ISSUE 14 WINTER 2011

Prescriptions for Excellence in
HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON SCHOOL OF POPULATION HEALTH AND LILLY USA, LLC

Editor-in-Chief: *David B. Nash, MD, MBA* • Managing Editor: *Janice L. Clarke, RN, BBA* • Editorial Staff: *Dorah C. Meiris, Alexis Skoufalos, EdD*

Leveraging Electronic Health Records in Comparative Effectiveness Research

By Andrew Masica, MD, MSCI and Ashley Collinsworth, MPH

Comparative Effectiveness Research (CER) has been identified as a key component of US health care reform. The Institute of Medicine defines CER as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve delivery of care" for the purpose of allowing "consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels."[1]

CER ultimately seeks to provide pragmatic knowledge that can be applied toward delivering "the right treatment to the right patient at the right time."[2] Achieving this goal in a complex health care environment will require robust, accessible data sources capable of providing detailed patient-level information in a time- and cost-efficient fashion. Electronic health records (EHRs) are well suited to fill that need, but current technical aspects and methodologies of using these systems as research tools are at an early stage of development.

The Federal Coordinating Council for CER (established by the American Recovery and Reinvestment Act of 2009, which also included a $1.1 billion appropriation for CER) advocated a strategic framework[2] that reflects the importance of EHRs in the CER enterprise. As shown in Table 1, the core components of CER outlined by the Council are strongly influenced and enhanced by EHRs, particularly those with functionalities that allow interoperability and data exchange.

EHRs also help address the disconnection between the vast amount of health care data that are available and our ability to access and organize those data in a way that is meaningful for CER. More than ever before, health care is "information rich," as interactions between clinicians and patients produce a myriad of data points including diagnoses, laboratory results, images, interventions, and responses to treatments.[3]

Historically, it has been difficult to use data collected as a part of routine patient care to perform research efficiently because the material of interest often was buried in paper charts or archived records and scattered across the siloed care sites. This incongruity has hampered the development of evidence to determine which intervention(s) works best for individual patients. EHRs offer a potential mechanism to identify and compile relevant clinical information for the full spectrum of patients across the continuum of care, to structure that data, and to enable

Table 1. Relationships between the Comparative Effectiveness Research (CER) Strategic Framework and Electronic Health Records (EHRs)

CER Activity/Investment	EHR Support of Activity/Investment
Research Content	• End product of investigators applying EHRs effectively • Accelerated research production time frame
Human and Scientific Capital	• Human resources to extract and configure electronic data • EHR appropriate study design and analysis methodologies • Hardware/software that facilitates research
Data Infrastructure	• Longitudinal patient registries • Development of distributive data networks
Dissemination and Translation	• Clinical decision support embedded into EHR workflows

(continued on page 2)

Jefferson School of Population Health

Lilly

appropriate comparisons of treatments from a single source.

Until the recent movement toward widespread EHR implementation, the type of original research (excluding systematic literature reviews) that would satisfy criteria as a CER study would necessitate undertaking a clinical trial, conducting costly and time-consuming manual audits of paper charts, or relying on administrative data, which may be inaccurate and lacking in granular clinical information.

Although randomized controlled trials (RCTs) have long been considered the gold standard for comparing efficacy, these types of studies are performed in highly controlled environments in which patients are selected based on strict inclusion criteria and in which treatment adherence is closely monitored. Research regulations, study logistics, and negative perceptions of research in certain populations often make it difficult or impossible to include certain subgroups (eg, children, pregnant women, the elderly, minorities, people with multiple chronic conditions, those with rare diseases) in clinical trials.[4] Thus, the results of RCTs often have limited generalizability to an affected patient population, whereas a central tenet of CER is to determine what works in "real world" settings.[5] Lastly, RCTs are expensive and cannot be modified easily to include additional patient data over time or account for emerging care improvements.

EHRs also have a clear advantage over purely administrative data sources in retrospective studies, as they contain access to discrete, longitudinal observations (eg, blood pressure measurements, serial laboratory tests) that can be used to strengthen statistical models pertaining to the outcomes of interest.[6]

Early experience using EHRs as tools in CER has shown some promising results,[7] but methodological and practical challenges must be addressed to leverage these systems to their full potential. Current EHRs are designed for frontline patient care delivery rather than for research. As such, EHR data quality is subject to the idiosyncrasies of daily practice operations (eg, patients skipping appointments with resultant long intervals between observations, variations in provider behavior) and does not match the quality of data garnered from clinical trials.

Likewise, treatment decisions in practice generally are determined by patient- and provider- specific factors rather than randomly, so observational studies relying on EHR data need analytic techniques that account for confounding.

