Engaging With Stakeholders & Aligning With Health System Partners

Emily C. O'Brien, PhD

Associate Professor of Population Health Sciences

Duke University

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Learning goals

- Identify skills needed for a strong study team and consider the diversity of the team, including inclusive practices
- Describe the breadth of stakeholders to engage as partners and approaches for engaging them through all phases of the study
- Understand the real-world priorities and perspectives of healthcare system leaders and how to obtain their support
- Identify engagement practices to obtain patient and community perspectives
- Highlight challenges of partnering across diverse health systems
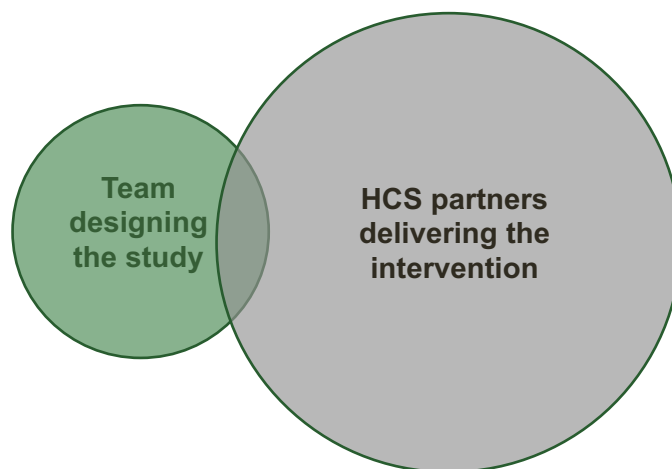- Q & A with attendees

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Important things to know

- ePCTs are a team sport
- Necessary expertise depends on the study aims and how the intervention will be implemented
- Plan for ongoing training—Clinical, IT, or other staff turnover may be high
- Plan for sustainability—If the intervention will be turned on at all sites at end of study, what are the plans to maintain or turn off intervention?

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Who is involved?

Team designing the study

HCS partners delivering the intervention

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Potential team members

- Principal investigator, co-investigator
- Health system leader or executive
- Biostatistician
- Lead clinician (eg, pediatrician, behavioral specialist, radiologist, pharmacist, physical therapist)
- Clinical staff (eg, nurse, operations manager, business manager)
- IT specialist for EHR data extraction or clinical decision support tool design

- Implementation science researcher
- Site champion/liaison
- Practice facilitator
- Research assistant
- Project coordinator
- Research participant, patient, or patient advocate
- Society leadership

NIH PRAGMATIC TRIALS COLLABORATORY
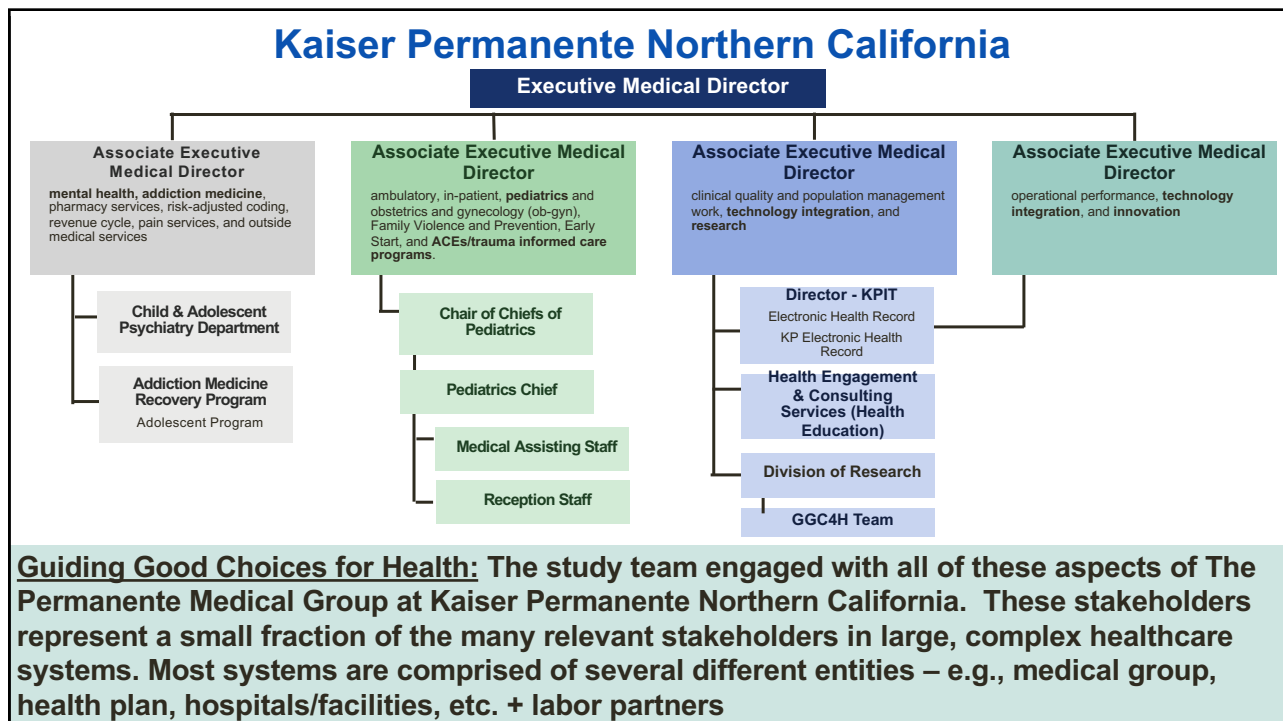Rethinking Clinical Trials®

