least one risk factor for CVD?

How representative of the total target population were the people who participated? Did they differ? If so, how?

Why did patients choose to participate? Decline?

Examples of combining RE-AIM and PRECIS

E

X

Follow – up Intensity

I
M
P
L
E
M
E
N
T
A
T
I
O
N

Where all the components of the protocol followed as planned?
What was the percent of perfect delivery? Explain.

Consistency of implementation across staff, setting, and over time.

What was the cost of implementing all this (time, space, resources)?

Examples of combining RE-AIM and PRECIS

E

X

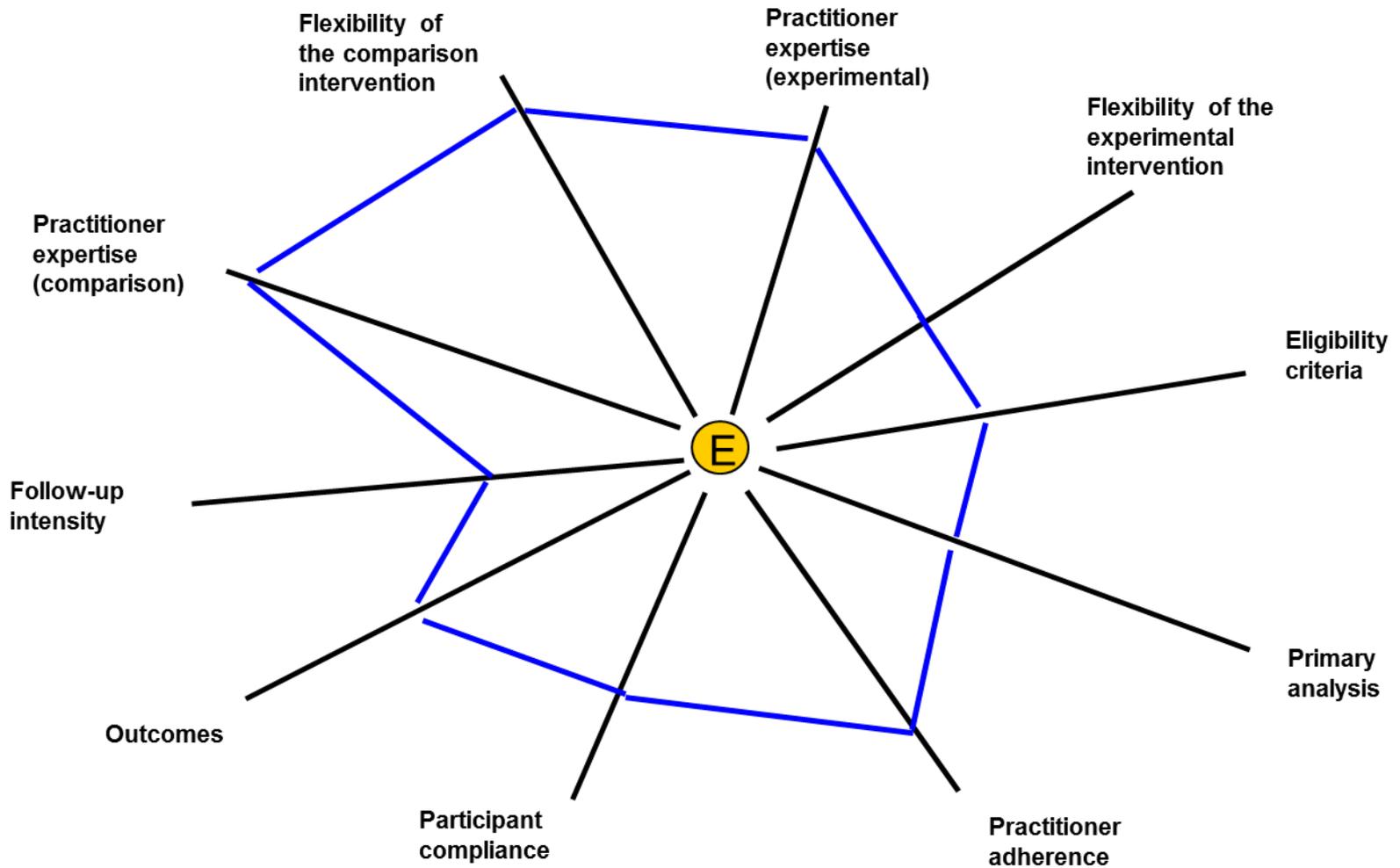
Practitioner Expertise (Experimental)

