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

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**11/12/2013**



# Outline

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- 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

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- 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



# Governance & Informatics Challenges

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- 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

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- 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



# Changing Milieu in Health Care Delivery and Research

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- 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



# Electronic Data Methods (EDM) Forum

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- 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

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- 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

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- 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

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- 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





# Electronic Data Methods Forum

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- 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



# EDM Forum Dissemination

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- ▶ 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](mailto:edmforum@academyhealth.org)
- ▶ Twitter and RSS feeds



# *eGEMs: Generating Evidence and Methods to improve patient outcomes*

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- 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/>



# Other EDM Forum Products

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- Two *Medical Care* supplements
  - 15 papers in July, 2012 issue
  - 13 papers in August, 2013 issueFree 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

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- 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

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- 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

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- 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/](http://repository.academyhealth.org/edm_briefs/11/)



# Parting Thoughts

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- 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!