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Trials, Not Tribulations: Minimizing the Burden of Research on Health Care Systems

Collaboratory Grand Rounds - June 7, 2013
Presented by Eric B. Larson, MD, MPH

Rethinking Clinical Trials

Overview

- Brief introduction to Pragmatic clinical trials (PCTs) – what are they and why now?

- What motivates health care systems (HCS) to partner on research?

- Keys to building trusting partnerships with HCS and patients.

- Practical strategies Collaboratory demonstration projects are using to minimize the participation burden on patients and HCS.
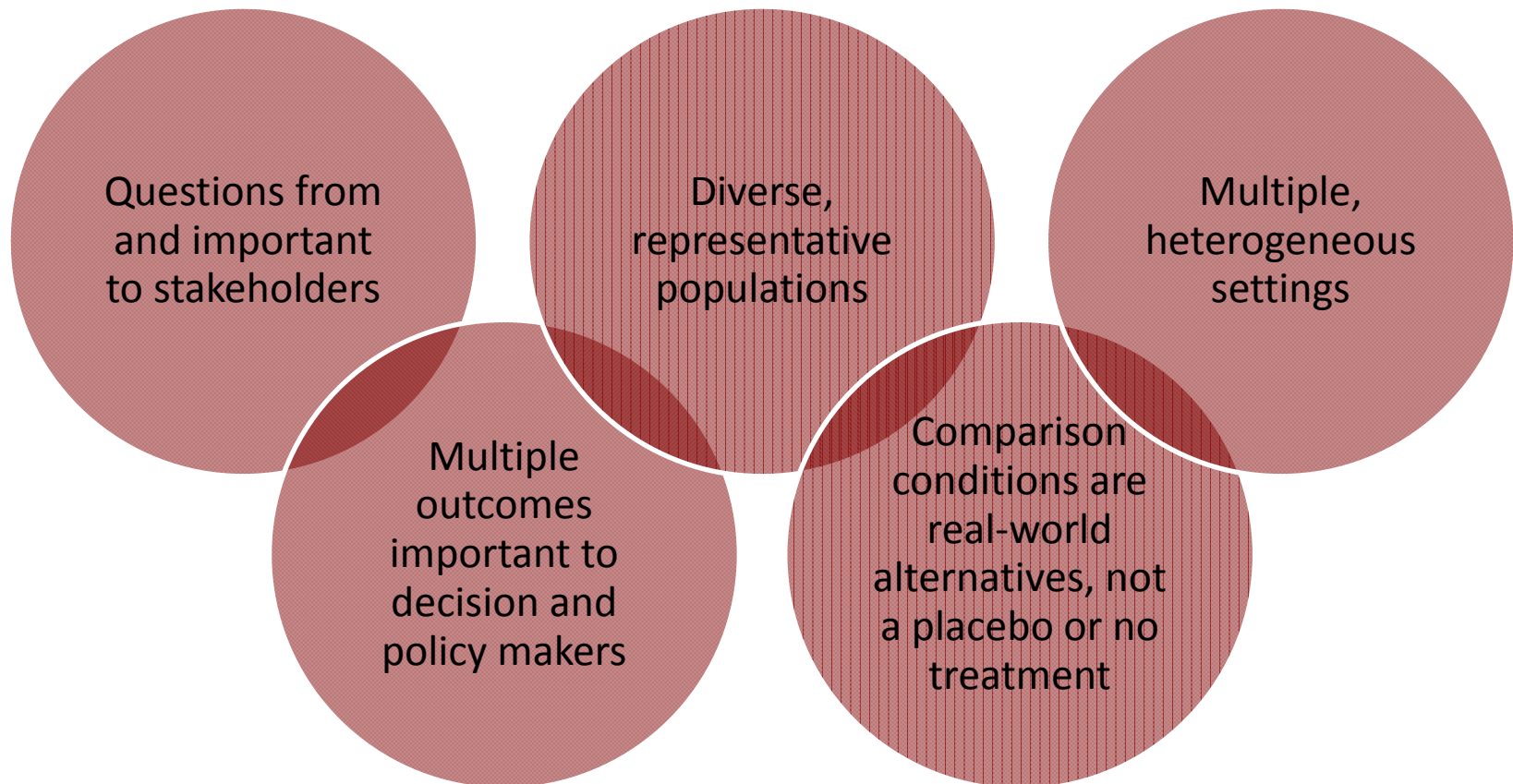
PCTs: What are they?

- Pragmatic clinical trials (PCTs) are designed to **improve practice & policy**.

- Unlike most traditional randomized controlled trials (RCTs), they take place in settings **where everyday care happens**, such as clinics, specialty centers, hospitals, and health systems.

