Using EHRs to integrate research with patient care: promises and challenges

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ABSTRACT

Clinical research is the foundation for advancing the practice of medicine. However, the lack of seamless integration between clinical research and patient care workflow impedes recruitment efficiency, escalates research costs, and hence threatens the entire clinical research enterprise. Increased use of electronic health records (EHRs) holds promise for facilitating this integration but must surmount regulatory obstacles. Among the unintended consequences of current research oversight are barriers to accessing patient information for prescreening and recruitment, coordinating scheduling of clinical and research visits, and reconciling information about clinical and research drugs. We conclude that the EHR alone cannot overcome barriers in conducting clinical trials and comparative effectiveness research. Patient privacy and human subject protection policies should be clarified at the local level to exploit optimally the full potential of EHRs, while continuing to ensure participant safety. Increased alignment of policies that regulate the clinical and research use of EHRs could help fulfill the vision of more efficiently obtaining clinical research evidence to improve human health.

Clinical research, including clinical trials and comparative effectiveness research,[1] provides the foundation for improving medical treatment. However, recruitment efforts and research workflow inefficiency are driving up the costs of research and hence threatening the clinical research enterprise.[2] Clinical research requires collaboration between clinicians and researchers, but such collaborations are poorly supported. A fundamental problem is the lack of alignment between clinical research and patient care workflows. Efforts to recruit patients into studies often interrupt clinical workflow and place heavy burdens on time-pressured clinicians and administrators.[3] Another major barrier to participation in clinical research for clinicians is that the time commitment to accommodate research generally goes unrewarded. Research activities can also create conflict at practice-based clinical research sites over limited resources (eg, staff, exam rooms, and equipment), discouraging many clinical sites from participating in research. The lack of coordination between research and clinical workflows often results in redundant visits and tests for patients, discouraging their participation as well.[4]

With the goal of transforming the US clinical research enterprise, the Institute of Medicine has called for a 'learning healthcare system' to accelerate cost-effective generation of new evidence directly from and applicable to patient care processes.[5][6] This new model envisions conducting clinical research as a byproduct of patient care.[7] The increasing adoption of electronic health records (EHRs) offers the exciting opportunity to permit rich data collection and longitudinal analysis of patients[8] and to increase coordination between patient care and patient-oriented research activities, while reducing the burden on physicians, patients, and healthcare delivery. EHRs can be used to automate prescreening and, in turn, can significantly improve recruitment efficiency and reduce costs by excluding up to 90% of ineligible patients who do not merit further review.[9] Yet, clinicians still have the potential to play a key role in assisting researchers with recruitment. For example, one study demonstrated that discussing potentially eligible patients identified via EHR searches with treating clinicians excluded an additional 60% of potentially eligible patients for reasons not readily identifiable by EHR scanning, such as alcohol abuse, terminal illness, medication non-compliance, or limited mobility.[10] Therefore, a potentially cost-effective approach that would facilitate collaboration between clinicians and clinical researchers would make use of EHRs to (1) automatically prescreen patients to identify those who are potentially eligible for research studies,[9][10] (2) prompt clinicians about research opportunities for potentially eligible patients at the point of care,[11] (3) facilitate contact between researchers and clinicians to gather additional eligibility information, (4) monitor scheduled clinic visits for eligible patients, (5) automatically send information on eligibility and visit schedules to study coordinators, who could then approach potentially eligible patients in connection with clinical visits for final screening and possible consent,[10] and (6) allow co-scheduling of subsequent clinical and research visits for study participants to minimize unnecessarily redundant test orders.

Helpful as they can be, EHRs alone cannot transform the clinical research enterprise. Table 1 lists major barriers to achieving the above vision, our recommendations for needed changes, and the identity of specific stakeholder groups that can act to overcome the barriers. The first important barrier is acquisition of clinical data directly from clinicians.[12] Information incompleteness and other data quality issues are typical complaints about EHR data for research. As a result of differences in priorities between patient care and clinical research settings, clinical data are not recorded with the same care as research data.[13] It is also believed that EHRs have led not to improvements in the quality

Table 1 Recommendations to optimize electronic health records (EHRs) for research

