On the Use of Electronic Health Records to Assess Patient Outcomes and Preventable Harm

Over the past decade, the health care industry—stimulated by new legislation, incentive programs, and technology developments—has undergone a fundamental transformation to enter the digital age. Gone are the days of filing cabinets filled with medical records. The adoption rates of Electronic Health Record (EHR) systems have risen rapidly, and with adoption comes the expectation of “meaningful use of EHRs” to improve health care quality and outcomes and to reduce cost. Recent research has demonstrated that it is indeed feasible to analyze EHR data and to extract valuable information to improve medical decision making. This demonstrated ability to improve patient outcomes and to eliminate harm, together with incentive programs for health care providers to implement EHR systems that realize such meaningful use criteria, creates not only an opportunity but also an obligation for health care providers to develop, to deploy, and to adopt such systems. Patients and their closest relatives can now see from their EHR data whether they received the best care or whether they were exposed to preventable harm. We pos-

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tulate that the transition to digital information and its meaningful use in health care will usher in a new wave of data-driven investigations—and corresponding litigations—of cases with adverse outcomes. This new wave will be driven by an unprecedented transparency of health care providers through patient access to EHR data guaranteed by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Legislative Background


The government has intended that providers roll out meaningful use in three stages from 2011–2016, with the following main components:

- Stage 1 (2011–2012): Data capture and sharing
- Stage 2 (2014): Advance clinical processes
- Stage 3 (2016): Improved outcomes.

Meaningful Use Criteria and How to Attain Meaningful Use, HealthIT.gov (2014), http://www.healthit.gov/providers-professionals/how-attain-meaningful-use (last visited June 12, 2014). While meaningful use Stages 1 and 2 each focus on the ability to capture relevant health information in EHR systems and use it for clinical processes such as e-prescribing and electronic health data transmissions, Stage 3 attempts to leverage information contained in EHR data for decision making to improve outcomes and prevent harm.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which intended to maintain the privacy and security of individually identifiable health information, established a Privacy Rule that grants individuals the right of access to inspect and obtain a copy of their protected health information (PHI) in designated record sets held by a covered entity. Office for Civil Rights, U.S. Dep’t of Health and Human Services, The HIPAA Privacy Rule’s Right of Access and Health Information Technology (2014), http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/eaccess.pdf. This rule applies to both paper-based and electronic health records. As a result, the Privacy Rule, with limited exceptions, offers patients an enforceable means to request copies of their EHR data from a health care provider, and the request must be granted in a timely manner.

Technology Background

Since the enactment of the HITECH Act, health care providers have made steady progress in the deployment of EHR systems and implementation of meaningful use criteria. In 2012, 44 percent of hospitals reported having and using at least a basic EHR system, up from 9.1 percent in 2009, and 42.2 percent met all of the meaningful use Stage 1 criteria. C. M. DesRoches, Adoption of Electronic Health Records Grows Rapidly, But Fewer than Half of US Hospitals Had at Least a Basic System in 2012, 32 Health Affairs 1478–85 (2013); A.K. Jha, Use of Electronic Health Records in US Hospitals, New England Journal of Medicine 1628–38 (2009). However, a strong disparity among hospital systems can be observed, with small, non-teaching, and rural hospitals being at a significant disadvantage. C. M. DesRoches, Small, Non-teaching, and Rural Hospitals Continue to Be Slow in Adopting Electronic Health Record Systems, 31 Health Affairs 1092–99 (2012).

At the same time, considerable research on mining of EHR data has been conducted, partly stimulated by the availability of EHR data from the new systems, and partly incentivized by research funding made available under the HITECH Act as well as the Patient Protection and Affordable Care Act of 2010. The research shows that while the development of analytic techniques to prepare and to mine EHR data for medical decision support is very challenging, it is nonetheless possible to obtain valuable insights both at the patient and the population level. C. Bennett & T. Doub, Data Mining and Electronic Health Records: Selecting Optimal Clinical Treatments in Practice, 1112 arXiv preprint 1668 (2011); T. Botsis, Secondary Use of EHR: Data Quality Issues and Informatics Opportunities, in AMIA Summits on Translational Science Proceedings 2010 1 (2010); N. Ramakrishnan, D. Hanauer, & B. Keller, Mining Electronic Health Records, 43 Computer 77–81 (2010); P.B. Jensen, L.J. Jensen, & S. Brunak, Mining Electronic Health Records: Towards Better Research Applications and Clinical Care, 13 Nature Reviews Genetics 395–405 (2012); S. Bandypadhyay, Data Mining for Censored Time-to-Event Data: A Bayesian Network Model for Predicting Cardiovascular Risk from Electronic Health Record Data, 1404 arXiv preprint 2189 (2014). As such, the work demonstrates the feasibility of achieving meaningful use Stage 3, that is, improving outcomes with EHR data.
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Clinical personnel. In addition, major revisions to existing systems are mandated by law, such as upgrading medical diagnosis and procedure coding systems to the ICD-10 standard by October 1, 2015, further adding to the strain on personnel and budget. Most hospitals are also operating under very narrow financial margins. As a result of all of these constraints, the necessary work to develop, to deploy, and to adopt new techniques focused on improving patient outcomes and eliminating unnecessary harm is often not high enough on the priority list of all the activities that a hospital must undertake to receive required funding and resources.

