



NIH Collaboratory

Health Care Systems Research Collaboratory

Rethinking Clinical Trials®

Engaging Stakeholders and Aligning with Health System Partners

Leah Tuzzio, MPH

Kaiser Permanente Washington Health Research Institute

NIH Collaboratory Health Care Systems Interactions Core

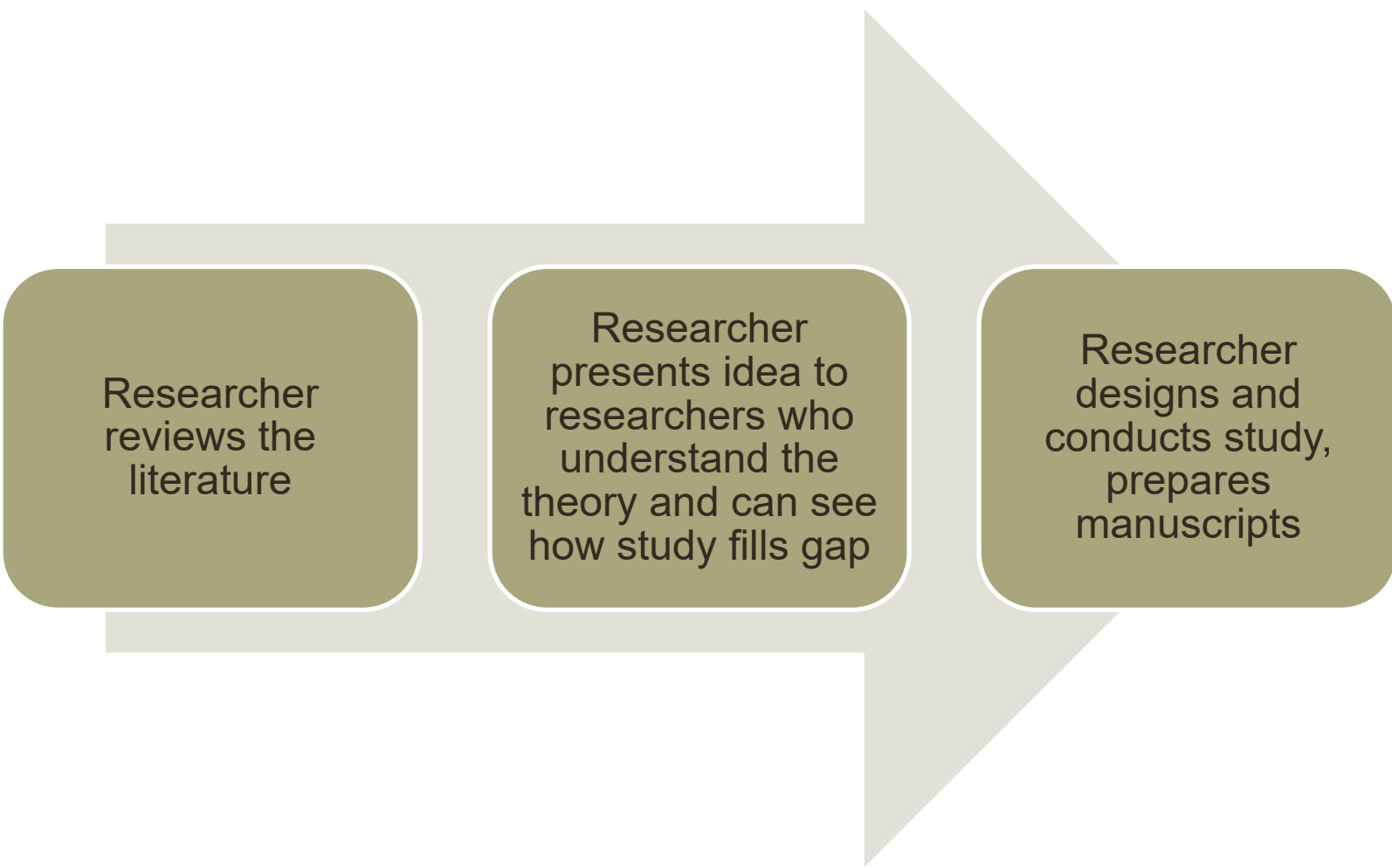
Essentials of Embedded Pragmatic Clinical Trials Seminar



Learning goals

- Describe the breadth of stakeholders to engage as partners in ePCTs
- Highlight strategies for understanding the priorities and perspectives of health system stakeholders through all phases of the study