Important things to do

- Identify the skills that are needed during the planning phase
- Recruit team members during the planning phase and engage them throughout for the duration of the trial
- Plan for staff turnover, especially clinical and IT
- Plan for dissemination, implementation, de-implementation at the start

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

What skills will be needed?

- Best skill set depends on the study aims and how the intervention will be embedded in the healthcare system workflow
- Questions to ask:
  - What clinical specialties will be needed to carry out the intervention?
  - What roles will support clinic operations?
  - Who will be the liaison between HCS departments for interventions that are multidisciplinary?
  - What aspects of the trial will require IT staff expertise?
  - Will the trial need training videos, online materials, or toolkits?

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Kaiser Permanente Northern California

Executive Medical Director

Associate Executive Medical Director	Associate Executive Medical Director	Associate Executive Medical Director	Associate Executive Medical Director
mental health, addiction medicine, pharmacy services, risk-adjusted coding, revenue cycle, pain services, and outside medical services	ambulatory, in-patient, **pediatrics** and obstetrics and gynecology (ob-gyn), Family Violence and Prevention, Early Start, and **ACEs/trauma informed care programs**.	clinical quality and population management work, **technology integration**, and **research**	operational performance, **technology integration**, and **innovation**

Child & Adolescent Psychiatry Department

Addiction Medicine Recovery Program
Adolescent Program

Chair of Chiefs of Pediatrics

Pediatrics Chief

Medical Assisting Staff

Reception Staff

Director - KPIT
Electronic Health Record
KP Electronic Health Record

Health Engagement & Consulting Services (Health Education)

Division of Research

GGC4H Team

Guiding Good Choices for Health: The study team engaged with all of these aspects of The Permanente Medical Group at Kaiser Permanente Northern California. These stakeholders represent a small fraction of the many relevant stakeholders in large, complex healthcare systems. Most systems are comprised of several different entities – e.g., medical group, health plan, hospitals/facilities, etc. + labor partners

Considerations for Training Front-Line Staff and Clinicians on Pragmatic Clinical Trial Procedures

EPCT QUICK START GUIDE FOR RESEARCHER AND HEALTHCARE SYSTEMS LEADER PARTNERSHIPS

This Quick Start Guide is designed to help clinical investigators successfully partner with healthcare system leaders to support the successful conduct of an embedded pragmatic clinical trial (ePCT) within their healthcare system. It provides advice from the Collaboratory and serves as an annotated Table of Contents, pointing readers to essential content in the *Living Textbook* regarding partnering to conduct an ePCT.

Healthcare 4 (2016) 138–141

Contents lists available at ScienceDirect

Healthcare

journal homepage: www.elsevier.com/locate/hjdsi

ELSEVIER

Perspectives

Trials without tribulations: Minimizing the burden of pragmatic research on healthcare systems

Eric B. Larson [a], Chris Tachibana [a], Ella Thompson [a], Gloria D. Coronado [b], Lynn DeBar [b], Laura M. Dember [c], Stacey Honda [d], Susan S. Huang [e], Jeffrey G. Jarvik [f], Christine Nelson [g], Edward Septimus [h], Greg Simon [a], Karin E. Johnson [a,*]

Review article

Pragmatic clinical trials offer unique opportunities for disseminating, implementing, and sustaining evidence-based practices into clinical care: Proceedings of a workshop

