PRECIS-2-Provider Strategies: A Tool for Developing Implementation Trials with Purpose and Intent

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Disclosures

- I have no financial relationships to disclose.

- The opinions expressed herein are mine and not official positions of the National Cancer Institute, the National Institutes of Health, or the U.S. federal government.

Agenda

- Brief presentation (~10 min)
- Q&A, Interactive Case Studies (~20 min)
- Handout: PRECIS-2-PS table, select resources, select references

Learning Objectives

1. Understand how to conceptualize implementation trials along the explanatory-pragmatic continuum.
2. Recognize key elements of implementation trials that can make them more explanatory or more pragmatic in overall intent.
3. Identify differences between planning for intervention trials along the explanatory-pragmatic continuum or planning for implementation trials along the explanatory-pragmatic continuum.
4. Review case studies of implementation trials along the explanatory-pragmatic continuum.

Clinical Trials: Explanatory-Pragmatic Continuum

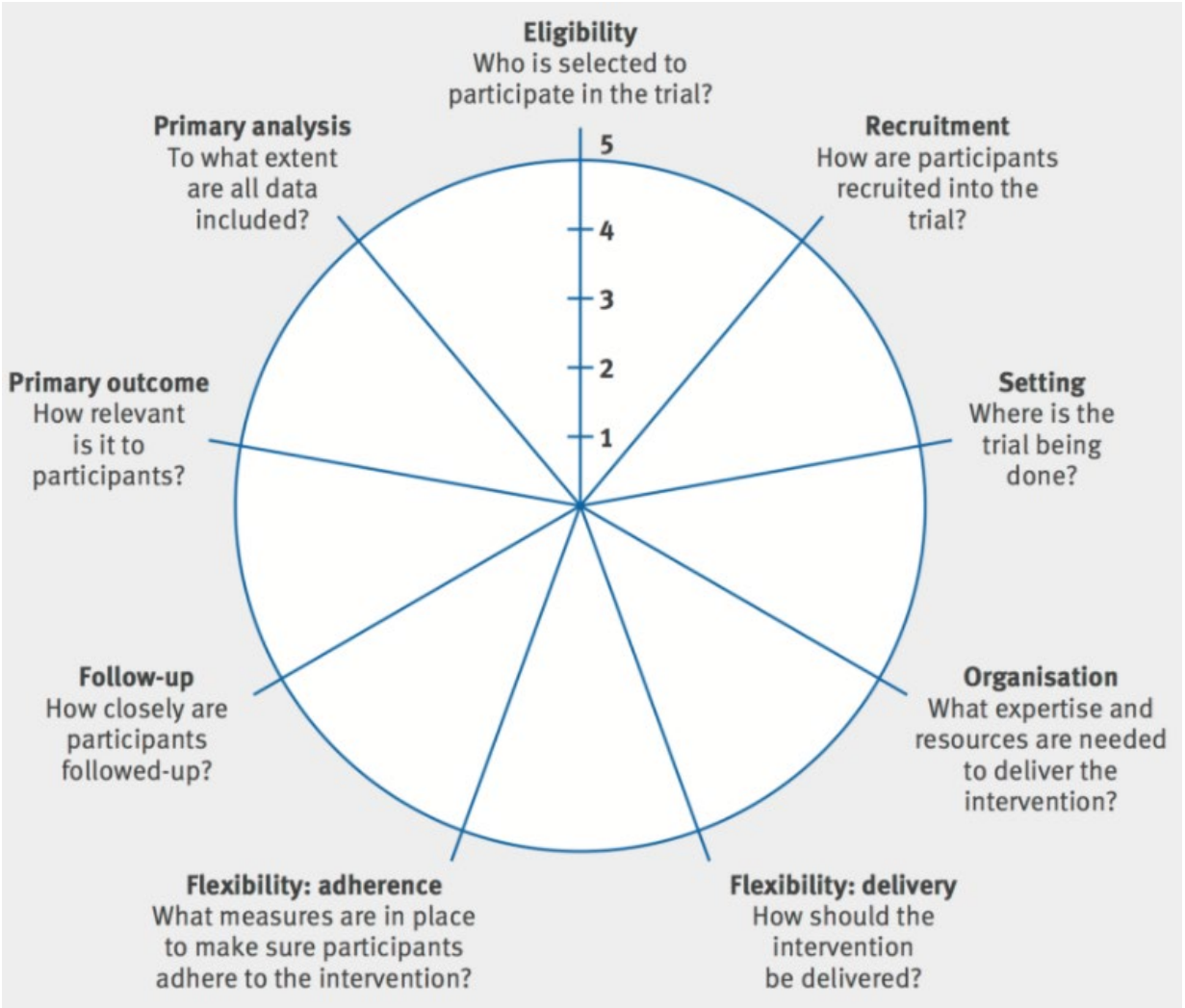
- *Explanatory Trial*: Understanding, ‘efficacy’ trials, laboratory conditions, maximize internal validity, less concerned with external validity.

