Use of PRECIS-2 Ratings in the NIH Health Care Systems Research Collaboratory

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Overview

- Background & Objectives
- Methods & PRECIS-2 Domains
- Results
- Conclusions

Acknowledgements

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- Demonstration project team members for input on study interpretation
- Russ Glasgow for his guidance and conducting the trainings

Background: What is PRECIS-2?

- CONSORT workgroup on Pragmatic Trials created the **PR**agmatic-**E**xplanatory **C**ontinuum **I**ndex **S**ummary criteria to help trialists design trials that are pragmatic across multiple domains (Thorpe *J Clin Epi* 2009)
- University of Dundee team created second version based on initial use (Loudon *BMJ* 2015)
  - Reduces domains 10->9
  - Makes comparisons to usual care without explicit rating of control conditions
  - Considers external validity in the recruitment and settings domains.

Background: What is the NIH Health Care Systems Research Collaboratory?

- Advances large scale pragmatic clinical trials through demonstration projects
- Studies occur in large and diverse health care settings around the United States
- Trials have a planning (UH2) and implementation (UH3) phase

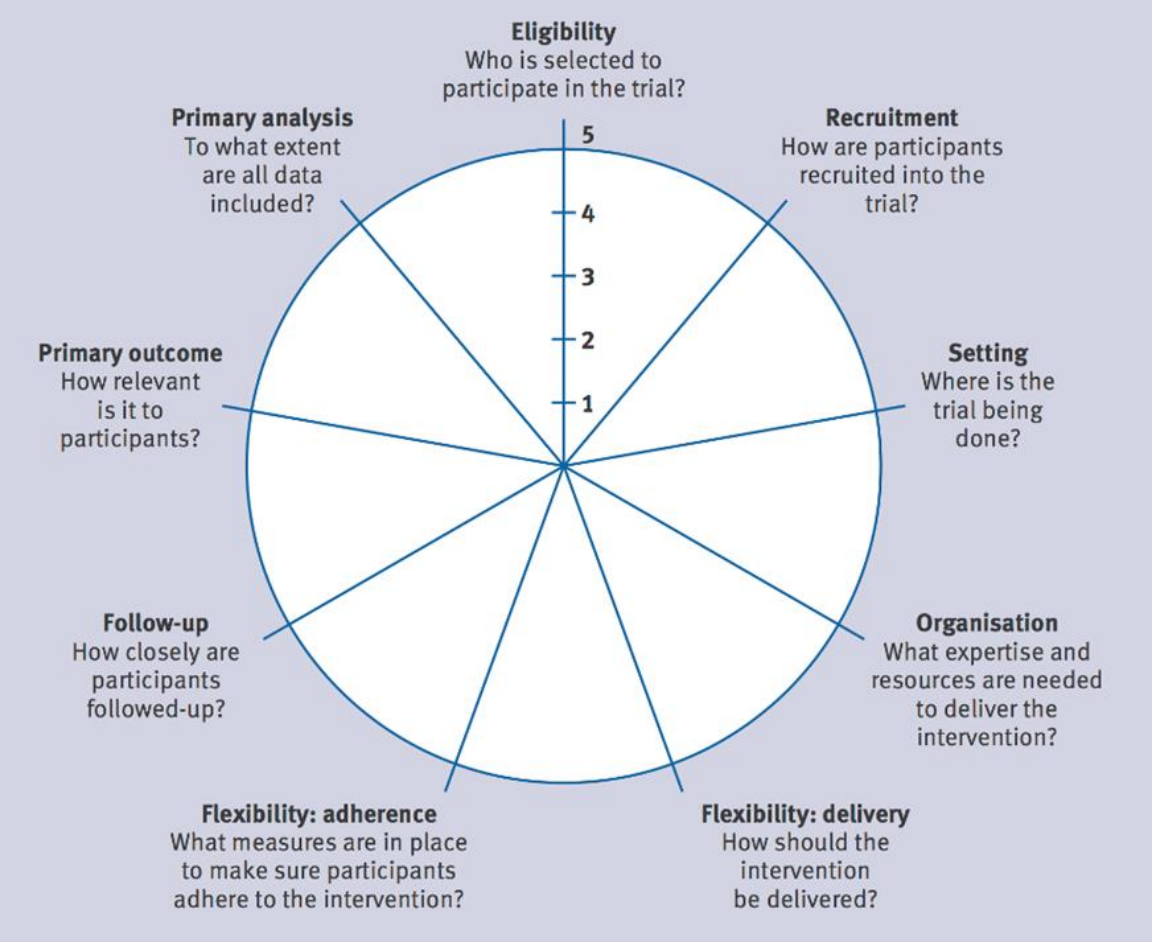
Objectives

1. Measure the degree to which the NIH Collaboratory trials are pragmatic at both the planning (UH2) and implementation (UH3) phases
2. Study whether and how trial design changed from UH2 and UH3 phases
3. Assess PRECIS-2 usability for assessing pragmatic features across studies and over time
4. Provide an opportunity for study teams to better understand the other projects

