Pragmatic Clinical Trials & Learning Health Care Systems: Strategies to Facilitate Implementation of Results into Clinical Care

Eric B. Larson, MD MPH & Leah Tuzzio, MPH
NIH Collaboratory Health Care Systems Interactions Core
May 12, 2017
Agenda

1) NIH Collaboratory Health Care Systems Interactions Core & Pragmatic Clinical Trials (PCTs)
2) Building Blocks & Strategies to Guide PCTs in Implementing Findings
3) The Learning Health Care System as a Framework for PCTs
4) Discussion
Goals for today’s presentation

- The potential for PCTs as the key to improving care
- Share strategies that guide the implementation of results into health care systems
- Describe the bi-directional relationship between PCTs and learning health care systems
The NIH Collaboratory, funded by the NIH Common Fund in 2012, creates infrastructure for collaborative research to demonstrate the value of PCTs embedded in health care systems. Currently, there are 9 PCTs conducted in hospitals, community health centers, integrated delivery systems, nursing homes, and acute and specialty facilities.
Facilitates collaborative learning across the projects and synthesizes lessons learned.

- Addressing the challenges working within real-world dynamic systems that deal with EHR transformation, leadership and staffing turnover, changes in clinical guidelines and policy.
- Building and sustaining trusting partnerships between research teams, system leaders, clinicians, staff, policy makers and other decision makers.

Eric B. Larson, MD MPH  
Chair, HCS Interactions Core

Leah Tuzzio, MPH  
Research Associate

James Fraser  
Project Manager
Several products from the HCS Interactions Core

- Contributions to IOM reports and *Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials*


Are PCTs a key to improving health care?

- PCTs embedded in health care systems include broad populations and study relevant questions that are tested in real-world settings.
- Trials that test promising interventions designed to provide evidence and improve healthcare leading to better outcomes defined broadly.
- The results of PCTs are implementable and sustainable if they align around the goals of health care systems.
- In a learning health care system, the PCT partnerships drive improvement and evidence-based practice.
Bi-directional relationship: PCTs and learning health care systems

In a learning health care system, research influences practice and practice influences research.

- **EVALUATE**: Collect data and analyze results to show what works and what doesn’t.
- **IMPLEMENT**: Apply plan in pilot and control settings.
- **ADJUST**: Use evidence to influence continual improvement.
- **DESIGN**: Design care and evaluation based on evidence generated here and elsewhere.
- **DISSEMINATE**: Share results to improve care for everyone.
- **INTERNAL AND EXTERNAL SCAN**: Identify problems and potentially innovative solutions.

What are some of the key strategies that PCTs can use to promote implementation and sustainability during design and conduct phases?

- In the summer of 2016, we interviewed project leaders from NIH Collaboratory PCTs.
- We asked them about how they designed and rolled-out their trials in ways that would lead to successful implementation of the results, if the desired outcomes were achieved.
Building Blocks and Strategies

- Collaboratively choose relevant interventions
- Pilot test, evaluate, and continuously improve
- Nurture partnerships
- Plan for dissemination, implementation and sustainability
- Develop sustainable resources
Plan for dissemination, implementation and sustainability from the beginning

8 Key Implementation Outcomes

- Acceptability
- Feasibility
- Appropriateness
- Adoption
- Costs
- Fidelity
- Penetration
- Sustainability
Establish, *or build off past relationships*, and nurture trusting partnerships

- Build relationships early in the process
- Set expectations to work collaboratively
- Partner to define relevant, clinically important questions and on the design and implementation

  “Engage health systems early. The problem has to be one that both the researcher and the system find important to resolve.” – Laura Dember, MD (TIME)

- Include multiple disciplines and expertise on the PCT team (e.g., clinical, research, operational, informatics)

- Expect change and roadblocks – be flexible and adjust as needed

  “There can be incredible delay and waste if people don’t trust each other. It’s inevitable there will be challenges even if you assume the best intentions.”

  – Doug Zatzick, MD (TSOS)

- Develop solutions together
Maintain communication

“We used a collaborative learning model, meeting monthly.”
– Gloria Coronado, PhD
(STOP CRC)

“The linearity of knowledge changes over time, so you need to keep looking at what’s relevant and of interest to your partners and stakeholders.”
– Lynn DeBar, PhD MPH(PPACT)
Learn about each other

“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)
Learn about each other’s…

- Goals, needs and priorities to assess if the intervention will add long-term value
  
  “Build on relationships to understand perspective of various partners and to make sure the intervention is in alignment with their priorities.”
  – Vincent Mor, PhD (PROVEN)

- Motivations for implementing a trial
  - For example, are there local, regional or national policy changes that the PCT could influence to benefit the system?