How researchers approach stakeholders in traditional RCTs

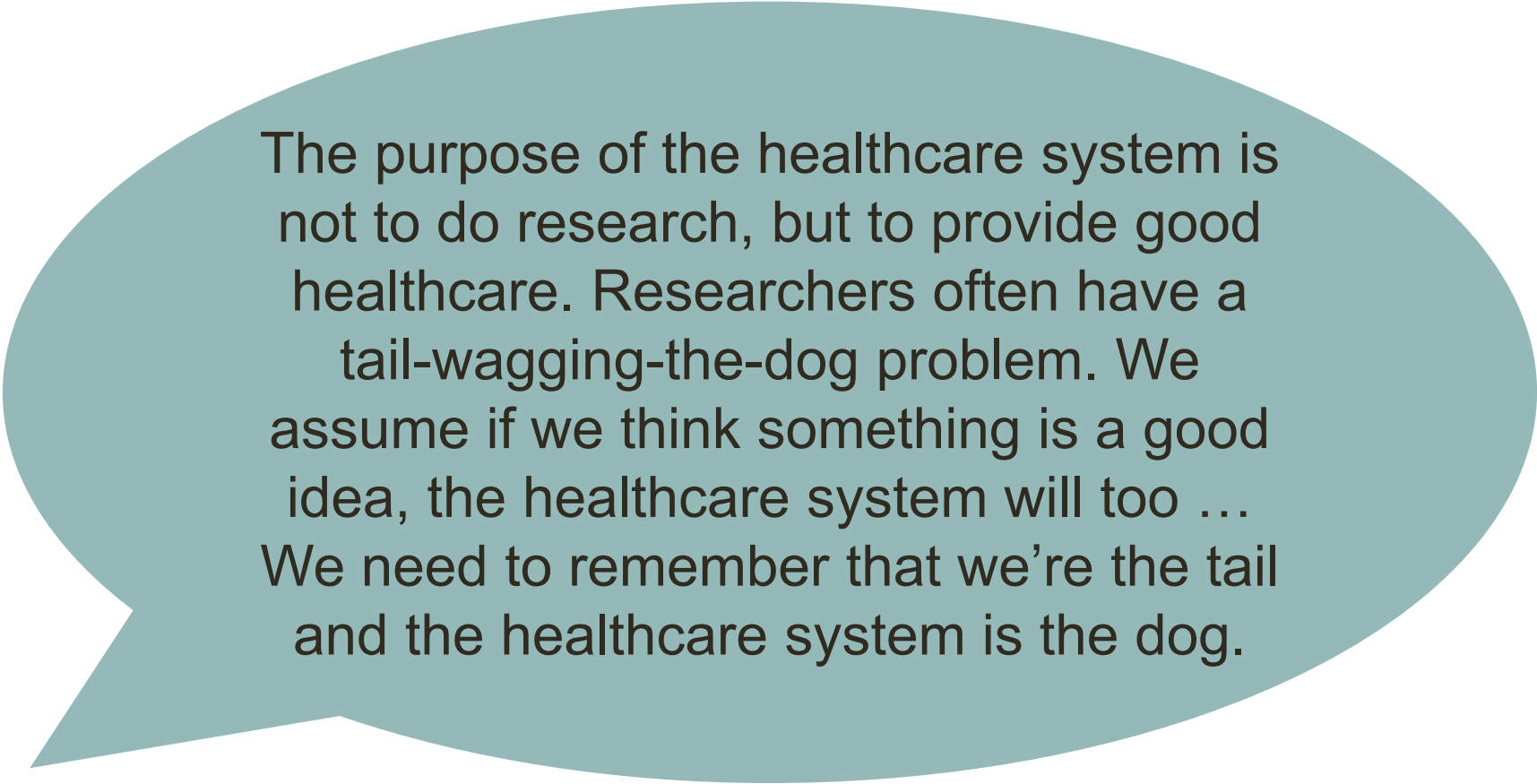


Researcher reviews the literature

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

Researcher designs and conducts study, prepares manuscripts

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.