A
D
O
P
T
I
O
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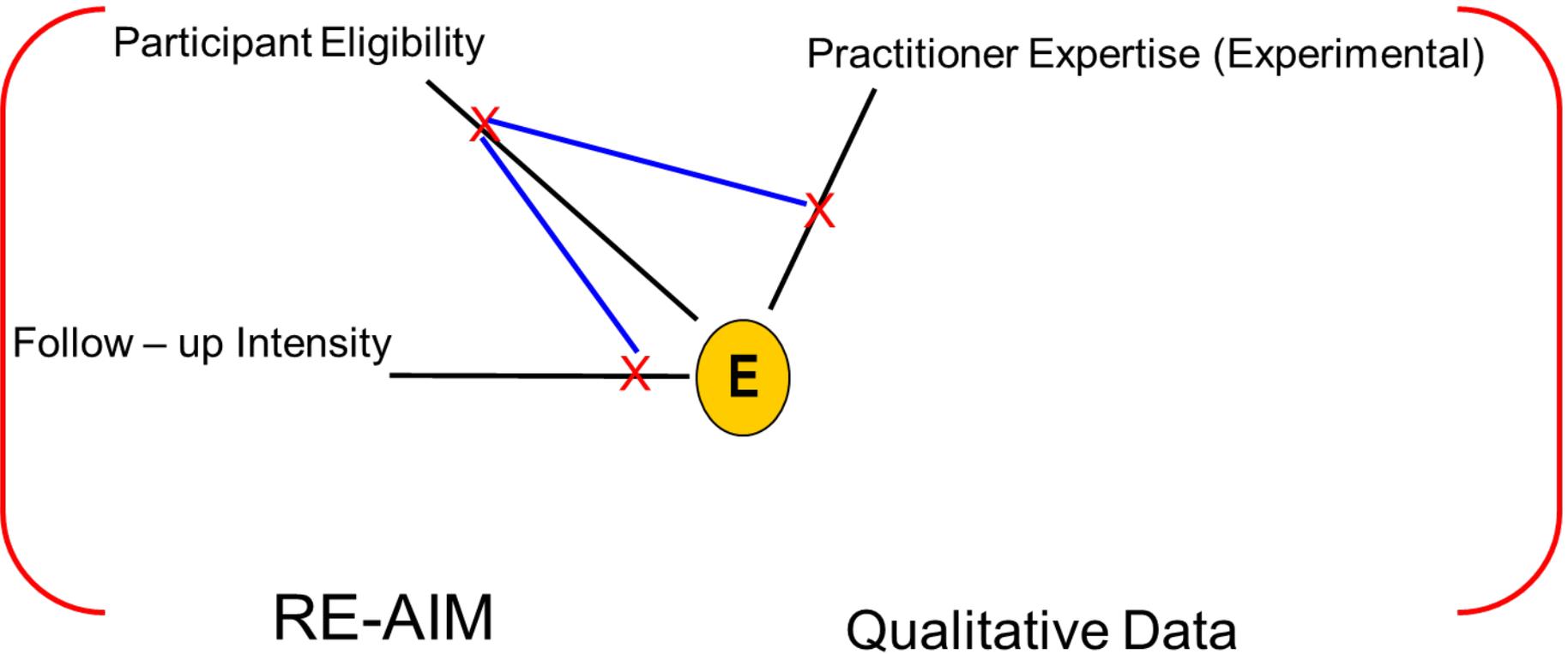
How many staff were offered the option to participate?

How many staff were excluded from being able to serve as a counselor for this project?

Characteristics of staff participants versus non-participants or typical staff?



