The EDM Forum Approach to Overcome Traditional Barriers in Using Electronic Data Sources for CER and QI

Organizations may not re-use material presented at this AMCP conference for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use material presented at [conference] without the written consent of the presenter the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

Gurvaneet Randhawa, MD, MPH
Center for Outcomes and Evidence
11/12/2013
Outline

• Brief overview of challenges in conducting research
• Brief overview of ARRA investments in electronic data methods and infrastructure for CER and other purposes
• Overview of Electronic Data Methods Forum
Challenges in Conducting Research

- Resource availability and feasibility influences study design and analysis, which influences the validity and generalizability of conclusions.
- Retrospective observational studies, especially claims-based, are relatively fast and cheap but have a greater risk of bias (inadequate clinical data; potentially non-comparable populations or delivery of interventions; confounding).
- Prospective studies are expensive and slower.
- RCTs (efficacy) typically conducted in non-generalizable settings with short-term outcomes.
• Privacy and proprietary considerations limit data sharing across organizations
• End-users of research rarely involved in specifying research questions, especially outcomes of interest
• Variability in data quality
• Data standardization and interoperability across EHRs remains an important area of activity
• Variability in IRB decision-making complicates multi-site research or QI projects
• Distributed research is a viable alternative to traditional research but does not solve all problems
Rationale for CER

- Large gaps in knowledge of the impact of therapeutics and diagnostics on patient outcomes in the real-world
  - Lack of alignment in goals of researchers, clinicians, policymakers; short-term outcomes, one-off projects; information and expertise is in silos; end-users need to be involved to ask “right” questions
  - Limitations in existing data infrastructure and study methods
• Increased EHR adoption (meaningful use incentives); interest in “mobile” health
• Increased focus on PCOR and CER (PCORI, AHRQ)
• Resource constraints and desire for demonstrating value – multi-functional electronic data infrastructure (clinical care, QI, research)
• Moving to a user-driven research paradigm; need appropriate incentives to engage end-users early in the research process
• One of four programs that were part of a $100 million ARRA investment to build a multi-functional (for CER, QI and decision support) clinical electronic data infrastructure

• Advance methods and share lessons learned in creating and using the infrastructure

• Focus on four domains: analytic methods; clinical informatics; governance; and learning health system
Four Programs on Electronic Data Infrastructure & Methods

• PROSPECT: Prospective Outcome Systems using Patient-specific Electronic data to Compare Test and therapies (six grants)
• Scalable Distributed Research Networks (three grants)
• Enhanced registries for QI and CER (two grants)
• EDM Forum (one grant)
Objectives of the Electronic Data Infrastructure Projects

- Link multiple healthcare delivery sites
- Connect multiple databases
- Focus on priority populations and conditions
- Prospective, patient-centered outcomes
- Conduct CER
- Valid and generalizable conclusions
- Focus on governance and sustainability
- For registries: also conduct QI; leverage existing registry
- For DRNs: multiple diseases and populations; near-real time data collection and analysis
Highlights of Selected Projects

- Pediatric Enhanced Registry: Largest pediatric IBD registry; a third of patient population; 30 states
- SCOAP-CERTAIN: Surgical care registry covers 55 of 60 hospitals in Washington state
- SUPREME-DM: 11 HMORN sites; 1.1 diabetes patients in datalink/registry
- SAFTINet: Built on DARTNet approach; only DRN focused on care of medically under-served
- WICER: Inner city community-based network based at Columbia University
- Indiana PROSPECT: Built on Indiana’s state-wide Health Information Exchange
Location of Projects
Convenes investigators and other stakeholders to understand, prioritize, and tackle challenges in building, and using, electronic data infrastructure for diverse purposes

Conducts collaborative methods projects

Creates a variety of products and uses diverse channels to disseminate knowledge and inform a broad audience
Community Web Portal (http://www.edm-forum.org)

Online Repository (http://repository.academyhealth.org) contains links to publications, issue briefs, archived webinars, symposia materials

eGEMs (http://repository.academyhealth.org/egems) a new open-access journal; we need more contributors and reviewers – please participate!

EDM Forum Monthly Newsletter (nearly 2000 subscribers)
  - Sign up: edmforum@academyhealth.org

Twitter and RSS feeds
eGEMs: Generating Evidence and Methods to improve patient outcomes

- Free, peer-reviewed, open access, e-publication launched in January, 2013
  - 23 publications to date (several in pipeline)
  - About 9,000 downloads to date
  - One special issue on decision making released in October, 2013
  - Special issue on analytic methods (release in December, 2013)

- Focus on research and QI using electronic data to improve patient outcomes in the four domains

- Submissions evaluated on usefulness, credibility, and novelty

- Visit: [http://repository.academyhealth.org/egems/](http://repository.academyhealth.org/egems/)
Other EDM Forum Products

• Two *Medical Care* supplements
  - 15 papers in July, 2012 issue
  - 13 papers in August, 2013 issue
    Free access; links on EDM Forum website

• A paper in the 2012 issue (on a survey of informatics platforms for distributed CER, written by Sittig and colleagues) recognized by IMIA as among the best in clinical research informatics

• 12 issue briefs, including a CER Project profiles (in 2012), and on informatics tools created or adapted by the infrastructure projects (in 2013)
Collaborative Projects: Highlights

- Data Quality: Two papers in Medical Care supplements (framework for data quality assessment, practical approaches to ensure data quality); draft white paper
- Governance: Two eGEMs publications (review of data governance programs; pathways for success in multi-site research); Governance toolkit: examples of data use and data access agreements; six articles in Medical Care supplements
Other Medical Care Papers of Interest

• Standardizing medication adherence terminology (Raebel and others; 2013 supplement)
• Privacy and security policy framework (Kim and others; 2013 supplement)
• Caveats for use of EHRs in CER (Hersh and others; 2013 supplement)
• Approaches to facilitate IRB approval of multi-center research (Marsolo; 2012 supplement)
• Strategies to de-identify EHR data (Kushida and others; 2012 supplement)
• Data model considerations for CER (Kahn and others; 2012 supplement)
Informatics and Analytic Tools: A New Resource for Researchers

- 31 new or adapted informatics and analytics tools and approaches used by the 11 infrastructure projects
- Belong to one of four domains:
  - person-level data collection
  - data access, exchange, and aggregation
  - population level analytics
  - provider, researcher or patient decision support
- Issue brief on these tools is available at: http://repository.academyhealth.org/edm_briefs/11/
Parting Thoughts

- Governance, trust and stakeholder engagement as important as scientific and technical issues
- Multi-site, EHR-based data networks have tremendous potential for improving patient outcomes and advancing scientific knowledge but...
- Need upfront buy-in from multiple decision-makers and stakeholders – more work at the beginning but pays off at the end
- Multi-purpose networks enhance value and help to achieve infrastructure sustainability
- Need to find the right balance between scientific advancement, improved health, and business needs
- EDM Forum is a valuable national resource for methodological issues related to CER, PCOR, QI and decision support – please do participate!