Leah Tuzzio [*], Eric B. Larson, David A. Chambers, Gloria D. Coronado, Lesley H. Curtis, Wendy J. Weber, Douglas F. Zatzick, Catherine M. Meyers

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

9

How researchers approach stakeholders in traditional RCTs

Researcher reviews the literature

Researcher presents idea to researchers who understand the theory and can see how study fills gap

Researcher designs and conducts study, prepares manuscripts
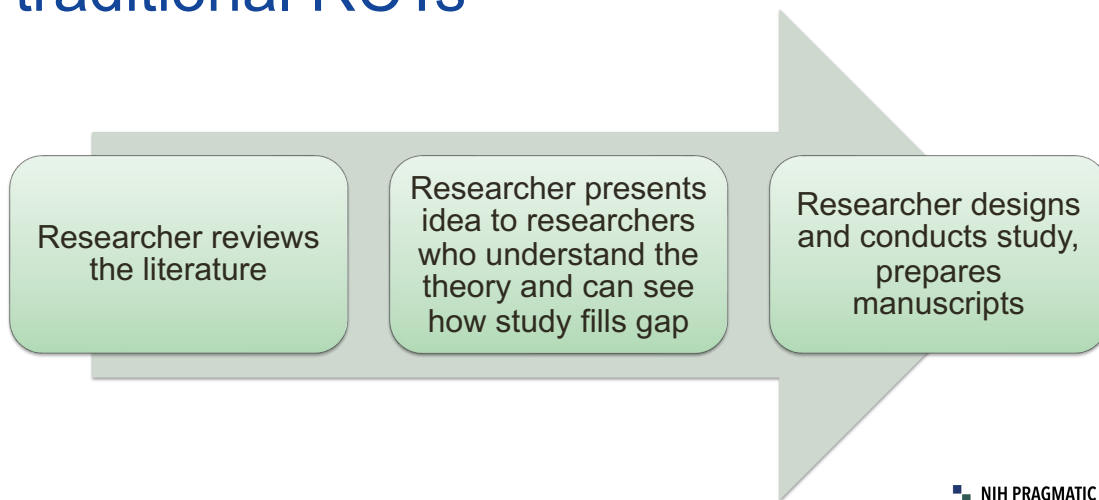
NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

10

Researchers partner with stakeholders in ePCTs differently.

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)

Important things to know 👓

- **Start engagement early**, even before you have a research question or study design
- Be patient: Relationships take time to build and nurture
- Consider whether your intervention will add value
- Expect changes and disruptions
- Engage stakeholders continuously

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Who will be impacted? Who are the decision makers?

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

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Roles of stakeholders

1. Designing the trial
2. Successfully conducting the research
3. Disseminating the results

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Roles of stakeholders

1. **Designing the trial**
2. Successfully conducting the research
3. Disseminating the results

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Choosing a salient question

We want to know what you need.
What research should we be doing?

Source: Greg Simon, MD, MPH

Designing the intervention for sustainment
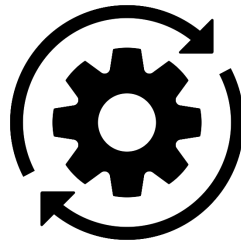
Designing the intervention to minimize burden for patients and clinicians
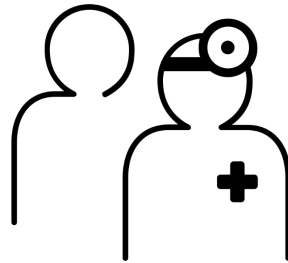
Selecting outcome measures
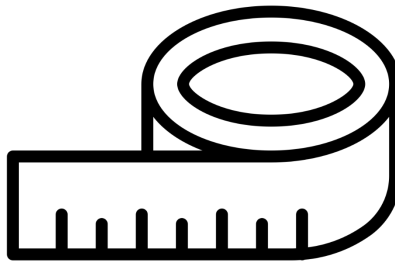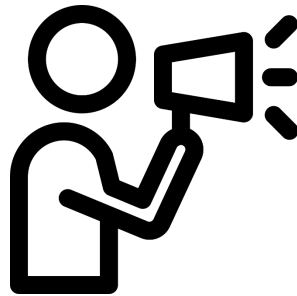
Determining inclusion and
exclusion criteria
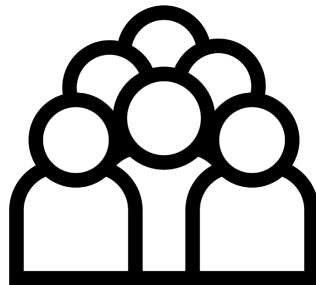
Roles of stakeholders

