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Opinion paper

Challenges in patient safety improvement research in the era of electronic health records ☆

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ABSTRACT

Electronic health record (EHR) data repositories contain large volumes of aggregated, longitudinal clinical data that could allow patient safety researchers to identify important safety issues and conduct comprehensive evaluations of health care delivery outcomes. However, few health systems have successfully converted this abundance of data into useful information or knowledge for safety improvement. In this paper, we use a case study involving a project on missed/delayed follow-up of test results to discuss real-world challenges in using EHR data for patient safety research. We identify three types of challenges that pose as barriers to advance patient safety improvement research: 1) gaining approval to access/review EHR data; 2) interpreting EHR data; 3) working with local IT/EHR personnel. We discuss the complexity of these challenges, all of which are unlikely to be unique to this project, and outline some key next steps that must be taken to support research that uses EHR data to improve safety. We recognize that all organizations face competing priorities between clinical operations and research. However, to leverage EHRs and their abundant data for patient safety improvement research, many current data access and security policies and procedures must be rewritten and standardized across health care organizations. These efforts are essential to help make EHRs and EHR data useful for progress in our journey to safer health care.

1. Introduction

Over the last six years, the US has spent over $30 billion to incentivize adoption and meaningful use of health information technology (HIT) with the goal of improving the quality, safety, and cost of health care.[1] The benefits of using HIT have long been awaited since the Institute of Medicine's 1999 report *To Err is Human*.[2–6] However, despite widespread adoption of electronic health records (EHRs), digital data is not routinely harnessed to improve patient safety.[7–14] Furthermore, EHR systems were not developed with aims of measuring and tracking patient safety, undermining the ability of EHRs to reduce the occurrence of adverse events.[6]

EHR data repositories contain large volumes of aggregated, longitudinal clinical data that could allow patient safety researchers to identify important safety issues and conduct comprehensive evaluations of health care delivery outcomes.[15] These evaluations could include better ways to measure clinical care and identify gaps in care and opportunities for improvement.[16–21] EHRs have the potential to be used to address many known safety issues using data that are already routinely documented. For instance, they can identify patients at risk for falls via reminders triggered by age and other risk factors, such as whether patients are prescribed psychotropic medications.[22–24] EHRs can also identify potential adverse events, which often go unreported.[25] Furthermore, EHRs allow mining of real-time clinical data, enabling detection of problems and intervention before harm occurs, as opposed to retrospective data sources such as claims files or Patient Safety Indicators.[26] Clinical data also better represents how patient care was delivered than administrative data,[27] which is optimized for billing purposes instead.[28] EHR data is thus potentially richer, more actionable, and more accurate than billing or claims-related data for patient safety improvement efforts.[29] However, few health systems have successfully converted this abundance of data into useful knowledge for system improvement,[30–32] even though the time to do that is ripe. In this paper, we use a case study to illustrate real-world challenges in

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using EHR data for patient safety research and outline some key next steps that must be taken to support emerging research in this area.

2. A case study: Patient safety research in EHR-based clinical settings

We previously used data from the Veterans Health Administration's well-established EHR to understand instances of missed and/or delayed diagnosis.[17,21] We identified several vulnerabilities, both technical (e.g., design flaws in EHR-based test results notification "in-boxes") and nontechnical (e.g., workflow issues and diffusion of responsibility), that affected timely follow-up of diagnostic test results.[33] The recent Institute of Medicine (IOM) report *Improving Diagnosis in Health Care* discussed the significance of delays in diagnosis and made several recommendations for optimizing the use of EHRs, including use of electronic data to measure and track potential diagnostic errors.[34] One strategy to accomplish this is by developing "trigger" algorithms that analyze patient data collected in EHRs and identify patients whose abnormal test results may not have been followed-up on a timely basis.[17,35,36] In a randomized controlled trial, we tested whether the prospective use of these EHR-based trigger algorithms could prevent delays in diagnostic evaluation for lung, colorectal, and prostate cancer. We found that EHR-based trigger interventions reduced the time to diagnostic evaluation of colorectal and prostate cancer and increased the proportion of patients who received appropriate follow-up.[17]