- **Collaborating providers and organizations are integral partners** and gain practical evidence on how to improve patient health and satisfaction.

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Core characteristics of pragmatic clinical trials (PCTs)

Questions from and important to stakeholders

Diverse, representative populations

Multiple, heterogeneous settings

Multiple outcomes important to decision and policy makers

Comparison conditions are real-world alternatives, not a placebo or no treatment

PCTs – Why now?

- **Major challenges to clinical trials** enterprise in the U.S.

- PCTs offer **key advantages over traditional randomized trials** in terms of relevance and applicability to everyday practice.

- **Widespread adoption of electronic health records** (EHRs) is creating "big data" within health care systems - and new opportunities to generate knowledge.

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Challenges to traditional research

- Traditional **RCTs are slow and expensive**. They rarely produce findings easily put into practice.

  - After an average of 17 years only 14% of findings will have led to widespread changes in care.

- Traditional RCTs study the effectiveness of treatments delivered to carefully selected patients under ideal conditions. This makes it **difficult to translate results to the real world**.

  - Even when a tested interventions is implemented into practice, a dramatic decrease in effectiveness or "voltage drop" is often seen.

- Patients and providers **don't have enough evidence to effectively inform clinical decisions**, despite > 18,000 RCTs being published each year.

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The RCT-PCT continuum

- **No clinical trial is completely explanatory or pragmatic.** RCTs and PCTs exist on a continuum.

- PCTs do not abandon the scientific methods that are responsible for breakthroughs and progress resulting from RCTs.

- PRECIS tool illustrates degree of pragmatism across ten domains.

Explanatory Trial
Can an intervention work under ideal conditions?

Pragmatic Trial
Does an intervention work under usual conditions?
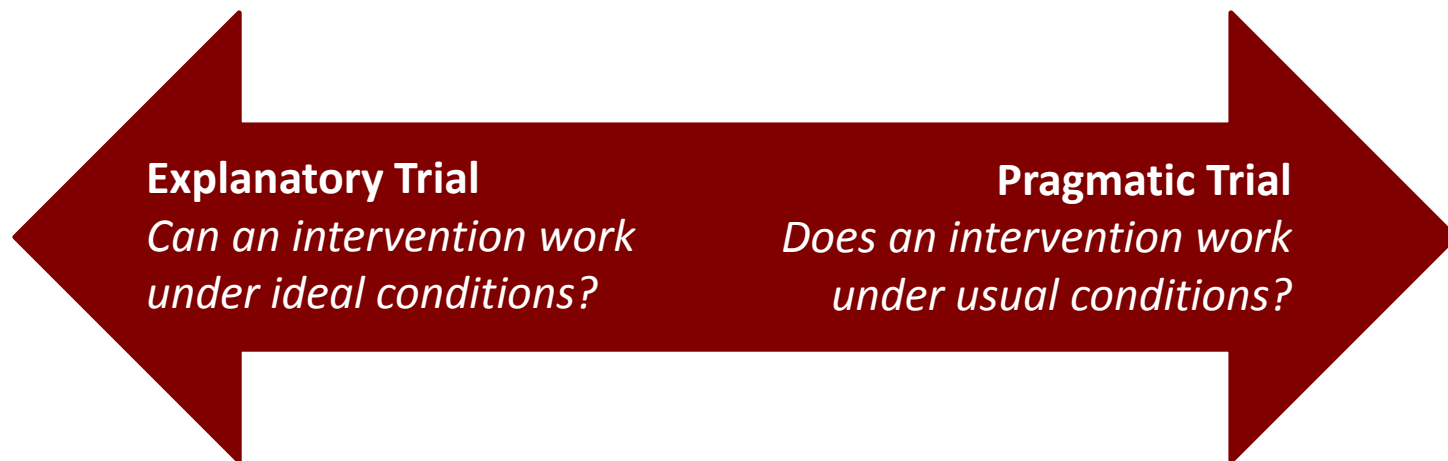
What's pragmatic about PCTs?

Practical
- Designed to test what will work in everyday care, with emphasis on successful implementation.

Inclusive
- Study diverse populations receiving care in real-world settings using broadly inclusive criteria for study participation.

Engaged
- Health systems, providers, and patients are involved in study design, collecting data, interpreting results, and acting on findings.

Relevant
- Results should provide timely information for decision making of providers, administrators, and policymakers.

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Advantages of PCTs

Actionable

Designed around application to practice, with an emphasis on successful implementation.

Patient-centered

Research questions and goals are strongly aligned with patient-centered research and care.

