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Engaging Health Systems in Research Partnerships: Insights from the NIH Collaboratory PCTs

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Introduction

- **Pragmatic clinical trials** (PCTs) evaluate the effectiveness of randomized, clinical interventions in real-world health care settings. Their goals are sustainable, generalizable, evidence-based ways to advance health care and improve patient health

- Successful design and execution of PCTs requires extensive collaboration between researchers and health care systems and clinicians, often requiring new skills and approaches

- Today's webinar will present insights for researchers and health care system partners as they work together to establish buy-in from providers and staff, develop research questions, and implement sustainable PCTs

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Key differences: PCTs and RCTs

	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
GOALS	To determine causes and effects of treatment	To improve practice and inform clinical & policy decisions
DESIGN	Tests the intervention against placebo using rigid study protocols & minimal variation	Tests two or more real-world treatments using flexible protocols & local customization
PARTICIPANTS	Highly defined & carefully selected	More representative because eligibility criteria are less strict
MEASURES	Require data collection outside routine clinical care	Brief and designed so data can be easily collected in clinical settings
RESULTS	Rarely relevant to everyday practice	Useful in everyday practice, especially clinical decision making

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Other key features of PCTs

- Frequently use electronic health records (EHRs) for efficient data collection, participant recruitment, and intervention implementation

- Often assess practical issues (reach, sustainability), cost comparisons, methods for successful clinical implementation

- Require unique methods and analytic approaches due to their inherently less controlled nature

- Necessitate careful, planned coordination between researchers and health care systems

- Make adjustments to study protocols so clinics are willing and able to implement. Engaging in such a partnership is often a new skill for both researchers and clinical staff

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Framework for PCT partnerships
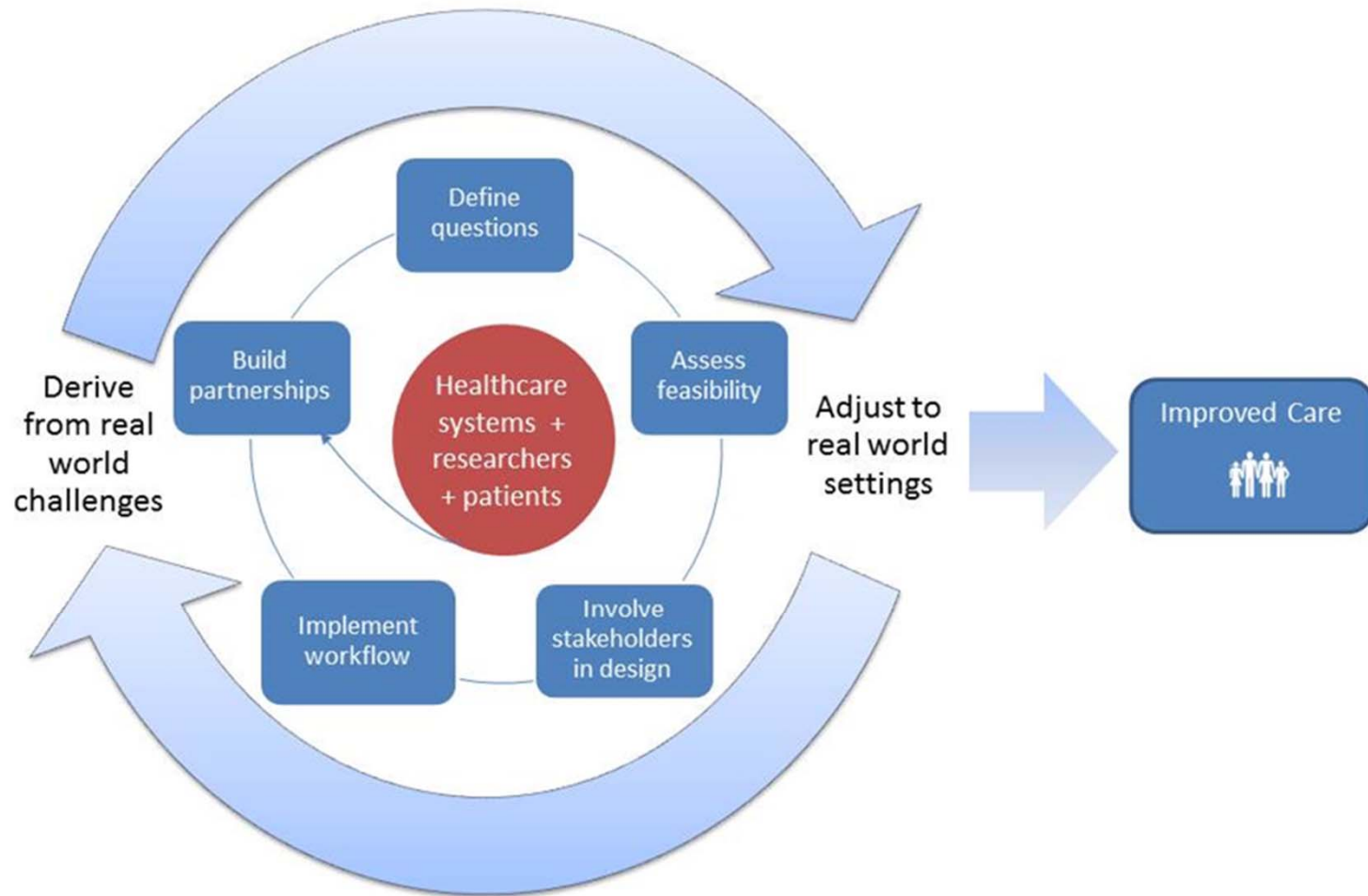
BUILD PARTNERSHIPS

