Next-Generation Registries:
Fusion of Data for Care, and Research

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Abstract
Disease-based registries are a critical tool for electronic data capture of high-quality, gold standard data for clinical research as well as for population management in clinical care. Yet, a legacy of significant operational costs, resource requirements, and poor data liquidity have limited their use. Research registries have engendered more than $3 Billion in HHS investment over the past 17 years. Health delivery systems and Accountable Care Organizations are investing heavily in registries to track care quality and follow-up of patient panels. Despite the investment, regulatory and financial models have often enforced a “single purpose” limitation on each registry, restricting the use of data to a pre-defined set of protocols. The need for cost effective, multi-sourced, and widely shareable registry data sets has never been greater, and requires next-generation platforms to robustly support multi-center studies, comparative effectiveness research, post-marketing surveillance and disease management.

This panel explores diverse registry efforts, both academic and commercial, that have been implemented in leading-edge clinical, research, and hybrid use cases. Panelists present their experience in these areas as well as lessons learned, challenges addressed, and near innovations and advances.

General Description of Program
The Institute of Medicine describes a Learning Healthcare System – a clinical medicine model in which outcomes are continuously monitored, the knowledgebase is continuously updated, and hypotheses may be rapidly tested. At its core, this represents a new paradigm for enlisting the health care enterprise as a creator and user of rich data for continuous improvement, innovation and discovery. A key tool in a learning health system is the clinical research registry, which historically has been especially useful to the study of select populations and rare diseases. Results have been important in advancing understanding and management of many conditions over the past decades, for example in cystic fibrosis, many forms of cancer, and drug and device safety surveillance. Classically, registries been manually populated by research staff interviewing patients and reviewing charts.

But now, electronic health records (EHRs) offer a complementary data source, large quantities of low-cost, ambient, and typically ad-hoc data gleaned from multiple health system sources, collected according to clinical workflows and requirements of regulators and payors. Such data sets are often incomplete, rarely validated, and not typically accompanied by sufficiently detailed metadata and according to standardized vocabularies so as to permit meaningful data combination across sites.

Further, with consumer-facing IT, patients become a potential direct source of data for registries.

Next-generation disease registry platforms must enable collection, aggregation and permissioned sharing of high quality data sets across the healthcare enterprise.

We have assembled an expert panel to
explore the benefits and challenges of using next-generation registry platforms for multi-sourced, multi-center studies, comparative effectiveness research, and post-marketing surveillance, and clinical management, focusing on how these systems may best contribute to accomplishing central infrastructure requirements of a Learning Healthcare System.

Kenneth D. Mandl, Director of the Intelligent Health Laboratory in the Boston Children’s Hospital Informatics Program will moderate the session. He will begin with a brief but broad overview of the use of registries in clinical care and research. He will explore the information value of data sources from the meticulously collected classic registry data, to patient-entered data, to EHR data. Each panelist will then be invited to make a presentation in an area of his or her expertise for 12 minutes. The total presentation time will be kept to one hour to allow lively discussion with the audience.

Marc D. Natter will discuss the advantages and challenges of creating a federated, multi-purpose chronic disease registry in use for the national 60-site Childhood Arthritis and Rheumatology Research Alliance (CARRA) Registry and other networks. He will outline the design and implementation of the i2b2 self-scaling registry (i2b2-SSR), a modular, self-scaling informatics platform for registry data federation built upon the widely adopted, open-source i2b2 data warehouse software and SHRINE peer-to-peer networking architecture.

Dr. Natter will describe the CARRA Registry’s approach to fostering investigator- and patient-centric clinical and translational research, focusing on the mechanisms employed to enable ready, permissioned sharing of research data across sites, investigators, and subspecialties. He will also outline a range of existing as well as newly-implemented applications for this open-source registry technology, including cross-network research data sharing, standards-based integration with electronic data capture data sharing, adaptation for dual usage in clinical research and pharma post-marketing surveillance, and incorporation of functionality for direct entry of patient-reported outcomes in concert with the REDCap software platform.

Chad Malone will provide a commercial perspective on registry infrastructure, taking the audience through a use case of a Remedy Informatics oncology registry implementation at Massachusetts General Hospital. He will focus on development of the ontologies for harmonizing data from disparate sources to support a readily queried application for “pattern recognition” by end users, including comprehensive views of each patient or research subject. The Mosaic Ontology harmonizes data across devices and otherwise disjointed clinical data sources.

Keith Marsolo will describe his work developing a next generation EHR-linked registry for ImproveCareNow. This registry populated through existing care processes and EHR data collection. ImproveCareNow encompassing more than 43 care centers, is a collaborative of pediatric gastroenterologists focused on improving the care and outcomes of pediatric Inflammatory Bowel Disease.
The data elements collected for their registry are harmonized with those collected as part of model IBD care. Thus, to lower transaction costs, reduce the need for double data entry and leverage the promise of EHRs, Dr. Marsolo and his team have been working to create a registry that allows data to be collected once at the point of care and be reused for quality improvement (monthly quality reports, pre-visit planning, patient activation, population management) and research.

Dr. Marsolo will discuss the architecture of this EHR-linked registry as well as interactions with the major EHR vendors around developing EHR data entry forms for their customers that would allow the registry data to be collected, stored as discrete elements and then extracted as a flat file report that could be uploaded into the registry.

Stephen Edge will discuss a cancer registry designed for direct use in clinical care. He will provide background on how cancer registries have historically been used for evaluating trends in population cancer incidence and stage and general patterns of care.

He will discuss uses of the National Cancer Data Base of the Commission on Cancer, to evaluate quality of care, to track care prospectively against quantifiable benchmarks, to interact with patients as part of an oncology medical home, and for linkage to biorepositories to support clinical and translational research.

The registry is integrated into clinical environments for tracking real-time care tracking, quality assessment and feedback, public reporting of quality metrics, survivorship care planning, and linkage to biospecimens. He will present two major initiatives: the rapid ascertainment system for quality reporting, and the use of this system for public reporting through CMS.

Questions for audience discussion
- Does your organization participate in registries?
- One or more than one?
- Are you aware of EHRs populating registries?
- Have you tried to set up your own registry?
- What funding models support registries you may be involved in?
- Are the registry data available for clinical care?
- Who enters data into the registries?

Statement from the Organizer
Each participant has agreed to take part on the panel.