Reg-ent within the Learning Health System

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Abstract

Clinical data registries are perhaps one of the most powerful outcomes of electronic medical records, and their benefits are projected to redound to patients and clinicians across the nation. The American Academy of Otolaryngology—Head and Neck Surgery Foundation’s Reg-ent fits within the conceptual framework of a learning health system. Because the data within this system are deidentified, research informed consent is not legally required. But ethical concerns remain regarding whether and how to best notify and whether to obtain consent from patients whose data are included. Particularly because data corroborate that a substantial minority of survey respondents believe that consent should be obtained for each research protocol (even for deidentified research) and because data breaches are, unfortunately, a serious risk, we recommend that the American Academy of Otolaryngology—Head and Neck Surgery Foundation ensure best practices for patient engagement as it continues to build Reg-ent.

Keywords

learning health system, electronic medical record, data registry, research ethics, informed consent

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As clinical practices continue to shift to implementation of electronic medical records (EMRs), advantages include ease of access and data sharing for the patient sitting in front of us—but also to patients and clinicians across the nation. Clinical data registries are perhaps one of the most powerful outcomes of EMRs, many of which have been initiated by specialty area. Many professional societies have already started this exploration of what clinical data registries can do to help not only the individual patient but also the practice, the specialty, and the future of care. National registries also exist, such as the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, but only 1.7% of these visits focused on otolaryngology complaints.1 Given the distinct nature of diseases with which we grapple,2 the American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) has created its own data registry, Reg-ent, to capture data for quality assurance, outcome improvement, and guideline adherence.2

Clinical data registries such as Reg-ent fit within the conceptual framework of “learning health systems” (LHSs), defined by the Institute of Medicine in 2007 as health care systems “in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.”3 LHSs can be institutionally or practice oriented, but they raise complex questions about the clinical care–research divide. From a legal perspective, that divide is sharp: while medical practice is generally given wide latitude by federal and state regulators, research is highly scrutinized. Human subjects research, under the latest federal revisions, includes studies that involve an intervention or interaction with a living individual or analysis of his or her identifiable biospecimens or data.4 Therefore, under the law, the step of deidentifying EHR data—done in Reg-ent by the “Registry Practice Connector.” But if federally funded researchers wanted to access identified data from Reg-ent, patients would generally have to provide informed research consent. Because the data are deidentified, such consent is not legally required.

But while the law might be satisfied, ethical concerns remain. The ethics of LHSs rest on a 2013 foundational framework laying forth several ethical obligations.5 Many of these are ubiquitous, such as respect for persons, but several are new—including an ethical duty for health care professionals, institutions, and patients to “be active contributors to learning in health care.”6 As the authors describe, the goals of LHSs “cannot be reached efficiently without near-universal participation in learning activities, through which patients benefit from the past contributions of other patients whose information has helped advance knowledge and improve care. . . . A learning health care system

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must have continuous access to information about as many patients as possible to be efficient, affordable, fair, and of highest quality.”5 Faden et al do not suggest that this obligation to learning hold regardless of risk or burden. If research is invasive, full informed consent is appropriate. But the authors specifically highlight learning activities such as “participation in a registry” or “reviews of deidentified medical records” as circumstances in which patients would have such an obligation to contribute.5 Still, of note, this framework and others like it assume (at least) notice of both benefiting from as well as participating in such a learning system.

This normative assumption favoring patient notification of involvement in LHSs is also backed by empirical data. While the majority of survey respondents with cancer think that secondary research use of data is important (72%), a substantial minority believe that consent should be obtained each time, even for deidentified research.6 Of particular concern is not just use of data but the user: pharmaceutical and insurance company access to such data systems is considered suspect.8,9 Throughout, trust acts as a bedrock element of comfort in contributing to the LHS enterprise.7 In addition, we cannot guarantee that such systems will not be breached. Data systems, including EMR ones, are frequently compromised—we also know that some types of “deidentified” data can be reidentified.

Beyond HIPAA-mandated disclosure of use of protected health information is a heightening ethical debate about how we use biospecimens and health data for research in this country. In the shadow of Henrietta Lacks10 and stories like hers, the tide of deidentified research without consent is beginning to turn.4 In the new human subjects research regulations, for example, those entering into the system as research participants will generally need to be notified that their data may be stripped of identifiers and used in infinite secondary research protocols if this is a possibility.4

In addition, learning health systems are two-way streets. It is not just patients who will benefit—practitioners will as well. This includes largely altruistic gains, such as improved performance, but potentially more self-serving ones, such as streamlining reporting for the Merit-based Incentive Payment System.

Given these concerns, we believe that the AAO-HNSF should ensure best practices for patient engagement as it continues to build Reg-ent. This may include recommending a more formal notification/consent process for patients or additional community review of proposed systems and protocols. Patient voices should be a critical component of this process. Data registries and LHSs are indeed the future. But we all recognize the critical nature of trust to the doctor-patient relationship. Let us not forget the complex ways in which it is both forged and compromised.

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