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Electronic Health Records for Effectiveness Research: Gold Mine or Tower of Babel?

Healthcare systems that have adopted electronic health records (EHRs) are quickly amassing a treasure-trove of data on clinical treatments and patient outcomes. Although EHRs are primarily designed to assist clinicians in caring for patients, health services researchers and policymakers are interested in using EHR data to study treatment effectiveness for therapies with uncertain outcomes. Given the high cost and time requirements of randomized clinical trials (RCTs), there is growing interest in determining whether researchers can generate credible effectiveness evaluations of new and existing medical technologies using EHR data.

Compared to RCTs that study relatively small numbers of carefully selected patients in controlled clinical settings, EHR data encompass large numbers of patients in clinical-practice settings over relatively long time periods. EHRs can provide important clinical data such as glucose levels, blood pressure readings, or tumor size and staging that are not present in claims data. But this information is observational, without randomization or carefully-defined control groups, raising concern that analysis based on EHR data is susceptible to confounding and selection bias.

On June 4, 2008, The Health Industry Forum's Evidence Workgroup met to examine whether and under what conditions EHR data can be used to develop credible evidence on the effectiveness of new and existing medical therapies. Representatives from the Palo Alto Medical Clinic, Veterans Health Administration, and Geisinger Health System reviewed the current capabilities of their EHR systems to generate evidence of effectiveness. Participants then discussed technical and policy changes necessary to support such analyses. Key themes from the meeting are summarized below.

The rich clinical data available from EHRs offer an opportunity to expand the base of medical evidence.

The use of electronic health records is growing. These records offer detailed, longitudinal, patient-level data specifying diagnoses, procedures, diagnostic information and medications. Because EHRs contain much more clinical detail than administrative data like health insurance claims, they have the potential to support evaluations of quality, outcomes, and the effectiveness of alternative treatment regimens across large patient populations. For example, a recent analysis found that electronic records accurately identified 98 percent of patients with diabetes compared with gold-standard chart review, while claims data missed nearly a quarter of them.

EHRs can also support research by ensuring that specific data or supplemental information are entered into the record. Geisinger Health System, for instance, is developing interactive patient modules connected to their EHR to collect quality-of-life data. Since clinicians consult a patient's medical record at each encounter, researchers can build in prompts to augment data collection for specific research questions. EHRs also allow guidelines based on effectiveness research to be delivered to clinicians at the time of service.

Because EHRs are designed to support clinical practice rather than research, the routine data they collect may be insufficient to answer key questions.

The primary role of electronic records is to document patient care and share information across caregivers. The data captured for these objectives are not always compatible with research. EHRs frequently suffer from problems of completeness and specificity, in large part because individual physicians differ significantly in how they document specific events. While EHRs do a reasonable job describing “what” medical treatments were administered, they generally do not provide a structured way to document “why” care occurred. Information, such as the reasons for discontinuing treatment, may be available from free-text progress notes, but are non-standard, making systematic analysis difficult.

Another impediment stems from the limited penetration of EHR systems. Currently, EHRs are primarily utilized by urban, academically-oriented provider systems, potentially limiting generalizability. Even in systems with comprehensive EHRs, all pertinent information may not be recorded if patients receive care from other providers. Even in the Veterans Health Administration, many veterans receive care from other Medicare-funded providers. Furthermore, most current EHR systems are not interoperable, and different systems use different codes for important clinical variables.

Perhaps most importantly are concerns that observational data collected through EHRs may not be adequate to support causal inferences about treatment effectiveness. For example, researchers studying bariatric surgery outcomes cannot be completely confident that the surgical patients are identical to a similar group of medically-managed obese patients. Without randomization into treatment and control groups, such analyses may suffer from unmeasured confounding.

Important areas for public policy include improving coding standards, developing new observational research methods, and creating incentives for high quality data generation.

As more providers implement electronic health records, early targeted policy efforts can improve the feasibility of EHR-based effectiveness research. Many of these steps are consistent with other goals like quality reporting and safety monitoring. Just as national committees have formed to develop data standards and quality metrics, similar efforts are needed if EHR data are to be used for research. The level of clinical detail available for research is limited by the current ICD-9 coding system; implementation of ICD-10 or a more advanced system would be highly beneficial. Standardized physician prompts and templates could help researchers collect clinical details in a way that allows consistent comparisons across studies. Here, the role of technology vendors will be critical; as provider groups purchase off-the-shelf EHR systems, companies like EPIC can develop standard data extraction modules to unobtrusively capture data within the normal clinical workflow.

Efforts are also necessary to expand the penetration of EHR systems. Both payers and government must help create a more compelling business case for physicians to adopt EHRs. One way is for payers to link payments to data reporting that could most effectively be done through EHRs: beginning with quality measures and expanding into data that would support comparative effectiveness research. A major challenge for EHR-based research will be to develop mechanisms to provide reasonable data access to researchers without compromising institutional or patient privacy. The current Veterans Health Administration initiative to establish an agency-wide Center for Scientific Computing illustrates both the possibilities and challenges of trying to gather EHRs across multiple hospitals/clinics and make them accessible for investigators .

Most importantly, policy makers need to invest in developing new research methods to improve the quality and consistency of observational data analyses. Clinicians, insurers, and patients must trust the results of EHR-based effectiveness research, and research methods must be unassailable if they are used to determine whether expensive technologies or pharmaceuticals are worth the cost. The research community will need to create “best practices” for EHR-based research, similar to those developed for clinical trials or meta-analyses. Participants discussed whether a national entity, similar to the National Committee for Quality Assurance, could serve as a central coordinating agency.

While concerns about observational data will limit some EHR research applications, there are many opportunities for using EHRs to supplement or enhance clinical trial findings.

Although randomized controlled trials (RCTs) are still considered the “gold standard” of effectiveness research, RCTs have many limitations. It is essential that investigators match their data and study design to the research questions under consideration in order to best use scarce research resources. In the immediate future, EHR data could be used to study populations that can not be well researched through other methods: for example, patients with multiple co-morbidities. EHR data could also be used to supplement or extend RCT results, for example by examining off-label use, related disease states, patients with different demographic or clinical characteristics, or specific sub-populations. At present, however, significant work is needed to improve the utility and credibility of EHR-based effectiveness research among payers, manufacturers, clinicians, and academic researchers.

This policy brief was prepared by Darren Zinner and Robert Mechanic of Brandeis University Conference presentations and a more detailed proceedings document are available at www.healthindustryforum.org

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