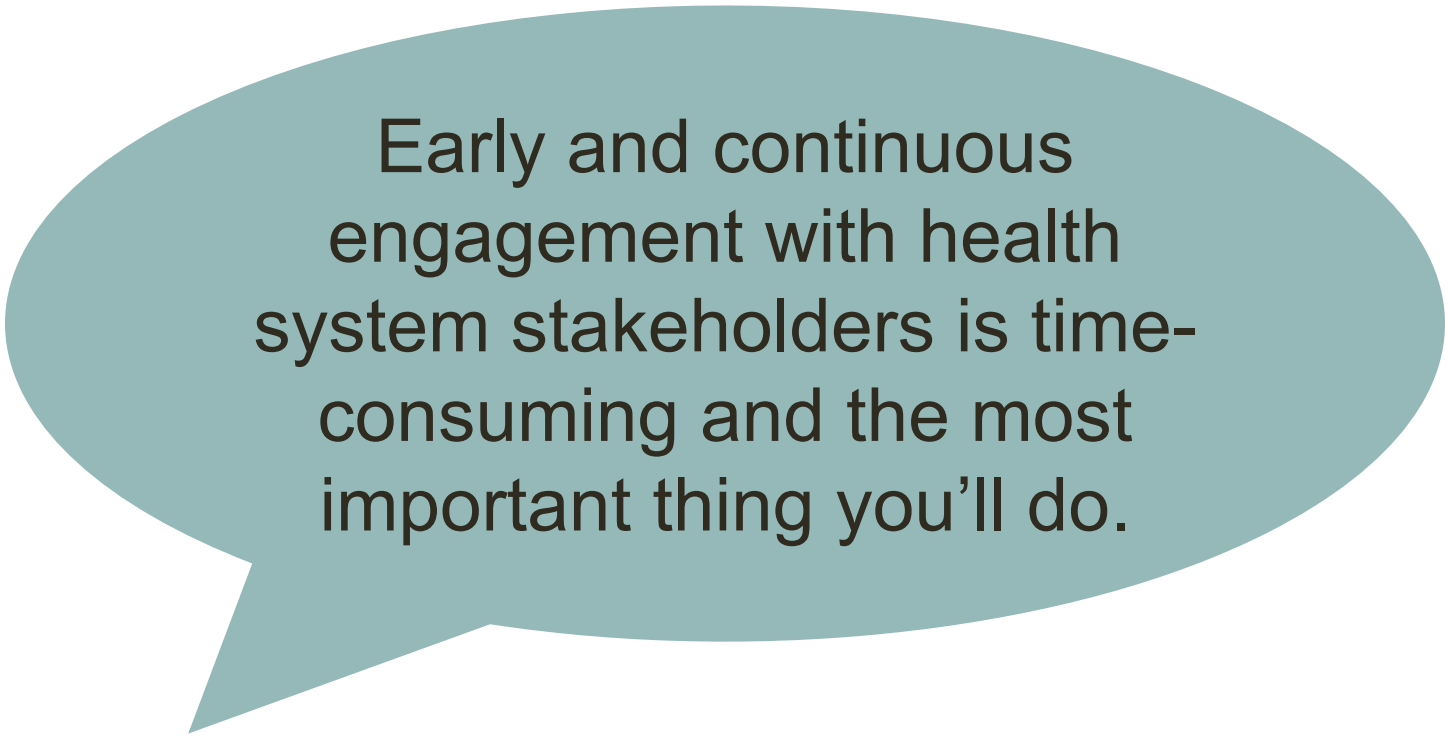
Greg Simon, MD, MPH
SPOT Demonstration Project Principal Investigator



Important things to know

- Start engagement much earlier than you think, 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 change and disruptions

Early and continuous engagement



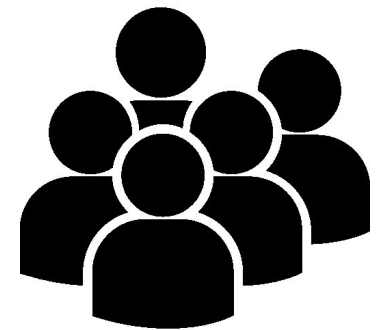
Early and continuous engagement with health system stakeholders is time-consuming and the most important thing you'll do.

NIH Collaboratory ePCT
Demonstration Project Principal Investigators

Who will ePCTs impact? Who will make decisions about what to do with the results?

Stakeholders have varied priorities, values, expectations.
For example,

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



What are some stakeholder questions?