We were subsequently funded to evaluate technical and nontechnical vulnerabilities of EHR-based test results notification systems in commercial EHRs. Our "sociotechnical" approach accounts for vulnerabilities that arise when health IT interacts with people, work processes, and other organizational factors.[37] We are conducting these studies in three private health care systems that use commercial EHR-based test result communication systems. Our project involves querying certain test results in EHR databases at each site on a weekly basis, performing chart reviews to determine appropriateness of follow-up of patients with abnormal results, and recruiting selected providers involved in care of these patients for interviews to understand and optimize EHR-based communication processes. Test results we are querying include abnormal Pap smear, abnormal urine culture, abnormal CT Chest, abnormal chest X-ray, abnormal pathology, abnormal electrocardiogram, TSH $>$ 10 mIU/L, urine microalbumin $>$ 30 g/mL, AFP $>$ 20 IU/mL, and hemoglobin between 8 and 11 g/dL. A case is considered delayed if no action was taken (e.g., including documenting that the test result was communicated to the patient, ordering repeat or follow-up testing, referring to a specialist, altering medications, documenting intentional inaction, indicating that a patient pursued care at an outside facility, or documenting that a patient declined action) within 14 days of the provider receiving the abnormal result. EHRs in use include Epic Systems (Verona, WI) (2 sites) and GE Centricity (Buckinghamshire, U. K.).

Based upon data we assimilated for reporting project milestones, documented external communication with study sites (including emails), documented internal research team communication (team meeting notes, emails), as well as our own personal experiences, we identified at least three types of barriers patient safety researchers are likely to face: 1) gaining approval to access/review EHR data; 2) interpreting EHR data; 3) working with local IT/EHR personnel. We have no reason to believe that these challenges are unique to institutions we worked with. Below, we discuss these challenges in detail and recommend next steps to advance research that helps realize EHRs' full potential to improve patient safety.

3. Challenges in gaining approval for researchers to access/review EHR data

3.1. Restrictions on remote access and review personnel

Researchers must be able to access and review EHR data to conduct patient safety research. However, we found superfluous restrictions on remote data access for researchers. This was best illustrated at Site A, where the organization's internal research oversight team would not provide approval for remote access to the organization's EHR despite approval by the local institutional review board (IRB). The local policy at this site prohibited EHR data from physically or electronically leaving the site or system, even with appropriate oversight and data protections. Thus, researchers were unable to access Site A patient charts even via a site-approved secure virtual private network (VPN). Moreover, Site A's research oversight team required an employee of their organization to perform record reviews at the clinic site. These restrictions seemed excessive considering security standards already in place to ensure secure remote access for employees of the institution. While this stipulation undermined one of the main benefits of EHRs (remote accessibility of patient information), we overcame this barrier by employing an eligible reviewer from an academic affiliate of Site A to review charts on site.

3.2. Restrictions on type of access

One important feature of our protocol was an explicit procedure to communicate with providers about any urgent test results that appeared to have been overlooked. We decided that the secure messaging feature within the EHR was the most efficient and secure means of alerting providers to potentially missed test results. While Site B clinical leadership supported this method, internal data security policies permitted only "minimal" remote chart access for researchers. This meant that we did not have the ability to use all features and functions of the EHR system, including EHR-based secure messaging. Thus, in order to be able to communicate with Site B providers, we devised a complicated workaround that involved gaining access to the site's secure intranet system and obtaining institutionally affiliated email addresses for our team members. After much trial and error, we concluded that the workaround was impractical, and we resorted to telephoning providers to discuss specific patient cases.

3.3. Restrictions on network connection

An additional barrier included strict data security protocols regarding access to Site C data from our team's institution. These protocols required use of Citrix virtualization servers to access remote facilities, as opposed to use of a direct network connection (e.g., VPN) to the external organization. Initially, a compatibility issue prevented any connection at all between our institution and Site C's data server. Our institution's IT personnel suggested workarounds using less secure methods, such as copying data to optical media from one of Site C's computers, and then physically transporting it to our facility. A timely and fortuitous upgrade of software at Site C allowed us to circumvent the security restrictions and overcome the compatibility issues with the virtualization portal method. However, unlike a direct VPN connection, data downloading via the virtualization portal was fraught with network connection quality issues, resulting in frequent disconnections when downloading larger amounts of data (Table 1).

Table 1.
Summary of barriers to researchers gaining approval to access/review EHR data.