Methods: Raters and Training

- Raters
  - Trial PIs or designees (4)
  - Coordinating Center Staff (1)
  - NIH staff (6)
- Russ Glasgow trained the raters on using the PRECIS-2 tool
  - Orientation webinar
  - Practice protocol

The PRagmatic-Explanatory Continuum Index Summary 2 (PRECIS-2) wheel



Scale:

1 = very explanatory

3=equally pragmatic and explanatory

5= very pragmatic

Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ.* 2015;350:h2147.

Domain 1: Eligibility

- To what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care?

1	Lots of exclusions (e.g. those who don't comply, respond to treatment, or are not at high risk for primary outcome, are children or elderly) Uses many selection tests not used in usual care
5	Essentially identical to usual care

Domain 2: Recruitment

- How much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients?

1	Targeted invitation letters, advertising in newspapers, radio plus incentives and other routes that would not be used in usual care
5	Very pragmatic recruitment through usual appointments or clinic

Domain 3: Setting

- How different is the setting of the trial and the usual care setting?

1	Only a single center, or specialized trial/academic centers
5	Identical settings to usual care

Domain 4: Organization

- How different are the resources, provider expertise and the organization of care delivery in the intervention arm of the trial and those available in usual care?

1	Very explanatory approach if the trial increases staff levels, gives additional training, requires more than usual experience or certification and increases resources
5	Very pragmatic choice that uses identical organization to usual care

Domain 5: Flexibility (delivery)

- How different is the flexibility in how the intervention is delivered and the flexibility likely in usual care?

1	Strict protocol, monitoring and measures to improve compliance, with specific advice on allowed co-interventions and complications
5	Identical flexibility to usual care

Domain 6: Flexibility (adherence)

- How different is the flexibility in how participants must adhere to the intervention and the flexibility likely in usual care?

1	Exclusion based on adherence, and measures to improve adherence if found wanting
5	No more than usual encouragement to adhere to the intervention

Domain 7: Follow-up

- How different is the intensity of measurement and follow-up of participants in the trial and the likely follow-up in usual care?

1	More frequent, longer visits, unscheduled visits triggered by primary outcome event or intervening event, and more extensive data collection
5	No more than usual follow up

Domain 8: Primary outcome

- To what extent is the trial's primary outcome relevant to participants?

1	Surrogate, physiological outcome Central adjudication or assessment expertise that is not available in usual care Measured earlier than in usual care
5	Outcome of obvious importance to participants

Domain 9: Primary analysis

- To what extent are all data included in the analysis of the primary outcome?

1	Excludes ineligible post-randomization participants, includes only completers or those following the treatment protocol
5	Intent to treat with all available data

