Improving Informed Consent and the Transition to Electronic Health Records

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The use of computerized record-keeping and information sharing has become commonplace in most every business sector worldwide. Yet, the healthcare system in the United States is still predominantly paper-based: fewer than 20 percent of all hospitals have fully integrated electronic health records (EHR) into their clinical processes.[1] Starting in fiscal 2011, the federal government is investing upwards of $30 billion in an effort to stimulate further adoption of these systems in both hospitals and private physician practices. While there are hundreds of systems from which to choose, most providers eligible for these incentive payments will select their EHR and supporting systems based not on whether these systems enhance the physician-patient relationship, but upon the functionality that meets the requirements set forth by the government in order to qualify for incentive payments.

To complicate this potentially lost opportunity, a growing number of ancillary systems are being introduced in order to manage the process of obtaining and documenting informed consent, and while they are marketed as tools to keep better track of the required forms, they are also marketed as tools to simplify the process of "informing" patients of risks, benefits and options. Furthermore, new laws related to privacy and security in EHRs add a new dimension to the issue. While considering the informed consent process, and the coming opportunities to improve it, three areas of concern emerge and must be addressed as we transform healthcare through technology: 1) Technology's dehumanizing effect; 2) Extending informed consent into the patient domain; 3) The growing complexity of "consent" requirements.

Technology's dehumanizing effect

As the healthcare sector becomes increasingly reliant on information technology to support care, it is critically important that clinicians are not the only beneficiaries. The most obvious benefits to a clinician using automated informed consent management systems are efficiency and reduced risk; and the patient gains too, as better document management translates into another level of checks and balances, with an expectation of improved patient safety.[2] It would be easy to start relying on consent management systems merely as a tool used to *obtain* consent, rather than as a technology used to *support* a more complex process of informing the patient about procedures, options and risks. Additionally, no automated documentation system is capable of judging the patient's capacity to consent. This can only come about through continued interaction between the clinician and patient.

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[1] American Hospital Association 2008 member survey

[2] Consent Redux: Derreberry; Health Management Technology, February, 2008

Therefore, it is imperative that automated systems are designed in such as way as to create a framework for the longer-term process of establishing a truly informed patient, with the expectation that this is not a stand-alone process, but an automated *component* of a process that involves more than obtaining a signature from the patient. The interaction between clinicians and patients must be maintained, and must be the primary dimension of the informed consent process. Otherwise, an over reliance on automation can widen the gap between healthcare professional and patient. The goal here is to share enough medical knowledge about a procedure so that consent is truly informed.

Clinicians have another advantage over technology in that they possess the ability to adjust to the patient's level of knowledge, reading ability, and capacity to understand. Creating easily comprehended documents that must explain complex concepts is not an easy task. Even when educational materials delivered through various media are created for a relatively modest reading comprehension level, misconceptions and misunderstandings still occur. Here, the process of obtaining informed consent benefits from the addition of an additional "check" for comprehension, which involves interacting with clinicians, not the computer or passive educational materials.[3] We must not lose the human component of the process.

Extending informed consent into the patient domain

Technology enables the clinician and patient. More medical information is found on the internet today than ever before, and more people are taking advantage of it. Still, the quality of the information available online varies widely, and it can be difficult to ascertain that which is trustworthy and consistent with today's best practices. Here again, technology brings this wealth of information to anyone with access to a computer, but at the same time complicates matters given the sheer volume of information. The trick is separating the noise from that which can benefit patients. The move to EHRs and personal health records (PHR) offers an opportunity to engage the patient in the care process. While an EHR contains information about a patient's history of care across domains, the PHR contains information that is primarily controlled by the patient.[4]

Currently, the PHR contains demographic information, allergies, medication and treatment information, as well as any advanced directives or medical power of attorney notices. Increasingly they will be used to record day-to-day clinical data (e.g. blood pressure, weight, etc.), and depending on its capabilities, will be increasingly used to interface with the primary care giver through the EHR. This is not yet common, as there

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[3] "Making Health Care Safer, A Critical Analysis of Patient Safety Practices": Evidence Report/Technology Assessment, No. 43; Chapter 48: Procedures for Obtaining Informed Consent.

[4] Federal government definitions, Health and Human Services, URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1256&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10741&cached=true

are many different models for PHRs. However, there is an opportunity to ensure that the PHR is truly used as an extension of the physician-patient relationship.

Here, the PHR could be used to transmit, store, and document the informed consent process. If the patient is given enough time to review materials provided, the educational component of obtaining informed consent can be done in the privacy of one's home, as opposed to sitting at a kiosk at the hospital or in a physician's office. While keeping informed consent records in a PHR would not constitute the legal medical record, these documents form an extension of the physician-patient relationship, which is an important but overlooked role for technology in today's healthcare environment.

Growing complexity of consent requirements

The concept of "consent" in healthcare is getting more complex and likely to create confusion not only to patients but also to clinicians and policy makers. Specifically, the term *consent* can be used in a variety of ways. First, as discussed above, it can refer to the process of determining whether or not a patient understands the clinical procedures and their inherent risks, and whether or not that patient has the capacity to understand and give their consent.

Secondly, EHRs and PHRs play a role in modifying this landscape. The HITECH provisions of the American Recovery and Reinvestment Act, passed February 17, 2009, include substantial financial incentives for the "meaningful use" of certified EHR systems. One of the qualifying requirements of meaningful use, by law, is the exchange of clinical data among physicians and hospitals using EHR systems.[5]

All of these connected systems will eventually feed data across the country through the Nationwide Health Information Network (NHIN), which is still under development. Initially, the meaningful use connectivity requirement will be accomplished through many local and regional Health Information Exchanges (HIE), each of which will likely create very different rules for the exchange of clinical data along the network. The rules will vary by state and organization, since there are no standardized business or legal models for HIE structure.

In this scenario, patients will be asked for their *consent* to move their clinical data along these networks, as well as to use their information in a variety of ways ranging from mundane billing to clinical research. Consent for this purpose will not be standardized, nor will it be easy to comprehend, since some HIE models will allow patients to opt in while others require an opt out. To further obfuscate the situation, patients will be empowered to allow the movement of some of their data while restricting or withholding other data either under certain conditions or altogether.

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[5] Health Information Technology Policy Committee final recommendations on Meaningful Use, August, 2009: URL: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10741_888532_0_0_18/FINAL%20MU%20RECOMMENDATIONS%20TABLE.pdf

We have an obligation to see that the value of information technology plays an appropriate and *supportive* role, and that we clearly articulate the difference between *information consent* and *clinical consent*.

Conclusion

We must make a distinction between information consent and clinical consent. Ethicists, clinicians and technologists make an effort to ensure that the use of information technology does not dehumanize the physician-patient relationship. We must recognize that it plays a role in expanding that relationship. We must take extra care to ensure that technology does not further complicate the process of making treatment decisions under difficult circumstances. If we do these things now, the transition to EHR can be a smoother one for all.