

What Are Embedded PCTs?

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Disclosures

- Dr. Wendy Weber has no financial disclosures to report. The views expressed in this presentation are those of the speaker and do not necessarily reflect the position or policy of the NIH or the U.S. government.

Learning goals



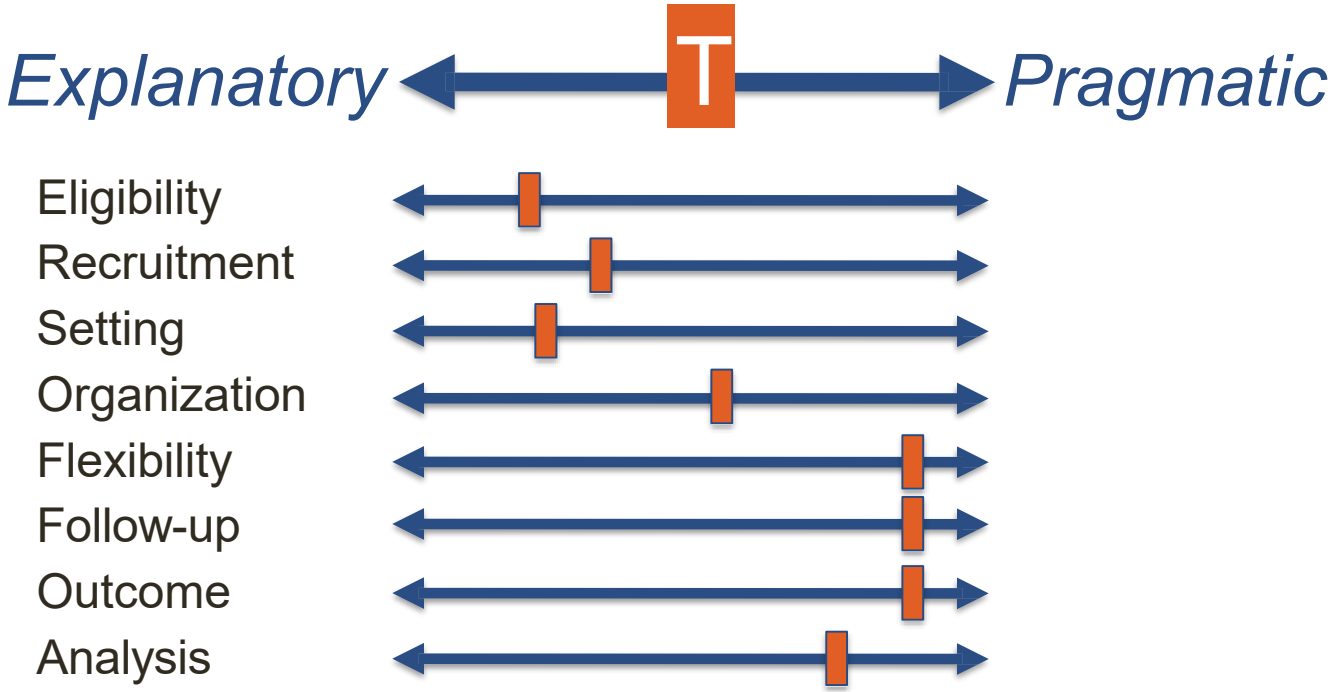
- Identify key considerations in the design and conduct of ePCTs and how they differ from explanatory trials
- Learn about the advantages and disadvantages of ePCTs, when a pragmatic approach can be used to answer the research questions

Important things to know

- ePCTs are designed to answer important, real-world clinical questions
- Broad stakeholder engagement and support are essential from beginning to end
- Trade-offs in flexibility, adherence, and generalizability are inevitable

Trials vary across a spectrum of explanatory and pragmatic elements

Different trial elements are, by design, more or less explanatory/pragmatic



Why conduct ePCTs?