Methods: Study Ratings

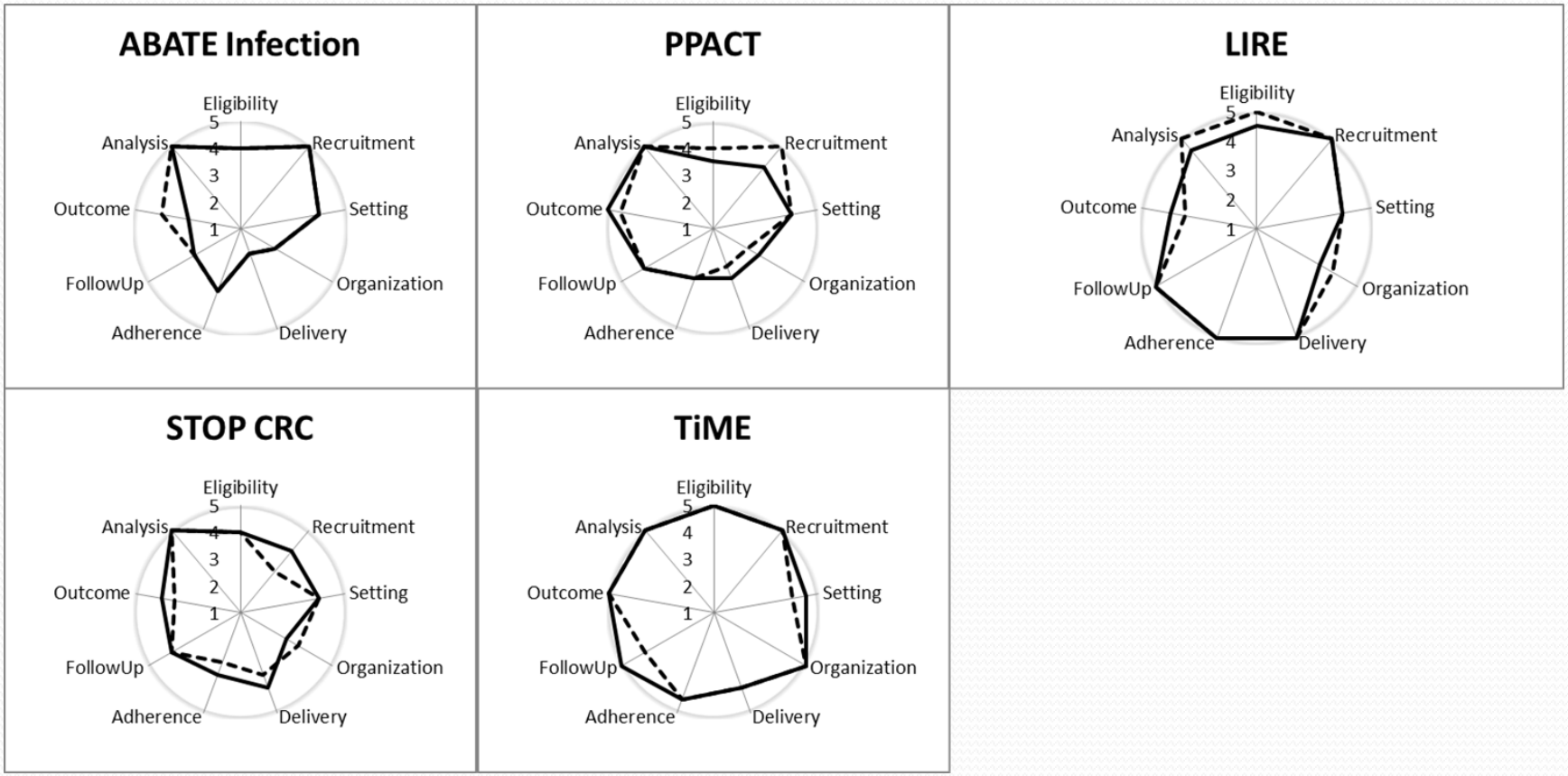
- 5 trials rated (ABATE Infection, LIRE, PPACT, STOP CRC, TiME)
- Each trial rated by 8 raters at 2 time points
  - UH2 ratings assessed from grant application
  - UH3 ratings assessed from transition report
- Rating form included space for comments
- Resulting ratings/wheels discussed with study PIs