- **Healthcare organization leaders:** *What's the cost to our system? What will the return on investment be?*
- **Clinicians:** *How can we minimize the impact on our workload?*
- **Operational personnel:** *How can we prevent hiring new staff?*
- **Patients, caregivers, patient advocacy groups:** *How can you make the intervention be meaningful and low cost to us?*
- **Payers, purchasers:** *How will the study help us make coverage decisions?*
- **Policymakers, regulators:** *How localized or broad will the benefits from the research reach?*
- **Research funders:** *What generalized knowledge will be gained?*
- **Researchers:** *How can we minimize regulatory issues?*
- **Product manufacturers:** *Will our market increase?*

Roles of stakeholders

- The wider community of stakeholders is needed to define the question and design the intervention. Researchers could ask:

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

- Each site has its own set of stakeholders who are essential to implementing the PCT at the health system level. To facilitate practicality, researchers could ask:

***What's a feasible way to do this research?
We really need your help to get this done.***

Designing the trial:

How stakeholders can partner

- Choose a research question
- Design the intervention & inform potential sustainability
- Select outcome measures
- Determine inclusion & exclusion criteria
- Design the study protocol to minimize burden for patients & clinicians
- Determine study requirements (eg, regulatory)
- Promote & support the study
- Draft/review study materials
- Provide resources

Conducting the trial: Stakeholder roles

- Develop recruitment strategies
- Promote & assess compliance with study requirements (eg, regulatory)
- Serve as study champions
- Track challenges and adaptations
- Solve problems & remove barriers
- Consider privacy & data sharing issues
- Advise on analyses
- Interpret study results

Disseminating the results:

Stakeholder roles

- Determine key messages for different stakeholder groups
- Identify avenues for dissemination
- Assist with the development of manuscripts & other dissemination materials
- Share findings via professional networks & social media
- Support implementation or de-implementation of intervention
- Consider changes to policies & guidelines

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?

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

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

Pilot and assess stakeholders' capacity and capabilities

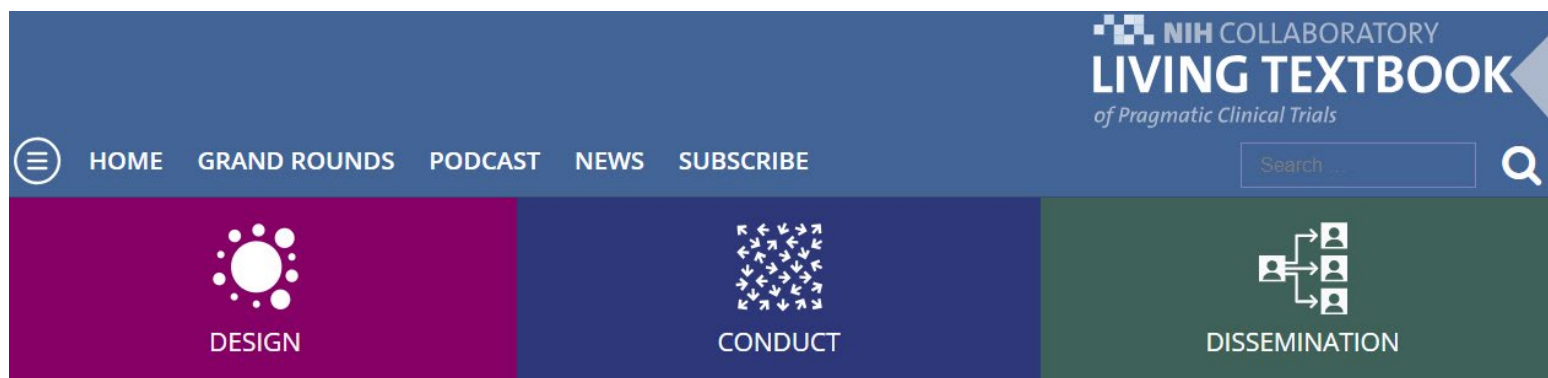
- Are sufficient patient numbers and data available for the analysis?
- Can data be collected at a few or all clinical sites?
- How do the sites vary in services and capabilities?
- Can the system's regulatory and administrative infrastructure support approval and oversight by ethics committees and review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



Resource: Engaging stakeholders

Engaging Stakeholders and Building Partnerships to Ensure a Successful Trial

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





Resources: Journal articles

Concannon TW, et al.

Multi-Group Stakeholder Engagement.
J Gen Intern Med 2019

Whicher DM, et al.

Gatekeepers for pragmatic clinical trials.
Clin Trials. 12:442–448. 2015

Johnson KE, et al.

A guide to research partnerships for
pragmatic clinical trials. *BMJ*. 2014



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