  “PCTs that can directly target regulatory policy have the potential to markedly shorten the research-to-implementation timeline.”
  – Doug Zatzick, MD (TSOS)
Learn about each other’s…

- Ideal “win” (e.g., discovery, improved health outcomes at reduced cost, adding to evidence base)
- Potential trouble spots (“pain points”), competing priorities, and conflicts

“Need to know the context – it wouldn’t be great to put something in the queue for programmers to implement at the same time they are transitioning EHRs.” – Jerry Jarvik, MD MPH (LIRE)

“Pragmatic trials must be aware and watch for conflicts with delivery system quality improvement projects.” – Greg Simon, MD MPH (SPOT)
Assess feasibility at the start and throughout

- **Assess capacity and capabilities**
  - For example: Are sufficient patient numbers and data available for analysis? Can data be collected at all clinical sites? Can the system’s regulatory and administrative infrastructure support approval and oversight by ethics committees and review boards?

- **Pilot test**
  - Piloting begins by testing feasibility of the design and can be a launching point to start sustaining the intervention in a learning health care system.
  - Helps determine if the system has the structure and capacity both short-term and long-term.

“A pilot study helps set the groundwork for conversations.”
– Jerry Jarvik, MD MPH (LIRE)
Co-create

- Develop study workflows
- Identify recruitment and implementation methods
- Design study materials
- Write policy

“SPOT is guided by Van de Ven’s concept of ‘engaged scholarship.’ The central idea is that there is knowledge co-created via continuous collaboration with customers and stakeholders.” – Greg Simon, MD MPH (SPOT)
Don’t start from scratch

- Integrate existing staff and adapt processes and workflows to implement the intervention. This can make it easier on the system as the don’t need to find new space, staff, etc.

> “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)

> “The more complicated the intervention is to 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)
Build sustainable infrastructure & resources

- Collaboratively build infrastructure for continued use (e.g., registries, EHR templates, operational manuals, training videos)
- Increase clinical staff and clinicians’ skills and capacity to learn, adapt and sustain effective interventions

“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)
Continuously learn and improve

- Evaluate what is working or not
- Identify barriers and facilitators
- Make adjustments
- Document and track lessons learned and adaptations so they can be replicated outside of the trial

“Different from a randomized controlled trial, PCTs use an iterative process and include a lot of refinement.”

– Lynn DeBar, PhD MPH (PPACT)
In summary

1. Collaboratively choose relevant interventions
2. Nurture partnerships
3. Develop sustainable resources
4. Pilot test, evaluate, and continuously improve
5. Plan for dissemination, implementation, and sustainability
Pragmatic Clinical Trials and Learning Health Care Systems
What is a learning health care system?

The Institute of Medicine’s (now 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.
A learning health care system

In a learning health care system, research influences practice and practice influences research.

- **Evaluate**: Collect data and analyze results to show what works and what doesn’t.
- **Adjust**: Use evidence to influence continual improvement.
- **Implement**: Apply plan in pilot and control settings.
- **Design**: Design care and evaluation based on evidence generated here and elsewhere.
- **Disseminate**: Share results to improve care for everyone.
- **Internal and External Scan**: Identify problems and potentially innovative solutions.

Value proposition

- A challenge to adoption of evidence-based interventions is the uncertainty about how to implement them and if the resource investment will lead to better results.
- 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.
- The strategies the NIH Collaboratoy PCTs have identified can facilitate the dissemination and implementation of the intervention into clinical care.
Innovation is not enough.
We must focus on what happens afterward.
NIH Collaboratory Workshop

- Register to attend this free event on Wednesday, May 24, 2017 (8 am – 4:30 pm EDT) either in-person or by webcast: [https://www.nihcollaboratory.org/](https://www.nihcollaboratory.org/) (“Upcoming Learning Opportunities”)

- Researchers and health care system partners will explore challenges and strategies for the dissemination, implementation and sustainability of pragmatic clinical trial findings during the following panel discussions.
  - Setting the stage for dissemination & implementation
  - Health system engagement: Partnerships, relationships and transparency
  - Swimming with the sharks: Translation of pragmatic trial results
  - Designing for sustainability
  - Stakeholder reactions discussion

- Lessons learned will be documented in the NIH Collaboratory’s Living Textbook: [https://sites.duke.edu/rethinkingclinicaltrials/](https://sites.duke.edu/rethinkingclinicaltrials/)