Results

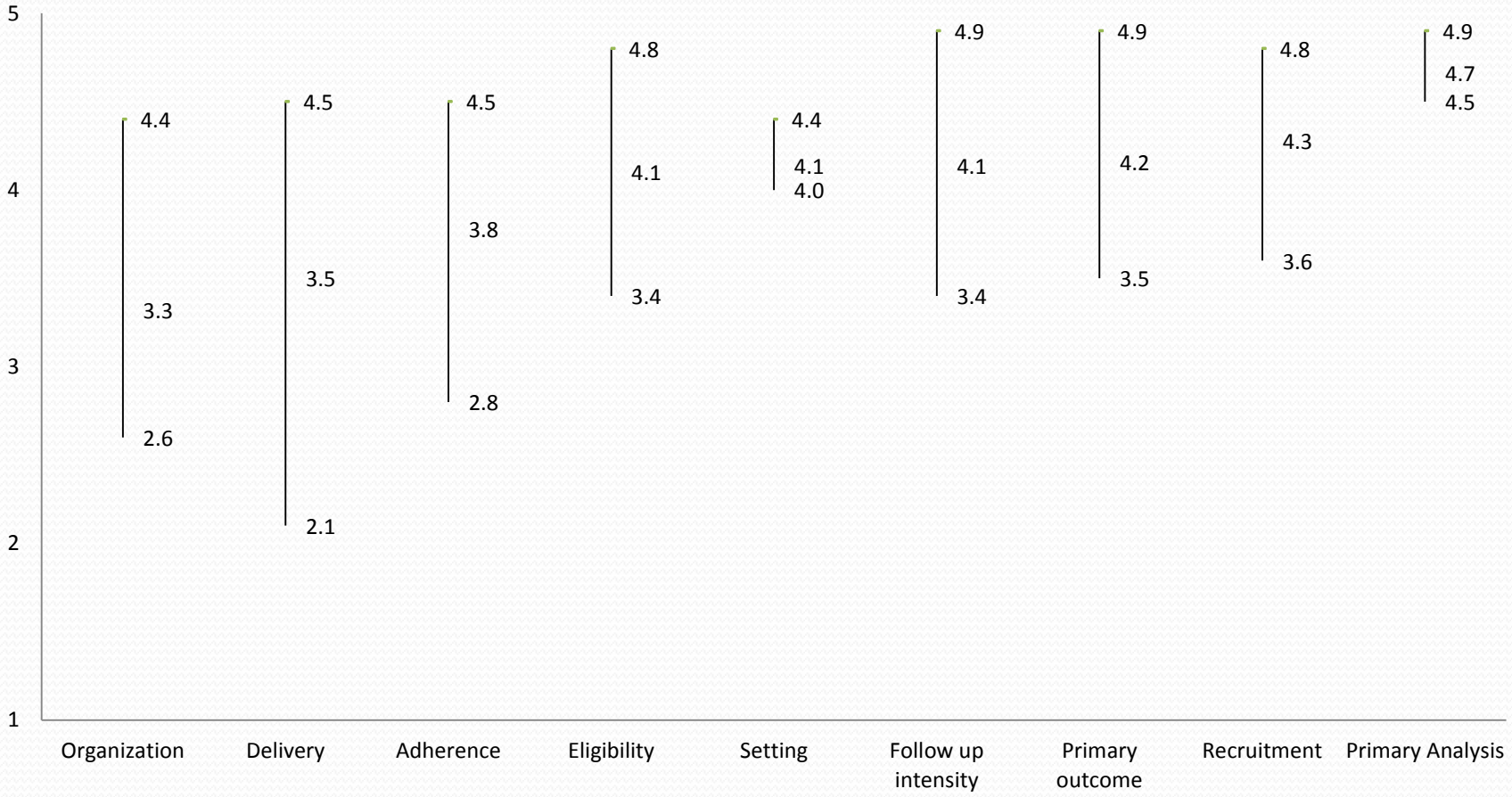
Results by study and phase

Dashed line indicates planning phase

Solid line indicates implementation phase



Mean score (and range) by domain



Interpretation of results

- All five demonstration projects were rated to be more pragmatic than explanatory
- TiME and LIRE rated as most pragmatic
- No conclusive changes over time
- Modest but statistically significant interrater agreement
- PRECIS-2 ratings not necessarily definitive but generate a starting point for discussion

Rating challenges

- Eligibility: organizational and patient eligibility
- Setting and organization: how to rate trial procedures relative to usual care in the U.S. given how much health systems vary?
- Flexibility of delivery/adherence: how to rate trial restrictions relative to usual care quality control protocols?
- Primary outcome: how to rate outcomes that matter to health systems more than patients?
- Criteria that pertain to more than one domain (e.g., organizational willingness to participate)

Conclusions

- The 5 NIH Collaboratory trials were designed as more pragmatic than explanatory as measured by all PRECIS-2 domains
- Using PRECIS-2 tool helps think through study nuances and could guide implementation e.g. where to focus training resources
- Suggestions for use and refinement
  - Guidance on how to rate an intervention that is designed to change usual care
  - Guidance on how care system nuances (for example, data systems) can influence ratings
  - People who are familiar with the study team should be involved in discussions

Resource and reminder

- PRECIS-2 toolkit available at: https://crs.dundee.ac.uk/precis
- Johnson KE, Neta G, Dember LM, Coronado GD, Suls J, Chambers DA, Rundell S, Smith DH, Liu B, Taplin S, Stoney CM, Farrell M, Glasgow RE. **Use of PRECIS-2 Ratings in the NIH Healthcare Systems Research Collaboratory.** *Trials*. 2016, *17*:32.
- Level of pragmatism not a marker of study quality but related to study question