- *Pragmatic Trial*: Decision making, ‘effectiveness’ trials, normal conditions (‘real-world’), balance internal and external validity.

- Tools for planning for trials along explanatory-pragmatic continuum…

Pragmatic Explanatory Continuum Indicator Summary-2 Tool (PRECIS-2)

Loudon et al. (2015), *BMJ*



Pragmatic Explanatory Continuum Indicator Summary-2-Provider Strategies Tool (PRECIS-2-PS)

Norton et al. (2021), *Implementation Science*

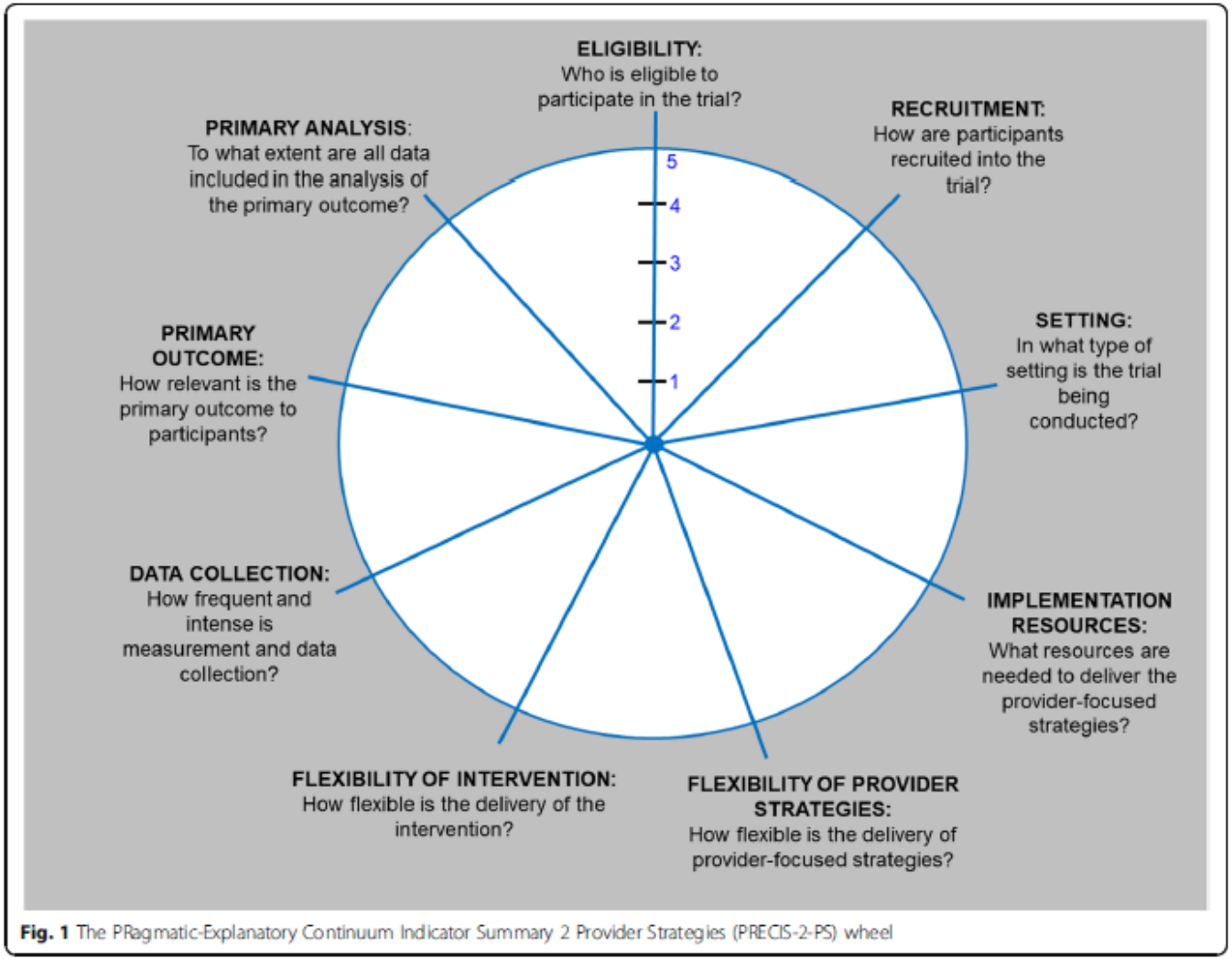


Fig. 1 The PRagmatic-Explanatory Continuum Indicator Summary 2 Provider Strategies (PRECIS-2-PS) wheel