Combining RE-AIM and PRECIS



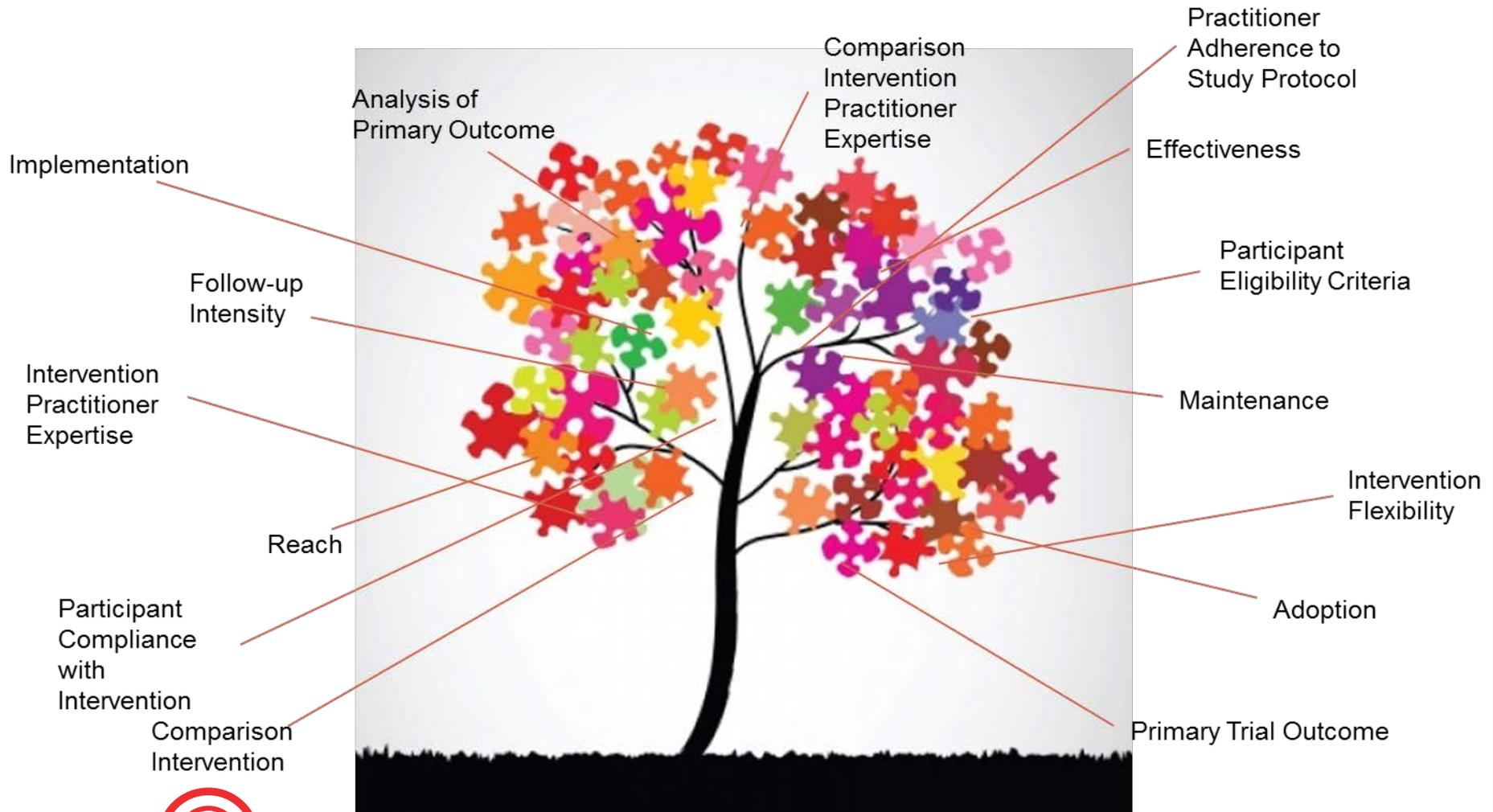
Discussion

- Combining domains from multiple frameworks and tools can highlight where and how an individual study or group of studies, is and is not pragmatic.
- Assessing domains within the same study allows for understanding the pragmatic versus explanatory design elements of the trial.
- Comparing domain across trials allows for meaningful judgments about which intervention has generalizability and applicability to a population of interest in a variety of settings.
- Assessment of characteristics should be done over the life course of the study to capture how a project has adapted/evolved over time.

Putting it all together



Putting it all together



Acknowledgements

- Siobhan M Phillips
- Suzanne Heurtin-Roberts
- Michael A Sanchez
- Russell E. Glasgow
- Sarah Chew

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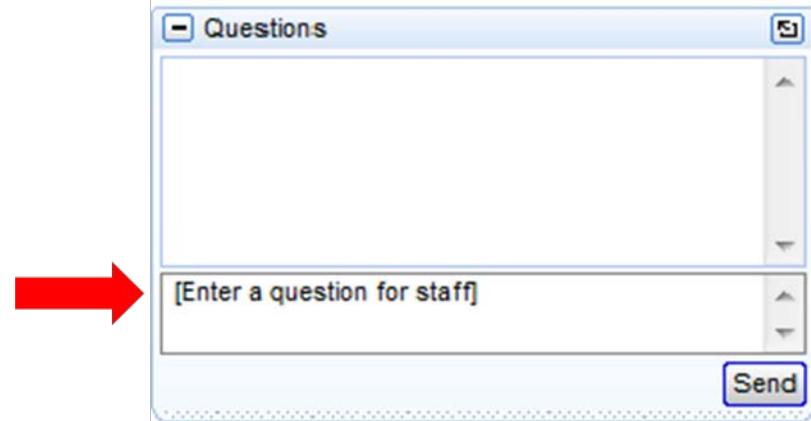
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