Case Study
The following case study is based on research conducted by one of the authors in 2010–2012, and was published in a book chapter. See J. Klenk, Y. Sharma, & J. Fan, Saving Lives with Big Data: Unlocking the Hidden Potential in Electronic Health Records—Saving Lives with Big Data, 85th Annual American Health Information Management Association Convention & Exhibit (2013); J. Klenk, & J. Fan, Saving Lives with Big Data, Predictive Analytics World Conference (2012).

Sepsis is an inflammation of the body caused by severe infection. If left untreated, it can rapidly progress to the more serious states of severe sepsis and septic shock and become fatal within a few hours. The death toll in the United States from severe sepsis exceeds 200,000 per year. The mortality rate for severe sepsis ranges from 20–35 percent, and for septic shock from 30–70 percent. J.A. Russel, The Current Management of Septic Shock, 99 Minerva medica 431–58.

The Surviving Sepsis Campaign has developed treatment “bundles” that define the standard of care. Society of Critical Care Management, Surviving Sepsis Campaign, Bundles(2004), http://www.survivingsepsis.org/Bundles/Pages/default.aspx (last visited June 12, 2014). The bundles, first published in 2004, are expected to create a reliable system that achieves the goal of 25 percent reduction in mortality due to sepsis. The bundles contain a series of conditional steps that must be executed in a particular order and within a particular time frame.

Hospitals are implementing training programs to train their staff to deploy the sepsis bundles. When a patient arrives at a hospital with sepsis present on admission, a rapid and correct diagnosis and treatment according to the bundles is critical to achieve the best possible outcome. However, sepsis can also be the result of a health care-associated infection (HAI), which means that it is acquired by a patient during a hospital stay—often as an unwanted and perhaps preventable byproduct of a procedure. The Centers for Disease Control and Prevention (CDC) estimated the prevalence of HAI’s in acute care hospitals at 721,800 in 201. S.S. Magill, Multi-state Point-Prevalence Survey of Health Care-Associated Infections. 370 New England Journal of Medicine 1198–1208 (2014).

With so many lives at stake, hospitals must act to train their staff to prevent unwanted HAI’s, to the extent possible, and to rapidly diagnose and correctly treat patients with an infection before it escalates into sepsis, severe sepsis, or septic shock. Against this backdrop, Mercy Health System engaged with one of the authors of this article and his colleagues in a study to calculate its compliance rates with the sepsis bundles and to develop an early detection system for at-risk patients for sepsis.

A fundamental problem of EHR data analysis lies in the fact that EHR systems are developed for billing purposes and not for clinical research. Data are notoriously dirty and ill formatted for advanced analytics. The key to calculating compliance rates with sepsis bundles from EHR data was a so-called event-centric ontology. J. Fan & J. Klenk, An Event-Centric Ontology (ECO) for Electronic Health Records (EHR), AMIA Annual Symposium (2011). This stitches together all EHR data of a patient into a complete episode of care and links the data to a standardized vocabulary, such as SNOMED-CT, to perform computer-based reasoning. With this setup, a patient’s complete record could be automatically compared against the sepsis bundle requirements, and any deviation from the bundle could be noted. This analysis was conducted for 27,000 patients and yielded a clear correlation between compliance and mortality. Mercy’s overall compliance rate was around 17 percent, in line with nationwide estimates at the time. Some hospitals in Mercy’s system had a much higher compliance rate and a significantly lower mortality rate.

Mercy realized the opportunity to reduce sepsis mortality by improving its compliance rate with the sepsis bundles and quickly implemented a training program for its doctors and nurses. The hospital system estimated that during the first nine months, the compliance rate climbed to above 80 percent, and the mortality rate for patients with severe sepsis and septic shock dropped by approximately 50 percent and 60 percent, respectively, saving nearly 100 lives.