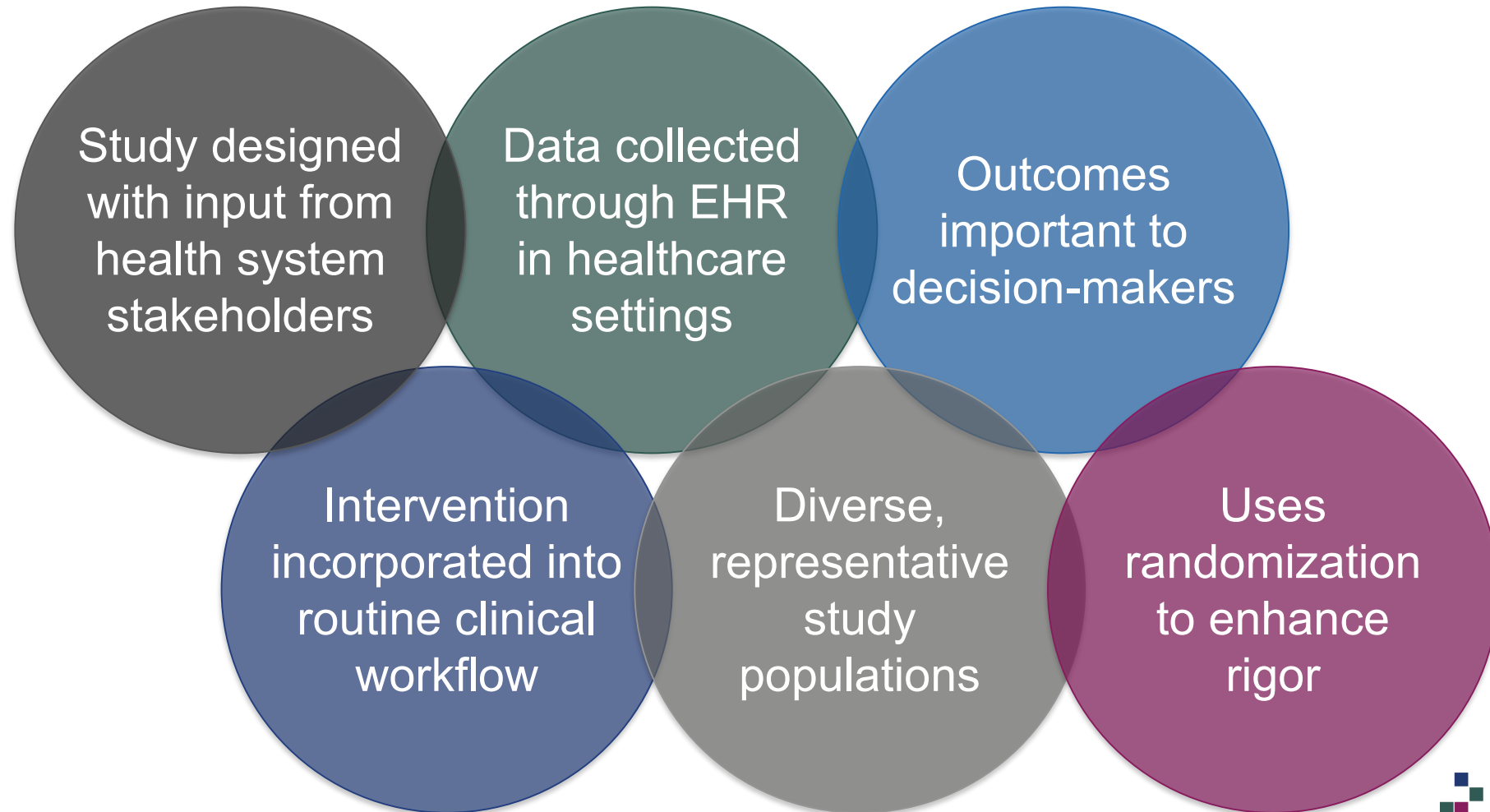
ePCTs have the potential to inform policy and practice with high-quality evidence at reduced cost and increased efficiency compared with traditional clinical trials

ePCT characteristics

- Conducted within healthcare systems
- Use streamlined procedures and existing infrastructure
- Answer important medical questions



ePCTs bridge clinical care into research



Who are your stakeholders?

Potential stakeholders have a variety of priorities, values, work cultures, and expectations:



- Healthcare delivery organization leaders
- Clinicians
- Operational personnel
- Patients, caregivers, patient advocacy groups
- Payers, purchasers
- Policy makers, regulators
- Research funders
- Researchers
- Product manufacturers

Integrating health equity into ePCTs

6 Best Practices for Getting Started

- Consider health equity in all domains of ePCT design
- Select a research question that matters to health disparity populations
- Collaborate with community members to ensure relevant, respectful, and inclusive research
- Allocate sufficient resources to ensure appropriate and inclusive engagement of health disparity populations
- Build a research team that is diverse and knowledgeable about health equity issues
- Design with health equity monitoring and reporting in mind