	Site A	Site B	Site C
Barrier Encountered	• No remote access to patient charts for researchers • Reviewer must be employee of organization	• Minimal chart access meant no internal messaging feature for communicating patient information to providers	• Our own organization security protocols kept us from directly importing data from this site (e.g., through VPN)
Workaround	• Employed an eligible reviewer who was credentialed by the organization • Traveled to the site weekly to review charts	• Called providers via telephone to discuss patient cases	• The site upgraded the portal used for accessing and downloading data (albeit with poor connection)

4. Challenges in interpreting EHR data

Researchers must be able to understand and query data in EHR data repositories (or work with IT personnel who can do so). We experienced two main barriers in retrieving (i.e., creating and executing EHR database queries) and interpreting data contained within EHRs. First, we found that sites had variable amounts of structured EHR data (i.e., lack of “normal” or “abnormal” codes for test results), and often the same field was structured at one site and unstructured at another site, making cross-site automated comparisons difficult or impossible. Structured data is important because it can help computer algorithms garner meaning from the data and has been a focus of meaningful use (MU) requirements.[38] Despite ongoing enthusiasm about ‘ "big data" and EHR analytics in health care, we faced challenges with accessing even basic levels of structured data. Notably, all three sites met Stage 1 MU requirements, meaning that they all used a certified EHR as prescribed by the meaningful use regulations associated with the 2009 HITECH Act.[39] However, at all three sites we were informed by IT staff that there was no method for the computer to automatically identify significantly abnormal radiology, pathology, microbiology, and certain clinical laboratory results. As a result, at each site, our reviewer received a list of all tests performed and manually sorted and organized them to determine which medical records to review. Second, native reporting and analytic capabilities of the EHRs in our study were limited, which required us to do a significant amount of manual work. For example, at Site B, the only method of data output was use of static portable data format (PDF) files, making transcription into editable databases a tedious and potentially error-prone process.

5. Challenges in working with local IT/EHR personnel

Researchers must be able to work closely with local IT/EHR personnel who are knowledgeable and responsive to needs for research for improving patient care. Despite clinical leadership buy-in, we experienced barriers to working with local IT/EHR personnel because of their competing operational priorities at all three sites. We found that organizational IT personnel at all sites were significantly resource-constrained and had many competing priorities, particularly related to MU implementation and EHR upgrade-related issues. This resulted in delays in understanding several data-related issues and in getting EHR queries operationalized. Site A was engaged in an EHR upgrade for approximately 4 months during which all research-related tasks remained untouched.

Additionally, IT staff at all three sites experienced difficulty in identifying, extracting, and understanding data needs from the clinical and research perspective.[40] For example, despite specific instructions provided by our team, the EHR database administrators at Site B failed to differentiate between test results for hemoglobin (e.g., used to identify patients with anemia) and hemoglobin A1c (e.g., used to identify patients with diabetes) results and provided a list of hemoglobin A1c results labeled as “hemoglobin.”

Again at Site B, after several weeks of reviews, we noticed unusual patterns in the proportion of tests being resulted. Further investigation revealed that the results of only those tests ordered during visits were included in the output. Since many physicians order pre-visit labs, the majority of results were not included. At Site C, after several failed attempts to develop reports that included only the tests results of interest delivered to study participants within a pre-specified time period, IT staff reported that they were unable to dedicate sufficient time to understand the needs of our research project.[41] As a solution, our team was granted more access to the data. However, this arrangement was not optimal due to frequent technical failures (e.g., server disconnects and crashes when querying large amounts of data), poor quality and incomplete data, and slow and inadequate analytic tools (e.g., limited filtering capability). Ultimately, to prevent data management and transfer problems, we decided to import all test result data each week and perform filtering and analytics locally using Microsoft Excel (Redmond, WA). This task was only able to be completed with the help of our local research team's programmer, who pulled the correct data set for our chart reviewers on a weekly basis.

6. Key lessons

To enable progress in patient safety improvement through EHRs and EHR-based research, we summarize key lessons learned and some next steps. Although our failure to gain easy remote EHR access was disappointing, it was not surprising given that most organizations fear a large-scale breach of protected health information,[42] especially in light of several recent highly publicized cases.[43] Because of such breaches, no matter the strength of security of the IT system, health care organizations will likely remain concerned with their potential occurrence. While these large scale breaches are worrisome, most do not appear to be targeted hacks by sophisticated groups, but rather the result of local IT organizations not taking appropriate security precautions.[44,45] After institutional review, patient safety research projects should be deemed safe to carry out, assuming the organization has implemented robust firewalls and advanced level 3 authentication procedures as outlined by the National Institute of Standards and Technology (NIST).[46] Applying these measures to all remote users would greatly reduce an organization's security risks[47] and allow clinicians and researchers alike to make better use of EHR data remotely to improve patient care.