Relevant

Transparent reporting of results that are focused on issues and data that are relevant for making decisions and taking action.

Key facilitator: health care "big data"

- Over 50% of doctors and 80% of hospitals now have EHRs. This number has more than doubled since 2012.

- **Big data in health care offers great potential** for helping achieve "the 'triple aim' in health care - better care for individuals, better care for all, and **greater value** for dollars spent".

- Learning Health Systems already use big data to **improve care**, such as targeting services, monitoring chronically ill populations, and improving decision making.

- NIH Health Care Systems Collaboratory projects are using big data in health care to **address research questions of importance** to health care systems, patients, and decision-makers.

Key considerations of the HCS

Is it important to us?

Will we be involved in formulating the research question(s)?

Can we do it here?

Is the study built around our normal clinical operations?

What are the real costs to our health system?

Will it take us more time?

Are the study protocols flexible?

Do they minimize intrusion in the daily work flow of our clinics?

Will it help our patients?

Will the study give us evidence we can use to improve patient care and clinical decision making?

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Keys to successful partnerships

- **Develop genuine ongoing collaboration**, common goals, shared expectations, and clear roles. Protect HCS business interests.

- **Align research with health system priorities**. Obtain buy-in from the highest levels, as well as front line providers and managers.

- **Establish clear value** and identify win-wins for multiple stakeholders (system, providers, researchers, patients, public).

- **Build trust** between researchers, providers, and patients. Patient safety and privacy are a top concern.

- **Benefit the public good** (not individuals or corporations).

- **Minimize impacts** to provider work flow and clinical operations.

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UH2 projects exemplify principles for success

- The seven Collaboratory demonstration projects are all building **genuine and trusting partnerships** with their HCS partners.

- The projects' **aims match closely with partner health system priorities**, will provide actionable information, and the knowledge they generate will benefit the public good.

- Each project has numerous strategies to **minimize intrusion** in the daily work flow of clinics.

  - How are the demonstration project researchers integrating their work into busy clinical practices?

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"A pilot project is essential"

Gloria Coronado, PhD, Kaiser Permanente Northwest

Strategies and Opportunities to Stop Colon Cancer in Priority Populations

- Evaluates an evidence-based, culturally tailored approach to increasing colorectal cancer screening in minority and low-income populations.

- Partnership:
  - Kaiser Foundation Hospitals
  - Oregon Community Health Information Network (OCHIN)
  - Federally Qualified Health Center Clinics (FQHCs)

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Strategies to minimize burden

- Doing a pilot in 2 clinics to discover and solve workflow, and process issues in advance of launching the full-scale project (e.g. selection of FIT kits, lab interfaces, testing for the uninsured).

- Giving clinics choices about the intervention.
  - Clinics could design additional intervention components; the clinics chose live telephone reminders using bilingual motivational interviewing.

- Working with what the systems already have -- following standard clinic workflows whenever possible, patient advisory councils, etc.

- Creating a learning community – project advisory board.

"Partnership from the get-go"

Lynn DeBar, PhD, Kaiser Permanente Northwest

Collaborative Care for Chronic Pain in Primary Care

- Involves primary care staff in testing a team-based program to help patients manage chronic pain.

- HCS Partnership:

  - Kaiser Permanente Georgia

  - Kaiser Permanente Northwest

  - Kaiser Permanente Hawaii

Strategies to minimize burden

- Meeting early-on with healthcare system leadership. Involving relevant people from the HCS from the very beginning on project choice, study design, implementation.

- Finding connections between what the delivery system needs to improve patient care and what the research can offer.

- Respecting the clinical staff in scheduling meetings and being present in the clinic. Being available but trying not to be underfoot at the most busy clinical times.

- Matching the study protocol to the clinical processes and language already in use at the clinics.

"Be parsimonious"

Laura Dember, MD, University of Pennsylvania

Time to Reduce Mortality in End-Stage Renal Disease

- Evaluates the impact on survival, hospitalizations, and quality of life of a facility-level approach to dialysis session duration for patients with kidney failure treated by two dialysis provider organizations.

- HCS Partnership:

    - Fresenius Medical Care North America

    - DaVita, Inc.

Strategies to minimize burden

- Being parsimonious in study design to reduce the impact on clinical personnel.

- Keeping the intervention simple.

- Collecting only those data elements that are absolutely necessary for answering the research questions.

- Utilizing centralized research teams.

- Working with the HCS partners as a team during protocol planning and implementation.

- Involving the HCS collaborators in discussions and decisions so that their perspectives are incorporated.