Another major obstacle in use of EHRs for CER is missing data. This issue stems largely from the relative immaturity of these systems and the recording of information in inaccessible "free text" fields, rendering it essentially lost to the researcher without manual chart review. With the exception of a few early adopter health care delivery organizations, most EHR patient populations have accrued less than 5 years of data. This can reduce the available sample size when retrospectively evaluating the associations between interventions and outcomes in chronic diseases because new user designs (wherein only those patients with an incident disease diagnosis captured in the EHR are eligible for the cohort) are optimal for these types of studies to minimize bias.[8]

Finally, the lack of standardization among vendors has hampered data-sharing efforts between sites. With disparate EHRs, a significant amount of data transformation and configuration are required for systems to exchange information.[9]

Applied solutions to the aforementioned challenges are actively being pursued by the CER and medical informatics communities. With a wide variety of uses, natural language processing (NLP) appears to be an extremely potent tactic to access data trapped in EHR free text fields, and the Agency for Healthcare Research and Quality (AHRQ) currently is funding a grant to create a common NLP platform that can interface with EHR data to conduct CER.[10] Statistical methods, such as propensity scoring and inverse probability weighting,[11,12] have been used successfully to help counter potential confounding in observational studies using EHR data.

The "Meaningful Use of EHRs" incentive program and plans for electronic reporting of Centers for Medicare and Medicaid Services Core measures has heightened the emphasis on standardization of EHR data element specifications, and data-sharing consortiums between systems, intended to support CER, also are developing independently.[13] Pooling data among multiple sites will resolve sample size problems and facilitate procuring CER information on subgroups.

Given that several federal agencies are sponsoring CER (eg, AHRQ's Effective Health Care Program, National Institutes of Health, and the recently formed Patient-Centered Outcomes Research Institute) as well as the interests of industry in this area, the pace of innovation surrounding use of EHRs in CER likely will be brisk.

Even though EHRs are viewed as a part of larger systemic changes to drive health care improvements,[3] expectations surrounding EHRs in CER must be pragmatic. EHRs should be promoted as powerful tools that can facilitate CER efficiency rather than as a singular solution. The broad rollout of EHRs across US health care delivery

(continued on page 3)

This newsletter was jointly developed and subject to editorial review by Jefferson School of Population Health and Lilly USA, LLC, and is supported through funding by Lilly USA, LLC.

organizations affords a window of opportunity to deploy these systems in a way that will help reach the vision of CER as a valuable resource for informed health care decision making.

Andrew Masica, MD, MSCI, *is the Director of Clinical Effectiveness for the Baylor Health Care System in Dallas, TX. He can be reached at andrew.masica@baylorhealth.edu.*

References

1. Institute of Medicine of the National Academies. *Initial National Priorities for Comparative Effectiveness Research*. Washington, DC: Institute of Medicine; 2009.

2. Federal Coordinating Council for Comparative Effectiveness Research. Report to the President and Congress. http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf. Accessed September 17, 2011.

3. D'Avolio LW, Farwell WR, Fiore LD. Comparative effectiveness research and medical informatics. *Am J Med.* 2010;123(12 suppl 1):e32-e37.

4. Etheredge LM. Creating a high-performance system for comparative effectiveness research. *Health Aff (Millwood).* 2010;29(10):1761-1767.

5. Slutsky JR, Clancy CM. Patient-centered comparative effectiveness research: essential for high-quality care. *Arch Intern Med.* 2010;170(5):403-404.

6. Sullivan P, Goldmann D. The promise of comparative effectiveness research. *JAMA.* 2011;305(4):400-401.

7. Pace WD, Cifuentes M, Valuck RJ, Staton EW, Brandt EC, West DR. An electronic practice-based network for observational comparative effectiveness research. *Ann Intern Med.* 2009;151(5):338-340.

8. Ray WA. Evaluating medication effects outside of clinical trials: new-user designs. *Am J Epidemiol.* 2003;158(9):915-920.

9. Kudyakov R, Bowen J, Ewen E, et al. Electronic health record use to classify patients with newly diagnosed versus preexisting type 2 diabetes: infrastructure for comparative effectiveness and population health management. *Popul Health Manag.* Epub ahead of print August 31, 2011.

10. Agency for Healthcare Research and Quality Grants On-line Database. Grant Summary: Enhancing Clinical Effectiveness Research with Natural L. http://gold.ahrq.gov/projectsearch/grant_summary.jsp?grant=R01+HS19828-01. Accessed September 17, 2011.

11. Toh S, García Rodríguez LA, Hernán MA. Confounding adjustment via a semi-automated high-dimensional propensity score algorithm: an application to electronic medical records. *Pharmacoepidemiol Drug Saf.* 2011;20(8):849-857.

12. Curtis LH, Hammill BG, Eisenstein EL, Kramer JM, Anstrom KJ. Using inverse probability-weighted estimators in comparative effectiveness analyses with observational databases. *Med Care.* 2007;45(10 suppl 2):S103-S107.

13. Dartmouth-Hitchcock. High value healthcare collaborative expands. http://www.dartmouth-hitchcock.org/news/newsdetail/59724/. Accessed September 17, 2011.

This newsletter was jointly developed and subject to editorial review by Jefferson School of Population Health and Lilly USA, LLC, and is supported through funding by Lilly USA, LLC.