1. Designing the trial
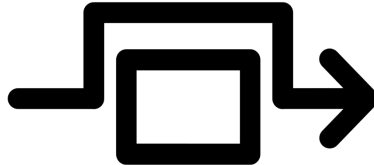2. **Successfully conducting the research**
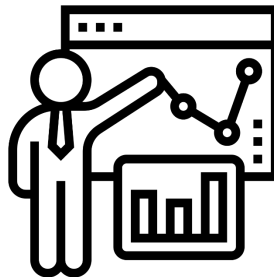3. Disseminating the results

Develop recruitment strategies

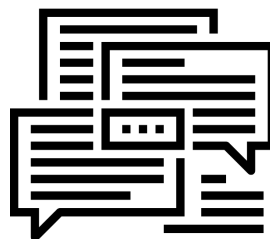# Serve as study champions

Track challenges and adaptations

Interpret study results

Roles of stakeholders
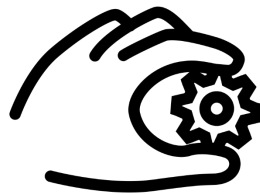
1. Designing the trial
2. Successfully conducting the research
3. **Disseminating the results**

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Determine key messages for
different stakeholder groups and
identify avenues for dissemination

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Support implementation or
de-implementation

Consider changes to policies
and guidelines

Roles of stakeholders

1. Designing the trial
2. Successfully conducting the research
3. Disseminating the results

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®

Resource: Engaging stakeholders

Engaging Stakeholders and Building Partnerships to Ensure a Successful Trial

From the *Living Textbook of Pragmatic Clinical Trials*
www.rethinkingclinicaltrials.org

NIH PRAGMATIC TRIALS
COLLABORATORY
Rethinking Clinical Trials®
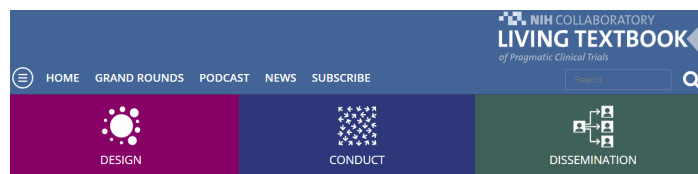
Resources: Journal articles

- Concannon TW et al. Practical guidance for involving stakeholders in health research. *J Gen Intern Med*. 2019 Mar;34(3):458-463.
- Whicher DM et al. Gatekeepers for pragmatic clinical trials. *Clin Trials*. 2015 Oct;12(5):442-448.
- Johnson KE et al. A guide to research partnerships for pragmatic clinical trials. *BMJ*. 2014 Dec 1;349:g6826.

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Important things to do

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

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Questions?

Stakeholder roles in:

<u>Design</u>	<u>Conduct</u>	<u>Dissemination</u>
• Question	• Recruitment	• Messaging
• Intervention	• Advocacy	• Venues
• Outcomes	• Challenges	• Implementation
• Population	• Interpretation	• Guidelines

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Ancillary slides

▪ Additional slides with ancillary content

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

How to engage stakeholders

If the goal of ePCTs is to provide health systems with effective, evidence-based, practical ways to improve healthcare, how should researchers engage stakeholders to achieve this goal?

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Identify and form collaborations

- Network at conferences, attend webinars, and use a snowball approach
- Meet regularly by phone, e-mail, video chat, in-person, consider establishing an advisory board
- Understand the frameworks the stakeholders use for quality improvement (QI) initiatives. Adapt research language using a framework that speaks to health system needs and the language they more readily understand
- Set expectations to work collaboratively and build trust from the beginning

Source: Bev Green, MD, MPH, and Lynn DeBar, PhD

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Get to know each other

- Learn about each other's goals, needs, priorities, motivations for implementing a trial, and what or who influences decisions
- Learn about ideal "wins" and potential conflicts and competing priorities
- Understand workflows and work together to make study-related activities feasible and least burdensome

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®

Pilot and assess stakeholders' capacity and capabilities

- Are sufficient patient numbers and data available for the analysis?
- Can data be collected at a few or all clinical sites?
- How do the sites vary in services and capabilities?
- Can the system's regulatory and administrative infrastructure support approval and oversight by ethics committees and review boards?
- Will the intervention add long-term value to the system?

NIH PRAGMATIC TRIALS COLLABORATORY
Rethinking Clinical Trials®