"Align with the goals, campaigns, and structure of the hospital"

Susan Huang, MD, MPH, University of California - Irvine

Decreasing Bioburden to Reduce Healthcare-Associated Infections and Readmissions

- Evaluates the effectiveness of antiseptic soap and nasal antibiotic ointment for reducing health care-associated infections.

- HCS Partnership:
  - Hospital Corporation of America (HCA)

Ed Septimus, MD
HCA Medical Director of Infection Prevention and Epidemiology

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Strategies to minimize burden

- Creating a culture that values research—listen to, respect, and be responsive to frontline clinical staff implementing the study.

- Using existing HCS tools and mechanisms.
  - Such as computer-based training models, routine communication channels for provider education, and established quality improvement personnel and procedures to implement the intervention.

- Using centralized health system data warehouse capabilities for outcome determination across many hospitals.

- Getting IRB approval through a single experienced trusted IRB so each hospital doesn't need to go through the IRB process.

"As automated as possible"

Jeffrey "Jerry" Jarvik, MD, University of Washington

A Pragmatic Trial of Lumbar Image Reporting with Epidemiology

- Tests the use of imaging benchmarks to improve interpretation of diagnostic tests for lower back pain using EHR data.

- HCS Partnership:
  - Kaiser Permanente Northern California
  - Group Health Cooperative
  - The Mayo Clinic
  - Henry Ford Health System

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Strategies to minimize burden

- Establishing and building on good working relationships.

- Making use of a previous HCS partnership that established trusted collaborative relationships as well as practical resources such as EHR code.

- Automating the intervention as much as possible.

  - In this case intervention language inserted in imaging reports will happen automatically once a site is randomly assigned to the intervention. Providers will not need to do anything actively.

- Having a knowledgeable and respected co-investigator at each study site who can solve local problems based on local expertise.

"Be flexible and cognizant of HCS operations"

Gary Rosenthal, MD, University of Iowa

Nighttime Dosing of Anti-Hypertensive Medications: A Pragmatic Clinical Trial

- Tests whether simply changing the timing of administration might improve the effectiveness of high blood pressure medications. Develops EHR and web-based means of obtaining informed consent.

- HCS Partnership:
  - University of Iowa
  - Duke University

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Strategies to minimize burden

- Being mindful of the tremendous time stress providers are under; proposing an intervention feasible in busy practice environments.

- Being flexible and changing the intervention or implementation if necessary, based on clinical staff feedback.
  - Providers were supportive of the intervention but concerned about the time needed to change medication dosing during clinical visits. Thus, the original plan was modified to a centralized way of advising intervention patients to change when they take their medication.

- Directly supporting the efforts of IT personnel to implement necessary study protocols to prevent overloading the HCS IT staff with requests.

"We're the tail, not the dog"

Gregory Simon, MD, MPH, Group Health Research Institute

Pragmatic Trial of Population-Based Programs to Prevent Suicide Attempt

- Identifies people at risk for suicidal behavior and compares the real-world effectiveness of two suicide prevention programs.

- HCS Partnership:

  - Group Health Cooperative

  - HealthPartners Institute for Education and Research

  - Kaiser Permanente Colorado

  - University of Pittsburgh Medical Center

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Strategies to minimize burden

- Remembering that the purpose of the health system is not to do research, but to provide good health care. Researchers need to remember that we're the tail and the health system is the dog.

- Choosing a topic that is already a high priority for delivery systems and clinical staff.

- Designing measurements that take minimal time and use the existing EHR.

- Using a largely online intervention.
    - Intervention personnel (program coaches) are paid from the grant and will work remotely, not at clinics.

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Common lessons

- Choose a high priority topic for the HCS likely to provide a pay-off for both patients and the health system.

- Build on previous research-HCS collaborations, when possible.

- Include a pilot project to inform the main pragmatic trial.

- Get HCS partners involved in planning phase early on; support of leadership is essential; clinic champions ensure compliance.

- Think carefully about what the study needs and who it will impact.

- Listen to/work with everyone affected by the study. Adjust your plan to meet their priorities, needs, and ability to participate.

- Use the EHR, current workflow, and other existing HCS resources and tools whenever possible.

Summary of key points

- High quality data can be obtained in a rigorous manner without unduly burdening the HCS. While may not be the level of data/detail that RCT fans want – keep in mind the different purposes of PCTs and RCTs.

- Pragmatic approaches have great potential to transparently, rapidly, and positively influence health and healthcare.

- PCTs require that researchers and providers sit down together to design study protocols that clinical staff are able and willing to carry out.

- Clinical and IT staff must make the study a part of the everyday workflow, patient interactions, and EHR.

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Discussion