Health Systems Engagement

Lessons Learned from the Health Care Systems Interactions Core

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May 15, 2018



Agenda

An Overview of the Health Care Systems Interactions Core

Expectations when conducting embedded PCTs with health systems

Lessons and discoveries from the ePCTs



Health Care Systems Interactions Core

Facilitates collaborative learning across the projects, synthesizes lessons learned and creates real-world generalizable knowledge about PCTs.

- Meet monthly, maintain an issues tracker, set priorities, publish manuscripts and contribute to the Living Textbook.
- Addresses the challenges working within real-world dynamic systems that deal with EHR transformation, leadership and staffing turnover, changes in clinical guidelines and policy.
- Shares lessons about building and sustaining trusting partnerships between research teams, system leaders, clinicians, staff, policy makers and other decision makers.

Products from the HCS Interactions Core

Contributions to reports of the *National Academy of Medicine* and to *Rethinking Clinical Trials: A Living Textbook of PCTs*

Johnson KE, et al. A guide to research partnerships for pragmatic clinical trials. *BMJ* 2014.

➤ Best practices on the methods to establish partnerships between researchers and healthcare systems to develop research questions and implement sustainable PCTs.

Larson EB, et al. Trials without tribulations: Minimizing the burden of pragmatic research on healthcare systems. *Healthcare* 2015.

Case studies that illustrate how PCT researchers design study procedures to minimize clinical burden by developing an understanding of the clinical setting, pilot testing, and collaborating and coordinating with stakeholders.

Additional articles

Larson EB, Johnson KE. Closer partnerships needed between researchers and healthcare executives. *Modern Healthcare*. August 25, 2015.

A Commentary on an IOM workshop and survey of healthcare executives reports on the gap between research approaches and delivery system needs and priorities

Johnson KE, et al. Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. *Trials*. 2016 Jan 16;17(1):32.

Findings from an analysis using PRECIS-2 PCT criteria to 5 PCTs were found to be highly pragmatic. Application of this tool highlighted challenges with its use

The Core's Work Aligns with the Concept of a Learning Health System

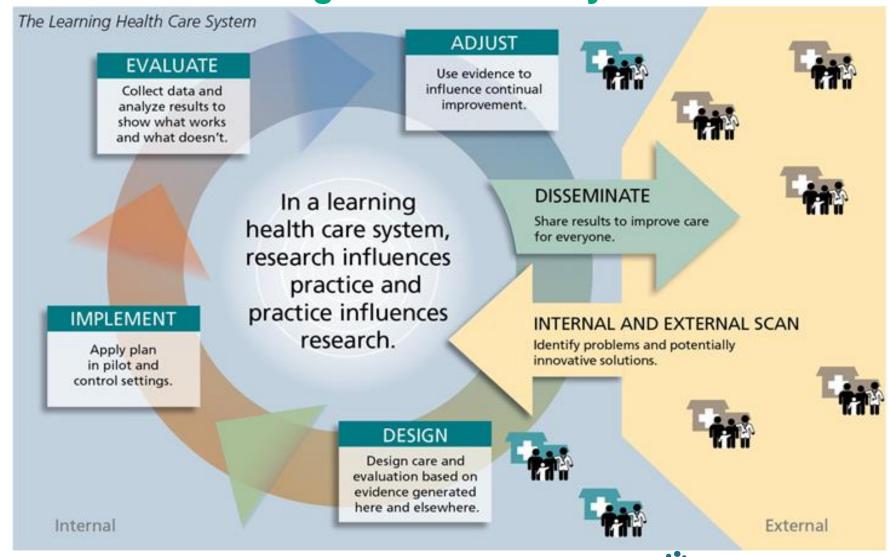
The National Academy of Medicine's vision:

- Research happens closer to clinical practice than in traditional university settings.
- Scientists, clinicians, and administrators work together.
- Studies occur in everyday practice settings.
- Electronic medical records are linked and mined for research.
- Recognition that clinical and health system data exist for the public good.

Summary: Evidence informs practice and practice informs evidence.



ePCTs & Learning Health Care System



What have we learned about the challenges to expect when working in real-world, dynamic health care systems where research is not the #1 priority?

EXPECT CHANGE TO HAPPEN!

- Change in priorities
- Staff turnover at all levels
- EHRs that are not easily changed for a research project or which change to meet system needs (not research needs)
- Changes in clinical guidelines and policy
- Changes in strategy and local markets



- Establish relationships early in the process and nurture trust
- Understand each other's goals and priorities

"The purpose of the healthcare system is not to do research, but to provide good healthcare. Researchers often have a tailwagging-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 test to assess feasibility and capacity
 - Discover unanticipated hitches
 - Check cost estimates
 - Make adjustments to study protocol
 - Assess programming capacity
 - Check if a system's regulatory and administrative infrastructure can support approval and oversight

A result from a pilot study was that a study arm was eliminated that turned out not to be feasible. The early success of a pilot can make it easier to recruit additional clinics into the trial.



Understand a system's competing priorities and roadblocks

"Researchers need to know the context – don't propose to put something in the queue for programmers to implement at the same time they are transitioning EHRs."

- Jerry Jarvik, MD MPH (LIRE)
- Minimize the impact on clinical workflow
 - Integrate existing staff
 - Adapt existing space, processes and workflows

- Continuously evaluate what's working or not and understand what's relevant and of interest
- Document and track lessons learned and adaptations so they can be replicated

"Different from a randomized controlled trial,

PCTs use an iterative process and include a lot of refinement."

Lynn DeBar, PhD MPH (PPACT)



Develop solutions and sustainable resources together

"Give the clinicians and staff the opportunity to have a positive learning experience with research by giving them the tools they need. If the trial is successful, we can create a generalizable toolkit for sharing with other healthcare facilities and systems for broader dissemination and implementation."

- Edward Septimus, MD (ABATE Infection Trial)



- Help system leaders make an informed decision about whether to sustain the intervention by providing them with brief details.
 - Reasons to invest in the intervention.
 - How the intervention aligns with organizational priorities, payers and policymakers
 - Level of acceptability by clinical teams and impacts on their workflows
 - Value and benefits to the systems (e.g., market growth, reputation)
 - Potential harms like liability issues
 - Downstream implications
 - Plans to sustain the intervention what resources might be needed



Summary

- The strategies that the NIH Collaboratory's Health Care Systems Interactions Core identified helps facilitate effective pilot testing, conduct of the trial, dissemination and implementation of the intervention and findings into clinical care.
- Embedded PCTs endorse the idea that a Learning Health Care System is a strategy and the context for achieving efficient, effective research that improves health outcomes and quality of care.
- Progress through the NIH Collaboratory endorses value of brining research and delivery systems together.