The lack of key structured data in EHRs was not surprising given that many organizations have implemented their current EHRs

to avoid making structured data entry by clinicians too onerous, and to minimize the complexity of structured data transmission at the interface between the EHR and external ancillary services (e.g., laboratory, pharmacy, and radiology).[48,49] For example, many laboratory-to-EHR interfaces use a rudimentary "print to file" or electronic fax feature to transfer laboratory test results into the EHR, which has the unintended side effect of converting structured data into free-text. If health care is to achieve the promised benefits from EHR implementation and use, all stakeholders in the EHR community (i.e., clinicians, health care organizations, EHR developers, payers, and regulators) must come together and identify a minimum set of coded data that should be routinely collected, maintained in coded form, and able to be exported electronically. Following the lead of the Veterans' Affairs health system, we would argue that the interpretation of all laboratory and radiology test results should have at least coded designations such as "normal" or "clinically significant abnormal" due to the high potential for missed abnormal results leading to patient harm.[50–52]

Most organizations' IT strategies prioritize goals related to tight MU implementation timelines, and IT personnel effort is allocated accordingly. Nevertheless, now that the majority of health care organizations have implemented EHRs, it's imperative to use them for safety improvement. Institutions such as the Department of Veterans Affairs, Intermountain Healthcare, and the University of Utah[53] for example, have invested in using EHR data for improvement over the past 20 years. We posit that all organizations (not just those with "research" as part of their mission) should dedicate additional IT personnel and implement near real-time clinical data warehouses with easy-to-use report writing capabilities[54,55] to support quality improvement and patient safety improvement efforts. This would allow current IT staff to focus on operational activities.[56] Unfortunately, our experiences reveal that the IT workforce for health care is often ill-prepared, lacks the necessary tools and resources, and is deficient in the clinical and workflow insights and experience necessary to address both research and non-research tasks related to extraction and analysis of EHR data.[57] If such knowledgeable and experienced IT professionals existed, then perhaps grant funding could pay IT personnel who serve the research needs of unaffiliated or affiliated scientists. If IT personnel cannot be paid out of grants, some of these problems could be overcome if research programmers could have better access to EHR data.

7. Path forward

There appear to be major barriers to advancing research designed to help realize the full potential of EHRs to improve patient safety. Lofty goals have been proposed for improving quality and safety using EHR data, but the reality is that little progress has been made toward achieving them.[6,31,32,58] Many leading EHR development organizations and health care organizations are creating near real-time, comprehensive, clinical data warehouses to allow for both operational demands and quality improvement and research efforts.[54,59] Concomitantly, some academic medical centers (AMCs) are now working to develop a new workforce of technically-trained, yet clinically-focused, staff required to create what the IOM refers to as a "Learning Health System."[60,61] Towards this end, some AMCs are also creating new departments of data science[62,63] or informatics institutes [64,65] to provide an academic home for this new workforce.

Finally, the development of the new SMART (Substitutable Medical Applications and Reusable Technologies) on FHIR (Fast Health Interoperability Resources)[66] standards-based application programming interfaces (APIs) for data transport, user authorization, and data display coupled with endorsement of several standard medical terminologies for coded data has potential to reshape the clinical data interchange, display, and access landscape for both clinicians and researchers (Table 2).[67]

Anecdotal and published evidence suggests that our experiences are not unique.[30,68] With the rapid implementation of commercially-developed EHRs at most large medical centers, access to underlying data and use of that data to improve safety is yet to become commonplace. We recognize that organizations generally face competing priorities between clinical operations and research. However, EHR-related patient safety research must be prioritized because it is so closely integrated with clinical operations and could lead to faster systems and process improvements than many other types of research.

To develop best practices to leverage EHRs and their abundant data to promote patient safety improvement research, many current data access security policies and procedures must be rewritten and standardized across health care organizations. Only this large-scale, systems-level effort will help make EHRs and EHR data useful for improving patient safety, quality, and efficiency. We hope this case study is valuable to stimulate actions that lead us closer to these goals.

Table 2.
Summary of challenges and solutions to improving health care through use of EHR data.

	Solutions	
Challenge	**EHR Vendor Responsibility**	**Health Care System Responsibility**
Researchers Gaining Approval to Access/Review EHR Data	Develop and integrate 2-factor authentication into existing EHR login procedures	Develop policies requiring 2-factor authentication, distribute remote access tokens, train clinicians to use them
Interpreting EHR Data	Develop and distribute current data dictionaries and create application programming interfaces for key data items used in the EHR application	Provide basic clinical informatics training to key IT personnel; create clinical data warehouses to facilitate access to clinical and administrative data
Working with Local IT/EHR Personnel	Provide or identify well-trained clinical informatics personnel to assist organizations in extracting key clinical and administrative data for QI and patient safety research	Re-prioritize IT staffing or add dedicated staff to ensure adequate coverage for quality improvement (QI) and patient safety research support

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Conflict of interest statement

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