EHR Core: Accomplishments, Impact, and Future Directions

Co-Chairs:
Rachel Richesson, PhD, MPH
Duke University School of Nursing

Greg Simon, MD
Kaiser Permanente Washington

NIH Collaboratory Steering Committee Meeting
May 15, 201
Outline

• Participants and Mission

• Past Activities and Lessons Learned

• Greatest Impact to Date

• Important Activities Moving Forward

• Comments/Discussion
Participation

Core leaders:
Rachel Richesson  Duke University
Greg Simon  Kaiser Permanente

Coordinating Center Support:
Jesse Hickerson  Project Manager
Tammy Reece  Project Director
Karen Staman  Senior Writer

Members:
Nick Anderson  University of Washington
Alan Bauck  Kaiser Permanente
Denise Cifelli  University of Pennsylvania
Lesley Curtis  Duke University
Pedro Gozalo  Brown University
Bev Green  Kaiser Permanente
Ed Hammond  Duke University
Lauren Heim  University of California Irvine
Susan Huang  University of California Irvine
Michael Kahn  Children’s Hospital of Colorado
Reesa Laws  Kaiser Permanente
Julie Lima  Brown University
Rosemary Madigan  University of Pennsylvania
Meghan Mayhew  Kaiser Permanente
Vincent Mor  Brown University
Brett Moran  University of Texas Southwestern
George “Holt” Oliver  University of Texas Southwestern
Jon Puro  OCHIN
Jerry Sheehan  National Library of Medicine
Kari Stephens  University of Washington
Erik Van Eaton  University of Washington
Ferdinand Velasco  Texas Health Resources
Barbara Wells  National Heart, Lung, and Blood Institute
Wolfgang Winkelmayer  Baylor University
Mission

• Share experiences using clinical information systems and EHRs to support research
• Identify generalizable approaches and best practices to promote consistent and practical methods for using clinical data to advance healthcare research
• Suggest where tools are needed
• Explore and advocate for cultural and policy changes related to the use of EHRs for identifying populations for research, including measures of quality and sufficiency
Various use cases for clinical phenotype definitions

Purpose determines the ideal definition; validation required

Sharing definitions can reduce variation

Information must be targeted to different audiences (clinical and technical)

Lack of standardized EHR data is a major challenge

NIH Collaboratory

Electronic health records based phenotyping in next-generation clinical trials: a perspective from the NIH Health Care Systems Collaboratory

Rachel L Richesson, 1 W Ed Hammond, 2,3,4 Meredith Nahn, 5 Douglas Wirtz, 5 Gregory F Simon, 6 Jennifer G Robinson, 7 Alan E Bauck, 8 Denise Cifelli, 9 Michelle M Smerak, 3 John Dickerson, 8 Reesa L Laws, 9 Rosemary A Madigan, 3,10 Shelley A Rusincovitch, 3 Cynthia Klutch, 11 Robert M Califf 15

ABSTRACT

Widespread sharing of data from electronic health records and patient-reported outcomes can strengthen the national capacity for conducting cost-effective clinical trials and allow research to be embedded within routine care delivery. While pragmatic clinical trials (PCTs) have been performed for decades, they now can draw on rich sources of clinical and operational data that are continuously fed back to inform research and practice. The Health Care Systems Collaboratory, initiated by the NIH Common Fund in 2012, engages healthcare systems as partners in discussing and promoting activities, tools, and strategies for supporting active participation in PCTs. The NIH Collaboratory consists of seven demonstration projects, and seven problem-specific working group “Centers,” aimed at leveraging the data captured in heterogeneous “real-world” environments for research, thereby improving the efficiency, reliability, and generalizability of trials. Here, we introduce the Collaboratory, focusing on its Phenotype, Data Standards, and Ethical Quality Core, and present early observations from researchers implementing PCTs within large healthcare systems. We also identify gaps in knowledge and present an informatics research agenda that includes identifying methods for the definition and appropriate application of phenotypes in diverse healthcare settings, and methods for validating both the definition and execution of electronic health records based phenotypes.

INTRODUCTION

The US healthcare system is poised to significantly enhance the relevance, number, speed, and cost-effectiveness of clinical trials by embedding them directly within the healthcare delivery system. This transformation will be enabled by capabilities offered by electronic health records (EHRs) and patient-reported outcomes (PROs), changes in the organization and delivery of healthcare, and cooperation toward the development of a learning health system in which evidence generated in clinical settings is routinely examined to inform research and practice. Widespread electronic collection of operational and clinical data have enhanced the potential for pragmatic clinical trials (PCTs), randomized controlled trials designed for broad generalizability, typically using multiple clinical sites and broader eligibility criteria. In contrast to explanatory trials, for which the goal is to detect biological effects of new treatments, PCTs are designed to support clinical decision-making by evaluating interventions in real-world practice conditions. PCTs therefore recruit participants from heterogeneous practice settings, and pose challenges for reconciling the variation in healthcare operations, widely disparate information systems, and differences in data capture folders. The routine implementation of PCTs is a key element in achieving the vision of the learning health system, but achieving this on a global scale will require innovations, including new ethical frameworks to assess consent and risks, new methodologies to work with observational data, and more effective partnerships among healthcare systems.

