



Topic 2: Engaging Stakeholders & Aligning with Healthcare System Partners

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Collaboratory ePCT Training Workshop

Agenda

- The breadth of stakeholders
- Challenges with stakeholder engagement in research
- Tactics and strategies to engage & align stakeholder priorities & perspectives with research
- Discussion

Lessons from NIH Collaboratory

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)

PILOT & ASSESS CAPACITY

“A pilot study helps set the groundwork for conversations.”

– Jerry Jarvik, MD, MPH (LIRE)

What's the value of engagement?

- Identifies priorities, values & perspectives early & throughout the research continuum
- Defines relevant questions & selects high-priority outcomes
- Improves efficiency of recruitment approaches, diversity of participants & enrollment rates
- Continuously helps improve methods & overcome challenges
- Reduces missing data & loss to follow-up
- Increases the uptake & impact of research

Who are ePCT stakeholders?

Stakeholders have different priorities, values, work cultures & expectations

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

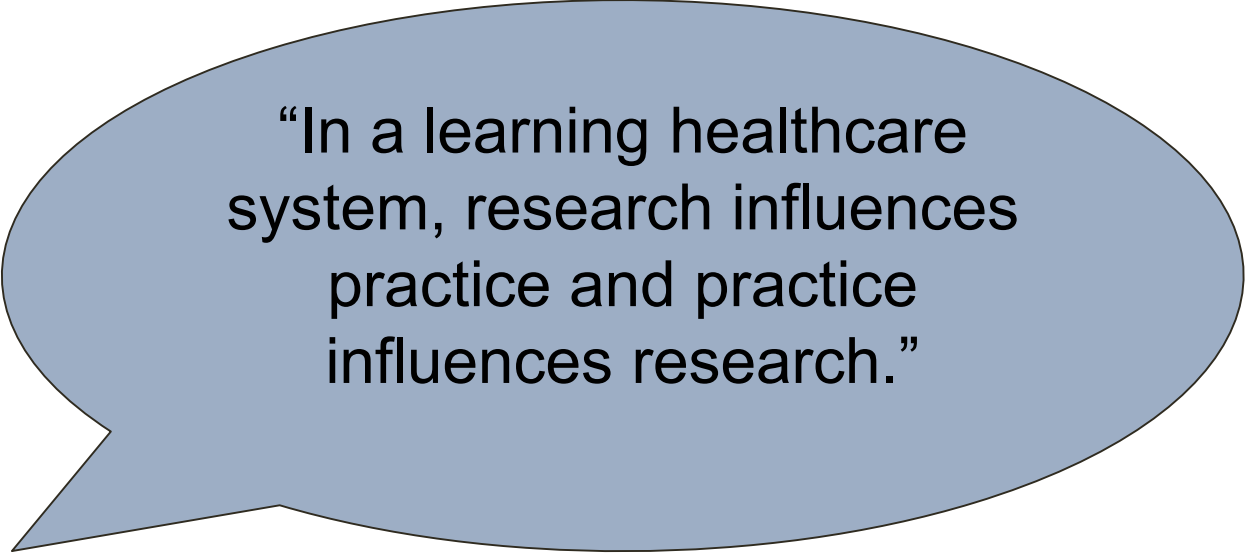
Which stakeholders are important for your trial?

1. Who can help minimize potential barriers to study completion?
2. Who will use the evidence from the study to make decisions or be affected by those decisions?



Strategies for Engagement Throughout the Life Cycle of the Trial

Learning healthcare systems & ePCTs



“In a learning healthcare system, research influences practice and practice influences research.”

Implementing the Learning Health System: From Concept to Action (See Figure 1)

Sarah M. Greene, MPH; Robert J. Reid, MD, PhD; Eric B. Larson, MD, MPH

Ann Intern Med. 2012;157(3):207-210. DOI: 10.7326/0003-4819-157-3-201208070-00012

Engagement during the life cycle



Identifying stakeholders



Designing the trial



Conducting the trial and analyzing results



Disseminating the results



Identify & assess potential HCS partners

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



Design phase: get to know each other

- Set expectations to work collaboratively & build trust from the beginning
- Learn about each other's goals, needs, priorities & motivations for implementing a trial
- Learn about ideal “wins” & potential conflicts & competing priorities



Design phase: 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
- Solve problems & remove barriers
- Consider privacy & data sharing issues
- Advise on analyses
- Interpret study results



Lessons from NIH Collaboratory

DON'T START FROM SCRATCH, ADAPT

“Each system is going to implement the trial in a slightly different way that works best for them and their workflows.”

– Miguel Vazquez, MD (ICD Pieces)



Lessons from NIH Collaboratory

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)



Nurturing relationships: challenges and solutions

Challenge	Solution
<p>Intervention is in the primary care setting where schedules are busy and space is tight</p>	<p>Teamed with clinicians to understand workflow and schedule study-related patient visits during slower clinic periods and held patient visits in less conventional ways (after hours, groups met in lobby spaces)</p>



Nurturing relationships: challenges and solutions

Challenge	Solution
<p>High amounts of leadership turnover at medical director and provider levels due to preexisting pressures and challenges inherent in community clinics.</p>	<p>Met regularly with leadership teams and established an advisory board and other infrastructure to help engage leaders and gatekeepers.</p>



Nurturing relationships: challenges and solutions

Challenge	Solution
<p>Leadership approval of the study was delayed because different departments within a single healthcare system were unable to initiate approval without the other departments going first. For example, Stakeholder A could not approve the study before Stakeholder B approved</p>	<p>Facilitated in-depth discussions of the project with all the relevant stakeholders on the phone or web at the same time, when face-to-face meetings were not possible. A prior history of collaboration among investigators and support from senior officers in the healthcare systems was instrumental in obtaining approval</p>



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



Tips for disseminating to HCS leaders

Prepare a brief, clear abstract that includes

- Reasons to invest in the intervention
- Ways the intervention is aligned with organizational priorities & benefits the system
- Level of acceptability by the clinical teams & impact on workflows
- Potential harms like liability issues
- Downstream implications
- Plans to sustain the intervention & what resources are needed
- How the intervention aligns with payers & policymakers

Reflections from Doug Zatzick & Gloria Coronado





Important things to know

- Be patient, relationships take time to build & nurture
- Expect change & disruptions
- “A successful PCT starts with a strong partnership between researcher and healthcare system, goes through a rigorous objective evaluation of the ability of the partner healthcare system(s) to participate, and ends with evidence about sustainable ways to improve care, as well as long-term scientific relationships.” *



Important things to do

- Set expectations to work collaboratively & build trust from the beginning & throughout the life cycle of your trial
- Get to know your stakeholders & their values, priorities & expectations
- Assess capacity & capabilities of your partners
- Keep in touch regularly, ask & track challenges, delays, potential solutions & adaptations to the intervention

Think, pair, share

Fill in the engagement worksheet for your study, then pair up and discuss

5 min



10 min