Establishing partnerships

Partnerships with health systems are the foundation of PCTs and can be established through several sources:

- Relationships between health systems and academic researchers may be new or may grow from existing research projects or consortia

- Relationships between health systems and embedded research departments (e.g., HMO Research Network)

- Collaborations facilitated through NIH-supported Clinical & Translational Science Awards consortium, or up-and-coming PCORnet infrastructure

Keep the research in perspective

Researchers partnering with health systems should keep 3 things in mind:

1. The overall goal of the health system is to deliver good care and improve healthcare— health care system leaders and clinical staff are experts in that area, and also bear responsibility

    Research questions are best when they focus on what the health system wants to learn, not only on what the scientists want to know

2. Generalizable knowledge is likely to be a worthwhile by-product of the research, but may not be the first priority

3. The primary objective for the health system is value for the organization. Research must have the potential to add value such as improved patient outcomes, experience or satisfaction; increased efficiency; or reduced burden for clinical staff

Make a business case

- Recognize the costs to the health system of participation and proactively work to minimize them

- Researchers may be able to contribute time, expertise, and effort into making a change the healthcare system already wants

- Strive for low entry costs, seamless integration with current clinic workflow, and as little impact as possible on productivity and the health system bottom line

- Stress the potential for gains

Accentuate the positive

PCT partnerships should emphasize how health systems, their patients and clinicians can benefit from participation:

- The opportunity for clinicians to join in research efforts and participate in care improvement activities on priority topics

- Establish our shared, overarching goal to improve health and healthcare

- The ability to support efficient implementation of new evidence to improve clinical practice and patient health; often including a rigorous cost-effectiveness evaluation

- Possible local recognition of the system as an innovator

- Potential for gains in patient outcomes, staff efficiency, or health information technology (IT) improvements

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Build relationships deliberately

Keys to establish solid partnerships with healthcare systems:

▪ Be transparent about expectations, decisions, and responsibilities

▪ Express a willingness to compromise and make adjustments to protocols

▪ Develop ongoing, bidirectional communication

▪ Involve of health system staff from early on – including choosing research questions to answer

▪ Engage front line staff - they know what is and what is not clinically feasible

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The health system's view...

"The purpose of pragmatic trials is to evaluate potential therapeutic benefits in real-world situations, to really look at clinical effectiveness rather than efficacy in idealized academic systems. Pragmatic trials can have a tremendous impact on what we all struggle with, which is translating our knowledge to clinical practice. Pragmatic trials give us insights into how we can do this in average clinical settings. The most important outcome is improving patient safety and saving lives."