An early detection system to flag patients at risk of developing severe sepsis or septic shock was also developed. Using signal detection, a predictive model was constructed that identified at-risk patients up to two hours before the point of diagnosis—a significant gain for a rapidly progressing condition such as sepsis.
Prevalence of Harm and Investigations

In a recent study the number of deaths per year associated with preventable harm in U.S. hospitals was estimated to be at least 210,000, and more likely about 400,000. J.T. James, A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care, 9 Journal of Patient Safety 122–28 (2013). In addition, serious harm appears to be 10- to 20-fold more common than lethal harm. With the number of U.S. hospitalizations per year reported by the CDC at 35.1 million, this means that a patient admitted to a hospital has about a 1 percent chance of dying from preventable harm and an over 10 percent chance of being harmed in some way. Centers for Disease Control and Prevention, FASTSTATS—Hospital Utilization (2014), http://www.cdc.gov/nchs/fastats/hospital.htm (last visited June 2, 2014)

According to the National Practitioner Data Bank 2012 Annual Report, the number of medical malpractice cases in 2012 was 12,598, and the number of adverse actions was 64,241, for a total of 76,839 reports. U.S. Dep’t of Health and Human Services, Health Resources Services Admin., Bureau of Health Professions, Div. of Practitioner Data Banks. This means that less than 20 percent of deaths associated with preventable harm in hospitals result in an investigation such as a medical malpractice case or an adverse action. That number drops to less than two percent for serious harm.

Discussion

As patients become more aware of their rights to access their EHR data under the Privacy Rule, it is now conceivable that patients exposed to preventable harm will be more likely to request their EHR data to understand better and to evaluate objectively if indeed a “breach of duty” occurred and was a direct or proximate cause of a sustained injury, such as harm, and perhaps, in the case of survivors, death. Currently, only a fraction of all cases of preventable harm are investigated, but the authors could hypothesize that the transition to digital health care may usher in a new wave of data-driven investigations and corresponding litigations or adverse actions.

Indeed, EHR data mining has the tremendous potential to be both a sword and a shield in medical liability litigation. The opportunity for health care providers to improve quality of care and outcomes carries with it, potentially, the obligation and duty to do so. Arguably, health care providers having EHR data and adopting meaningful use techniques to improve outcomes, as demonstrated by the case study above, may well find certain types of cases more effectively and efficiently defensible than ever before. This may become an important part of defending cases when the allegations relate to HAIs and corresponding harm.

Using the case study above as a reference, assume that “Patient A” is admitted to a hospital that has implemented an early detection system for at-risk patients. Although her presentation is unusual, she matches most of the criteria previously derived from EHR data and a presumptive diagnosis of sepsis is made. The sepsis bundle treatment protocol is initiated almost immediately after her history is taken and she is first examined. No time is wasted since the diagnosis is presumptively based on the statistical likelihood that she is developing sepsis. And, because the diagnosis is empirically based on proven statistical data, a clear record of rapid diagnosis and prudent compliance can be easily demonstrated to a judge or a jury if necessary. Even if “Patient A” suffers a poor outcome, which will certainly happen in some cases despite the best care, the defense can prove that she lost no “chance of a better recovery” due to any delay in diagnosis or effective treatment. The relevant EHR data and meaningful use criteria will be admissible with the proper foundation. Fed. R. Evid. 803(4), 803(6); Suire v. Lake Charles Memorial Hospital, 268 So.2d 619 (La. Ct. App. 1991); Hunter v. Office of Health Services and Environmental Quality, 385 So.2d 928 (La. Ct. App. 1980); Sumter v. West Jefferson Medical Center, 02-CA-1103 (La. Ct. App 2003), writ denied, 845 So.2d 1179 (Sept. 26, 2003).

Conversely, if “Patient A” was admitted with equivocal signs and symptoms, and a decision was made not to begin, or no decision was made to begin, the sepsis bundle treatment protocol immediately despite the EHR data, a defense would be challenged. The legal challenges might argue that Patient A did not receive care based on sound medical decision making or as a result of the failure of the health system or facility to adopt meaningful use criteria or promote its use. Either way, if the outcome is poor, or the EHR data is discovered, evaluated, and demonstrated by the plaintiff to have suggested a better treatment protocol, the case will be difficult to defend. In one sense, although courts in many states...