Lessons Learned from Virtual Clinical Trials: NIH Health Care Systems Research Collaboratory

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NIH Health Care System Research Collaboratory

- **Mission:** Strengthen the national capacity to implement cost-effective large-scale research studies that engage healthcare delivery organizations as research partners.

  - Leverage electronic health record data for clinical research
“Embedded Pragmatic Clinical Trials”
Overview

- Background NIH HCS Collaboratory
- Leveraging the EHR
- Lessons learned – expected and unexpected
Core Working Groups

Training Resources
Electronic Health Records

Co-Chairs: Rachel Richardson, Greg Simon
NIH Representatives: Jerry Sheehan, Barbara Wells
Project Manager: Jesse Hickerson

Products and Publications | Presentations

The ability to harness electronic health data is transforming the way clinical research is conducted. The Electronic Health Records (EHR) Core's goal is to facilitate multi-stakeholder research collaborations between investigators and data stewards. Core members have expertise in data models, data standards and quality, algorithms, and approaches to define clinical phenotypes, extract information, define endpoints, and discover errors in data from healthcare systems.

The secondary use of electronic health record (EHR) data for clinical research requires not only an understanding of data representation, exchange standards, and the influence of workflows, but also the development and implementation of valid approaches for identifying cohorts with clinical conditions. This involves collaboration among clinicians, EHR experts, and informaticists to develop algorithms, or computable phenotypes, for identifying patients with clinical conditions being studied by researchers.

There are many ways to identify patients who have been diagnosed with a specific condition, and understanding the pros and cons of the various approaches is essential for using EHRs effectively in pragmatic clinical trials. Also, comprehensive data characterization and data quality assessment enable investigators to match a research question with data of appropriate quality in order to conduct the research. The EHR Core supports these efforts across the Collaboratory and makes tools available to the wider research community.

Areas of Focus

- Develop and test phenotype algorithms for use within and across projects
  - Demonstration Projects
  - Existing literature
  - Mini-Sentinel

- Use standards organizations to move these measures into practice
  - Contribute to a learning healthcare system
  - Develop a suite of standards for clinical research
Leveraging the EHR

- Great resource of information that is collected as part of routine care
  - No Cost!

- What data is consistently collected
  - Billed services – procedures, hospital stays, medical visits, laboratory measures, medication fills (some)

- Are these outcomes useful for your study?
Challenges Faced when using EHR

- Missing data – field may exist, but may be empty
- Services received outside of the system
  - Free clinics, discounted medications, urgent care
- Most patient reported outcomes are not routinely collected (depression, pain, sleep, fatigue, etc)
- Adverse event reporting is scarce
- Follow up is not routine or on a schedule
Potential Solutions to Challenges

- Augment data collection with email link to web, IVR phone calls, mobile app, live person calls
  - Patient reported outcomes and adverse events
- Use creative analytic methods – trends over time and not exact time point analysis
- During planning period
  - Assess data sample for completeness
  - Identify other sources of care in the community
EXPECT THE UNEXPECTED
Lessons Learned

- Expected
  - Missing data
  - Staff turnover
  - Decreased fidelity to intervention
  - Evolving HCS
  - ICD9 to ICD10

- Unexpected
  - Frequency of staff turnover
  - New EHR launched
  - Systemic changes in HCS – stepped wedge
  - Time to get the data out of the EHR and clean it!
Embedded Pragmatic Clinical Trials

- Primary intent is to answer the question
  - “Does “it” work in this setting?”
  - Not evaluating how does it work, or what mediates effect
- Cost can be much less
  - Collaboratory trials $4.5 million direct over 5 years with 200-200,000 patients in each trial
When are Embedded PCTs good design choice?

- Outcome of interest is captured in the EHR
- Have a HCS partner interested in study outcome
- Familiar intervention
  - New indication for approved drug/biologic/device
- Few competing interventions or trials in the HCS
- Don’t need data collected at study visits