Edward J. Septimus, MD
Medical Director
Infection Prevention & Epidemiology Clinical Services
Hospital Corporation of America
and NIH Collaboratory PCT partner

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DEFINE QUESTIONS

Finding research topic ideas

To achieve the general health system commitment to approve and sustain a study, research topics will fit a health system's need for:

- Evidence-based insights on topics of high priority to leadership, providers and patients

- High likelihood of actionable results that can be used to improve care and patient outcomes

- Design for minimal impacts on staff productivity and patient experience

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Monitor the environment for change

- Opportunities for natural experiments arise when clinical practice is affected by changes to healthcare policy or insurance benefits, introduction of new diagnostics or therapies, or changes in clinical workflow

- These changes give researchers a chance to observe how a specific healthcare change that occurs in the ordinary clinical environment affects patient outcomes

- Researchers with an active connection to a health system are in a position to hear about natural experiment opportunities in time to plan for a PCT

Have a seat at the table

"For PCTs to be designed and implemented well while addressing questions that matter to clinicians and care systems, it is very important to have boundary-spanners—people who straddle the gap between care and research"

Leif Solberg, MD
HealthPartners

- Researchers with clinical experience can help to convey practice changes to doctors

- In turn, health system leaders with academic experience understand the culture, language, and priorities of researchers, which is important for effective communication

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ASSESS FEASIBILITY

Baseline facilitators

Health systems that can successfully participate in PCTs typically have:

- A culture that values research

- Previous experience with interventional research

- Boundary-spanners whom understand both research and clinical work

- Leaders and staff with good communication skills

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Project-specific feasibility

- Results of pragmatic clinical trials should always be able to promise clear value to the system

- Even in previously successful research partnerships, an objective pre-assessment of the health system's capabilities to execute the proposed study is essential

- If the pre-assessment process reveals a poor fit to a health system, researchers can still maintain relationships with site leaders for future studies and dissemination – or attempt to modify methods or protocols to improve the fit

Critical feasibility assessments Qs

1. Are sufficient patient numbers and data available to support the analysis?

2. Can data be collected at all clinical sites to be included in the research?

3. How much do clinical sites vary in services and capabilities?

4. Is the system's regulatory and administrative infrastructure likely to support Institutional Review Board approval and oversight?

5. Do research questions conflict with ongoing system changes or quality improvement projects that could compromise the trial?

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INVOLVE STAKEHOLDERS

Differing expectations and cultures

- Successful PCTs require clear communication about processes, shared expectations, and buy-in and expertise from multiple levels of a health system over the full course of the trial

- Collaboration with researchers is often a new experience for health system personnel, and vice versa. Both may come with differing expectations around timelines, use of the system's resources and staff, and long term sustainability

- Collaborators should acknowledge competing priorities and differences in culture. For example, researchers may discount the ongoing improvement work in health systems as not rigorous, while operations and clinical may see research as too slow, not relevant, expensive, and rigid

Roles and goals of partners

Participants	Roles	Goals	Considerations
Leadership	Promote and support study throughout the delivery system	Value: better patient outcomes, cost effectiveness, efficiency	Ideally, support is at all levels, but buy-in from top leaders is critical.
Business operations	Ensure study integration with HCS billing	Compliance with regulations, no revenue loss	This factor is typically complex due to local variations.
IT staff	Adapt EHR for study protocol and data collection	EHR and patient portal features that patients and clinicians use	IT staff, in particular, often have competing demands and resource limits.
Clinical department managers	Translate study objectives into clinical workflow changes	Ensure study success with minimal clinical disruption	Understand local considerations for this group; the research team must be flexible.
Clinic champions	Liaison between HCS and researchers	Integration and sustainability of study intervention	Find champions with local credibility. Look for ways to reward and recognize champions.
Frontline clinical staff	Carry out study protocol	Add study to workflow while maintaining high-quality patient care	Try to engage staff without intruding on their work. Provide precise reports on study progress and findings.
Researcher	Propose, design, and adapt study for HCS	Answer research questions and positively impact public health	Expect the unexpected and be prepared to be flexible and to learn.