Barriers	Recommendations	Actions needed from
Inaccurate diagnostic codes and problem lists can cause errors in electronic prescreening of patients	Improve the accuracy of problem lists in EHRs	Informaticians*
	Incentivize clinicians to keep accurate and complete problem lists	Clinicians Administrators
Independent payment systems for patient care and clinical research	Incentivize and compensate clinicians for their support for clinical research, especially during recruitment and research data collection	Administrators Policy makers
Institutional privacy rules can limit use of EHRs to prescreen patients for research	Allow granting of access to medical records to collaborating researchers	Policymakers (DHHS) Local IRBs
	Ensure that the implementation of patient privacy protection rules by local IRBs does not impede research	Policymakers (DHHS)
	Enable appropriate information sharing and awareness support between care and research teams	Informaticians Policymakers (DHHS)
Overly conservative interpretation of the 'common rule' regulations to require primary care providers to give permission to approach patients identified through EHR screening potentially negates some of the benefits of EHR screening	Limit requirements for PCP approval to higher-risk clinical research protocols and clarify rules for selecting appropriate care providers who can give permission to researchers for prescreening and patient contact	Administrators Local IRBs
Difficulty may exist in identifying primary clinicians caring for patients in EHRs, which is important for communication between researchers and clinicians	Improve the completeness of documentation and ability to retrieve the identity of clinical care teams in EHRs	Informaticians Clinicians
Failure to maximize potential for collaborative scheduling between clinical and research visits can occur as a result of privacy issues or lack of harmony between research and clinical uses of EHRs	Grant ongoing access to clinical visit schedules by researchers for coordinating clinical and research visits	Policymakers (DHHS) Administrators
	Enhance EHRs to coordinate clinical and research visits for research participants	Informaticians
Mechanisms are lacking to add data on clinically relevant research interventions (eg, study medications or therapies) or test results to research participants' EHRs, which can adversely affect clinical care	Create 'meaningful use of EHR' rules that maximize safety for research participants	Policymakers (ONC)
	Provide informatics innovations to allow authorized, specific information update in the EHR by researchers	Informaticians
	Provide medication reconciliation for research patients using data from both patient care and clinical research	Informaticians Policymakers (DHHS)

*Informaticians are professionals who practice informatics, including biomedical informatics researchers and EHR vendors.
DHHS, Department of Health and Human Services; EHR, electronic health record; IRB, institutional review board; ONC, Office of National Coordinator (the originator of the meaningful use rules for EHRs); PCP, primary care provider.

of the data being recorded, but rather to the recording of a greater quantity of bad data.[14] The imprecision of ICD-9 coding of medical problems and incompleteness in problem lists can cause errors in electronic prescreening of patients.[15] More structured data entry based on clinical data standards may improve data quality but can slow down clinicians.[16] As McDonald pointed out, 'we have not quite figured out how to capture the data from the physician in a structured and computer-understandable form.'[16]

To solve this multifaceted problem, we need to closely engage both informaticians and clinicians. Informaticians who design EHRs could improve the accuracy and completeness of problem lists and facilitate their use for research by providing a better documentation interface with built-in consistency and completeness validation. Structured narrative[17] should be explored as a potential solution that improves data documentation quality while maintaining flexibility for clinicians. Clinicians also need to be incentivized to keep up-to-date, accurate problem lists in some standardized fashion and be mindful of how their recording practices can impact clinical research. The current separation of payment systems between healthcare and research needs reform. Policies for compensating clinicians for supporting research need to be defined. Such policies may vary between academic medical centers and community-based practices. The clinical research and patient care processes can hardly be integrated if there is not a clear understanding of roles and compensation for work.

Another major barrier stems from local policies intended to comply with federal regulations to protect patient privacy. In May 2002, the HHS Office of Inspector General issued a report entitled, 'Clinical Trial Websites: A Promising Tool to Foster Informed Consent.'[18] The Office of Inspector General report recommended institutional review board (IRB) review of any prescreening used for specific trials, which therefore becomes an approach adopted by many IRBs. Indeed, in many institutions, as exemplified by the guidelines for research recruitment at the Johns Hopkins University,[19] the patient recruitment plan must be approved by the local IRB and researchers are required to obtain a waiver, The Application for IRB Waiver of HIPAA Privacy Authorization,[19] for using protected health information for prescreening. Even though scanning EHRs can efficiently identify potential research participants, IRBs may reject such requests from researchers out of concern that such practices violate the federal health information privacy regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA).