PRECIS-2-PS Domains

Domain	Key Question
1. Eligibility	*To what extent are the healthcare professionals in the trial similar to those in usual care?*
2. Recruitment	*How much extra effort is made to recruit healthcare professionals into the trial compared to what is available to encourage their engagement in usual care settings?*
3. Setting	*How different is the health care or public health setting (e.g., hospital, clinic, health department) in which the trial is conducted compared to usual care settings?*
4. Implementation Resources	*How different are the resources needed to support the delivery of the provider-focused strategies from resources that are readily available in usual care?*

PRECIS-2-PS Domains

Domain	Key Question
5. Flexibility of Provider-focused Strategies	*How different is the flexibility in how provider-focused strategies are delivered in the trial and the flexibility in how provider-focused strategies are likely to be delivered in usual care?*
6. Flexibility of Intervention	*How different is the flexibility in how the intervention is delivered by healthcare providers to patients and the flexibility in how the intervention would be delivered in usual care?*
7. Data Collection	*How different is the frequency and intensity of measurement and data collection throughout the trial compared to what is considered routine in usual care?*
8. Primary Outcome	*To what extent is the trial's primary outcome important to healthcare professionals?*
9. Primary Analysis	*To what extent are all data included in the analysis of the primary outcome?*

Questions? Comments?

Interactive Case Studies: PRECIS-2-PS Domains

Interactive Case Studies: *Eligibility*

- Participants may include substance use disorder treatment service providers, workgroup services, and agency executives/managers who provide or supervise direct services, at least 18 years of age, employed at one participating agency, and agree to participate in leadership training.

- *1 = very explanatory, 5 = very pragmatic*

Adapted from Aarons et al., 2017

Interactive Case Studies: *Recruitment*

- Executives who have agreed to allow recruitment at their agencies will first identify appropriate workgroups within their agencies that will be offered the opportunity to enroll in the study. Once workgroups are identified, executives at each agency will contact eligible workgroup supervisors to invite them to a group phone call with the investigative team to learn more about the study.

- *1 = very explanatory, 5 = very pragmatic*

Adapted from Aarons et al., 2017

Interactive Case Studies: *Setting*

- The study will take place with workshops from 60 substance use disorder treatment agencies in California, USA.
- California is home to 38M individuals encompassing urban and vast rural areas with a diverse population. Approximately 80% of the population have a high school educational degree.

- *1 = very explanatory, 5 = very pragmatic*

Adapted from Aarons et al., 2017

Interactive Case Studies: *Implementation Resources*

- Measurement Training and Feedback System for Implementation (MTFS-I).
- Online training system to enhance fidelity to evidence-based treatments (EBTs).
- Weekly email prompts to view online, brief (5-8 min) video vignettes, submit fidelity rating scores, immediate feedback.
- Time investment of ~20 minutes per week for online training and data submission, plus review of monthly feedback reports. Duration: 1 year.
- *1 = very explanatory, 5 = very pragmatic*

Adapted from Hogue et al., 2019

Interactive Case Studies:
Flexibility of Provider-focused Strategies

- Sites select consultation format for package of implementation strategies that best fits with extant site supervision practices: Weekly 20-30 min by phone, bi-weekly 40-60 min by phones, or monthly 90-120 min in person.
- Providers can select own training preference, identify own fidelity benchmarks, co-design report templates so feedback tailored to local quality preferences.
- *1 = very explanatory, 5 = very pragmatic*

Adapted from Hogue et al., 2019

Interactive Case Studies: *Flexibility of Intervention*

- *Physicians will be trained to use Motivational Interviewing (MI) with their patients in order to increase patients' medication adherence.*

- *As part of training, physicians will be encouraged to adapt the delivery and content of MI to meet the needs of their individual patients.*

- *1 = very explanatory, 5 = very pragmatic*

Interactive Case Studies: *Data Collection*

- Primary study outcome: We will be using EMR (electronic medical record) data routinely collected in primary care and managed by the Practice-based Research Network affiliated with the Canadian Primary Care Sentinel Surveillance Network.
- Additional data collection (secondary/exploratory): Survey for patients with potentially inappropriate prescriptions (1 survey), online survey for providers, interviews with patients, focus groups with providers at end of study.
- *1 = very explanatory, 5 = very pragmatic*

Adapted from Griever et al., 2019

Interactive Case Studies: *Primary Outcome*

- The primary study outcome is to determine whether the implementation strategy reduces potentially inappropriate prescriptions for patients aged 65 and older with polypharmacy when compared to usual care.