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Engaging system leadership

- Before study funding is assured, getting genuine attention from busy health system leaders can be difficult

- Finding the right partners within a health care organization requires networking to find people with the authority to contribute to the study and the bandwidth for regular contact with researchers

Engaging clinical staff

- To ensure clinicians are willing and able to carry out study protocols, providers who will be implementing the trial's intervention should be consulted about the study design

Clinicians can advise on how to make study participation easier for front-line staff by instructing researchers in how to make the best use of:

- Existing IT systems

- Clinical procedures

- Quality improvement protocols

- Clinic champions

Staff and clinicians can inform about the best ways to engage patients

Engaging business operations staff

- Early in the design process, business operations staff can help think through business and billing details to ensure the study is not cost prohibitive. Factors might include costs from wear and tear on medical devices, use of supplies and services, and potential savings through process changes or better patient outcomes

- The PCT team will need to work through details such as whether services or study interventions will be provided by the health system or outside vendors, and how the source of the services will affect staff participation, patient experience and care quality, and data collection

- Research teams will also need to ensure that double billing is not an issue and consider sustainability issues, such as what happens when patient costs paid by the study are no longer covered after the project

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Engaging Health IT staff

- PCTs can use EHRs as a low-cost tool for streamlining participant recruitment by identifying eligible patients, compiling existing data about study participants, or collecting new data, for example through local secure portals including secure messaging

- Health IT staff are thus another critical part of PCT teams. PCTs have high variability in clinical environments and patient populations and health IT staff can help identify and describe the nuances of their site's EHR sources

- In addition, health IT staff can advise about how to best implement additions or alterations to the EHR or patient portals in a way that will be useful to patients and clinicians, function beyond the study, and not interfere with other features or inadvertently get removed by other change efforts

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IMPLEMENTING WORKFLOW

Start with a pilot test

- Demonstration PCT leaders recommend testing a planned PCT with a pilot study to determine whether a project and partnership are likely to be sustainable

- Pilot tests can also alert the research team to technical issues, feasibility and logistical issues, training gaps and more

- Pilot testing allows necessary adjustments to be made prior to implementing a protocol to scale

- Carefully document local variations

Be flexible

- Because PCTs occur in the context of dynamic real-world systems, protocol design must be flexible

- PCT procedures should be designed to mimic normal clinical practice and use existing health system resources as much as possible

- As a PCT is underway, it might need to be adapted based on stakeholder input or broader changes in the care or delivery environment

- Being flexible not only aids study protocol compliance by clinicians but also facilitates long-term sustainability of tested interventions

Think sustainability from the start!!

- PCTs should plan for the long term, laying a foundation for implementing successful changes *and* considering how to remove an intervention if data indicate that it is not effective

- This part of study planning includes thinking about how to communicate tailored results to all groups involved in the study, including patients

- For intervention and relationship sustainability, tailor reports and follow-up information to the interests of different stakeholders

- Research activities should provide the health system with useful tools, information, and an evidence-based, effective intervention. If the intervention was not effective, offer a rigorous analysis of why and suggests what might be done to increase effectiveness

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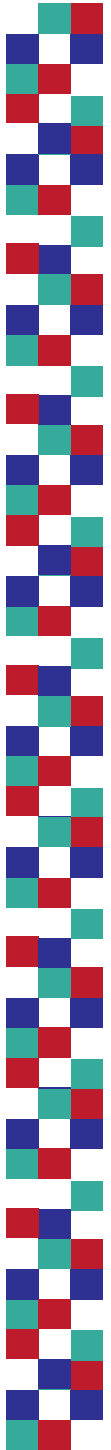Health Care Systems Research Collaboratory

SUMMARY

Secrets to success

- Participation in pragmatic clinical trials rewards health systems with tools to improve clinical care, professional opportunities for staff, and long-term research partnerships

- To be successful, pragmatic clinical trials will answer questions relevant to health system decision makers and incorporate input from clinicians, delivery system managers, health IT, and business operations staff into the study design

- A successful pragmatic clinical trial usually starts with a pilot project; goes through a careful, objective evaluation of the ability of the partner health system(s) to participate; and ends with evidence about sustainable ways to improve care, as well as a long-term scientific relationship

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Secrets to success (cont.)

- Close relationships should be fostered and actively maintained. They are usually gratifying

- Time commitments from all parties are needed to allow for good communication and negotiation to occur

- Health systems should be reminded that their patience and participation will pay off in actionable results and rigorously tested tools to improve clinical care

- Buy-in and input is needed from multiple levels of the system, starting from the very beginning

- The ultimate shared goal for both the researcher and health system is providing benefits for patients and clinicians through answering practical, relevant research questions

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Questions?