Advancing our understanding and ability to conduct PCT within healthcare systems using innovative approaches is a key focus of the NIH Collaboratories. The use of EHRs to support trial activities, including the identification of patient cohorts with precise clinical attributes, is an important component of this vision and the next generation of clinical trials. The Collaboratory is leveraging previous work in phenotype definition and execution, and adding new use cases and requirements to inform the practice of using EHRs for research, advancing the science for both informatics and evidence-based healthcare. In the following sections, we will describe the NIH Collaboratory and the Phenotype, Data Standards, and Ethical Quality (PSQ) “Core” working group, including their early experiences with EHR data queries, standards considerations, and data quality activities. We will conclude with a proposed research agenda and suggested future directions.

THE NIH COLLABORATORY

In 2012, The NIH Common Fund initiated the Health Care Systems Collaboratory (https://www.nihcollaboratory.org) program to engage healthcare systems as partners in efforts to improve research efficiency and relevance to patients, clinicians, and the healthcare community—and in doing so, advance the national capacity for conducting large, cost-effective studies. The Collaboratory is not a traditional research network but rather a participatory forum, developing and integrating practices that allow diverse healthcare systems to participate in clinical research. It also supports
Living Text Sections

- Using EHR Data in PCTs
- Clinical Phenotyping
- Data Quality
- Data Standards
  - ICD-10
  - RxNorm and Medication Data
- Demonstration project approaches and case studies
PCT Reporting Template

PSQ Core additions to the proposed guidance for reporting results from pragmatic trials.

Find a copy of the PCT Reporting Template in your meeting materials.

Reporting Specifications for PCTs

• How the population was identified
• Clinical phenotype definitions
  • location to obtain the detailed definitional logic
  • use public repository, e.g., PheKB, NLM VSAC, GitHub
• Data quality assessment methods
• Data management activities during the study, including description of data sources or processes used at different sites, linkage, etc.
• Plan for archiving or sharing the data after the study, including specific definitions for clinical phenotypes and specifications for coding system
• Competition for IT resources
• Need to optimize clinical data for research purposes
• Only small proportion of research in EHRs

• Need to capture intervention or control activities
  • Including standard of care
• Need to enable learning & research activities into EHR functions

https://academic.oup.com/jamia/article/24/5/996/3069877/Pragmatic-trial-informatics-a-perspective-from-the
Lessons Learned from Collaboratory PCTs

- Not all data needed for trial in EHR
- New data collection difficult
- Data quality issues
- Data transformation issues
- Dynamic and ongoing
Lessons Learned from Collaboratory PCTs

• **Difficult** to assimilate data across organizations
  • requires a reference standard
  • requires local data & systems experts
  • “Data sharing” is **not** straightforward in PCTs; has implications for providers and health systems (Greg Simon will address later)
  • Resource sharing is important and feasible for our core
Greatest Impact – “Success Factors for PCTs”

• Organizational “Research Readiness”
• Dedicated and or research-trained data operations staff
• Existence of resources that can support multiple research and QI studies
Greatest Impact – “Success Factors for PCTs”

- Existence of research processes or resources that can enable research and/or enable the site to join multi-site research projects
  - e.g., use of reference standards (e.g., LOINC or RxNorm) enable faster and more consistent roll-out of definitions, eligibility/enrollment, implementation tools, etc.
- The availability of standard clinical data elements and research functions in EHRs will facilitate conduct of PCTs and sustainability of interventions
Future Impact – Promote and Promulgate “Success Factors” for PCTs

• Validate checklist for assessing “research readiness”

• Measure and promote research readiness in organizations

• Identify and share tools and best practices (“Roadmap” papers from each demonstration project)

• Advocate for standards and functionality in EHRs to support PCTs
Feedback

• Charter and mission (next slide)

• Priority tasks or products for the next year:
  • Checklist for resource and data sharing package
  • Checklist or tool for assessing “research readiness”
  • Others??????
Mission -- for discussion

• Share experiences using clinical information systems and EHRs to support research
• Identify generalizable approaches and best practices to promote consistent and practical methods for using clinical data to advance healthcare research
• Suggest where tools are needed
• Explore and advocate for cultural and policy changes related to the use of EHRs for identifying populations for research, including measures of quality and sufficiency
Thank you