Best Practices for Integrating Health Equity into Embedded Pragmatic Clinical Trials for Dementia Care



6 Best Practices for Getting Started

Integrating Health Equity into ePCTs for Dementia Care



- 1** Consider health equity in all domains of ePCT design
There are health equity considerations in all ePCT design domains, as guided by the PRECIS-2 framework. The key is to consider these issues early in the design phase and throughout the trial's conduct.
- 2** Select a research question that matters to health disparity populations
All trials are ethically required to maximize their social value. One way to achieve this is to prioritize questions that address the needs of health disparity population including those that are historically disadvantaged, underrepresented, or otherwise underserved.
- 3** Collaborate with community members to ensure relevant, respectful, and inclusive research
Engage representative stakeholders who are knowledgeable about the community. Keep in mind there are many aspects of diversity (e.g., race/ethnicity, geography, education). Consultation with community members is valuable across the trial lifespan.
- 4** Allocate sufficient resources to ensure appropriate and inclusive engagement of health disparity populations
Plan for the effort and budget needed to support inclusive participant engagement. Examples include budgeting for: translation or interpretation services, remuneration of research activities for community partners, and project staff diversity training.
- 5** Build a research team that is diverse and knowledgeable about health equity issues
Your research team should include investigators, consultants, and project staff with the diversity, methodologic expertise, content knowledge, and training to enable rigorous integration of health-equity-relevant issues throughout the ePCT design.
- 6** Design with health equity monitoring & reporting in mind
When you design an ePCT, keep in mind the health-equity-relevant aspects that need to be monitored and reported. The Consort Equity Extension and Progress-Plus frameworks are useful guidelines.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection [Return to TOC](#) Page 2

How to Use this Packet

Health-equity-relevant considerations are necessary in all aspects of ePCTs. The key is to consider these issues early in the planning process, as well as systematically and throughout the conduct of the trial. Health-equity-relevant concepts can be nuanced and complex, and the degree to which researchers can incorporate health equity into each ePCT design component depends on the scope and objectives of the trial. These best practices are meant as a starting place for investigators to systematically explore how to integrate health equity into their ePCT design and identify potential pitfalls in their current research processes.



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Listen to the frontline

The purpose of the healthcare system is not to do research, but to provide good healthcare. Researchers often have a tail-wagging-the-dog problem. We assume if we think something is a good idea, the healthcare system will too... We need to remember that we're the tail and the healthcare system is the dog.

– Greg Simon, MD, MPH (SPOT)

Use existing workflows

The more complicated the intervention is to the existing workflow, the more difficult it is to get compliance—you can't just add on a new thing, you have to change what happens on the floor.

– Vincent Mor, PhD (PROVEN)

It's a balancing act



Achieving both relevance and efficiency is a goal of pragmatic trials, yet high relevance to real-world decision-making may come at the expense of trial efficiency

For example, a trial measuring outcomes that matter most to patients and health systems may not be able to rely exclusively on information from the EHR, and instead need to assess patient-reported outcomes, which is more expensive and less efficient

Important things to do

- Set expectations to work collaboratively and build trust from the beginning
- Get to know your partners' values, priorities, and expectations
- Assess your partners' capacity and capabilities
- Track goals reached, challenges, and adaptations throughout the lifecycle of your ePCT
- Show appreciation and celebrate accomplishments early and often to have sustained partnerships



Resource: The Living Textbook

Visit the *Living Textbook of Pragmatic Clinical Trials* at

www.rethinkingclinicaltrials.org

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Design View Chapters >

Data, Tools & Conduct View Chapters >

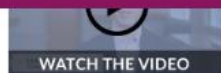
Dissemination View Chapters >

Ethics and Regulatory View Chapters >

What is a Pragmatic Clinical Trial?
Endpoints and Outcomes
Building Partnerships and Teams to Ensure a Successful Trial

Developing a Compelling Grant Application
Analysis Plan
Intervention Delivery and Complexity

Experimental Designs and Randomization Schemes
Using Electronic Health Record Data



Pragmatic Trials Collaboratory. Pragmatic clinical trials present an opportunity to efficiently generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than traditional clinical trials. The Living Textbook reflects a collection of special considerations and best practices in the design, conduct, and reporting of pragmatic clinical trials.

What is a
PRAGMATIC CLINICAL TRIAL? ▶

TRAINING RESOURCES ▶



Question & Answer



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