- *1 = very explanatory, 5 = very pragmatic*

Adapted from Griever et al., 2019

Interactive Case Studies: *Primary Analysis*

- The analysis will be on an intention to treat basis and include physicians who have agreed to participate but discontinue their engagement at any point during the study.

- *1 = very explanatory, 5 = very pragmatic*

Adapted from Griever et al., 2019

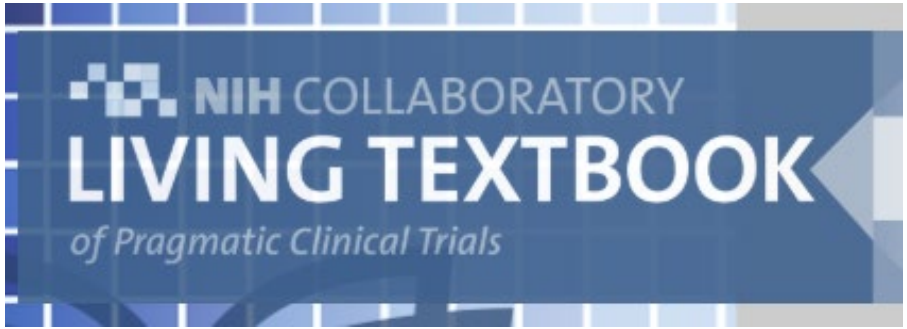
Select Resources on Pragmatic Trials

Select Resources

- PRECIS-2 Tookit, podcasts, webinars, how-to guide
- Database of 700+ trials that have been scored using PRECIS-2
- www.precis-2.org

Twitter account

Select Resources



Living Textbook of Pragmatic Clinical Trials

- Collection of knowledge from the NIH Health Care Systems Research Collaboratory
- Chapters on design, conduct, and dissemination of pragmatic clinical trials
- Training resources, newsletter, webinars

https://rethinkingclinicaltrials.org/

Pragmatic Trials: A Workshop Handbook

- Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS), Colorado Research and Implementation Science Program (CRISP)

http://www.crispebooks.org/workbook-18OF-1845R.html

Select Resources

Designing provider-focused implementation trials with purpose and intent: introducing the PRECIS-2-PS tool

Wynne E. Norton[1*], Kirsty Loudon[2], David A. Chambers[1] and Merrick Zwarenstein[3]

Implementation Science, 2021

Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory

Karin E. Johnson[1†], Gila Neta[2*†], Laura M. Dember[3], Gloria D. Coronado[4], Jerry Suls[2], David A. Chambers[2], Sean Rundell[5], David H. Smith[4], Benmei Liu[2], Stephen Taplin[2], Catherine M. Stoney[6], Margaret M. Farrell[2] and Russell E. Glasgow[7]

Trials, 2016

The PRECIS-2 tool: designing trials that are fit for purpose

Kirsty Loudon,[1] Shaun Treweek,[1] Frank Sullivan,[2] Peter Donnan,[3] Kevin E Thorpe,[4] Merrick Zwarenstein[5]

BMJ, 2015

'Pragmatic' and 'explanatory' attitudes to randomised trials

Zwarenstein (2017), *Journal of the Royal Society of Medicine*

Select Resources

Pragmatic Randomized Controlled Trials in Health Care

Pragmatic randomized controlled trials reliably work out which of several healthcare interventions works best under real-world conditions.

- Massive Open Online Course (MOOC; *archived*)
- Principles of pRCTs in combination with economic and qualitative methods, and how to apply these to develop your own research proposal.
- How to critique research proposals for these kinds of trials.

https://www.edx.org/course/pragmatic-randomized-controlled-trials-in-health-c

Summary

- Important to consider overall intent and purpose of study in planning phase for trials that test interventions (PRECIS-2) and/or implementation strategies (PRECIS-2-PS).
- Tools can help plan for trials along the continuum and help match intent of trial with characteristics and design of the trial.
- Ongoing work to advance and refine PRECIS-2 and further develop and validate PRECIS-2-IS.

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