Without explicit patient authorization, HIPAA regulations generally limit access to medical records in entities covered by the rules, that is, most health providers, health plans, and healthcare clearinghouses, to persons directly involved in treatment, billing, or healthcare operations. However, as noted by the Institute of Medicine committee charged with examining the effects of HIPAA on clinical research, many of the obstacles result from overly conservative interpretation of the HIPAA regulations or the federal regulations on protection of human subjects by local IRBs.[20] For example, according to the HIPAA regulations, researchers who are members of the covered entity's workforce can conduct activities preparatory to research involving access to patient data without patient authorization or a formal waiver (45 CFR 164.512(i)(1)(ii)). Contrary to the determinations of some IRBs, this regulation allows these researchers to use protected health information in the EHR to

identify and contact prospective research subjects even without a formal waiver,[21] although IRB approval may be desirable and in some places will be required by institutional policy or state law.[21 22] Although patients generally want to control access to their records for research purposes,[23] we know of no data documenting patients' views on access simply to identify their eligibility for research, which may be quite a different matter. Clinical administrators and IRBs need to use the flexibility already built into existing regulations to facilitate the research process.

Another barrier that impedes EHRs from making recruitment more efficient is the refusal by some IRBs to allow researchers to approach patients identified by automated EHR prescreening without obtaining permission from patients' primary care providers (PCPs).[24] Although not mandated under the federal research regulations (the 'common rule'), the requirement of first obtaining PCP consent before approaching patients is thought to protect patients' well-being and privacy,[24] but can be problematic for several reasons. First, allowing PCPs to decide for a patient whether even to consider research participation may violate patient autonomy,[25] and requiring PCPs to introduce the study may lead patients to feel unduly pressured to participate.[26] In addition, it is often difficult to ascertain the identity of patients' PCPs[27]; some commercial EHRs fail to record the members of the care team.[28] Currently, many complex multispecialty provider networks have no formal policies for identifying which clinicians can authorize researchers to contact potentially eligible patients. Even when appropriate PCPs can be identified, they may shy away from allowing their patients to be approached out of concern that they lack both the knowledge to respond to patients' questions about the studies and the time for such discussions. Nor is it practical to expect busy clinicians to familiarize themselves with the details of research protocols; thus, even when PCPs grant permission for patients to be approached, it may not reflect informed judgments by the PCPs. Although clearance by PCPs may make sense for some higher-risk studies—and an argument can be made that the increased ease of screening EHRs to identify potential subjects could lead to multiple requests of a particular patient, calling for someone to play a gatekeeper role—routine reliance on PCP agreement is neither sensible nor efficient. Policymakers should limit requirements for PCP approval to higher-risk clinical research protocols and clarify rules for selecting appropriate care providers who can give permission to researchers for prescreening and patient contact.

For collaborative scheduling of clinical and research visits, a significant barrier is that researchers often have difficulty accessing patients' clinical visit schedules. Researchers not directly involved in a patient's care may be precluded by HIPAA from ongoing access to scheduling information without specific patient authorization. Even with patient authorization, when research staff external to the covered entity need access to patient information, they may not be able to obtain it. A similar unsolved problem involves medication reconciliation for research participants. Often, researchers are not permitted to enter data into EHRs and therefore are unable to indicate that the patient is enrolled in a clinical trial or to note study medications and research laboratory results. Absence of such information could lead to adverse outcomes when uninformed care providers prescribe drugs that interact with research drugs. Although informaticians could create more sophisticated, research-friendly access models, and provide secure mechanisms to allow information sharing between researchers and clinicians, policymakers at the US Department of Health and Human Services (who oversee both HIPAA and human subject protection regulations) need to create appropriate privacy policies that reduce barriers for researchers. The collection of data to document the frequency and severity of the ways in which current regulatory approaches inhibit research will be essential to stimulate such changes.[29]

Integration of clinical research activities with the process of patient care would benefit patients, clinicians, and researchers, but cannot be achieved by increased use of EHRs alone. Policymakers, administrators, IRBs, and informaticians all have important roles to play. For example, regulatory changes are needed to reconcile the implementation of HIPAA regulations with federal regulations for human subject protection and to maximize the value of EHR data for research, for example, by clarifying and harmonizing rules governing activities preparatory to research, which may include access to EHR data.[20] Achieving this integration will likely require interdisciplinary collaboration among ethics researchers, informatics experts, clinicians, clinical researchers, and policy makers. Protecting the safety and privacy of research participants while utilizing technological advances to promote clinical research will require everyone involved to accommodate appropriate protections for research participants while capitalizing on EHRs' potential to facilitate research.

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