

HEALTH INFORMATION TECHNOLOGY

Electronic Consent Channels: Preserving Patient Privacy Without Handcuffing Researchers

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Advances in health information technology and electronic medical records have the tremendous potential to accelerate translational and clinical research. However, privacy concerns threaten to be a rate-limiting factor. By recognizing and responding to patient privacy concerns, policy-makers, researchers, and information technology leaders have the opportunity to transform trial recruitment and make it safer to electronically locate and convey sensitive health information.

Scientists, clinicians, policy-makers, and patients alike have recognized the transformative potential that improvements in health information technology (HIT) and the expanded use of electronic medical records (EMRs) have for the acceleration of translational and clinical research (1, 2). However, privacy concerns over access to and misuse of personal data threaten to be a rate-limiting factor in this evolution. Rather than viewing privacy concerns as an impediment, policy-makers, scientists, and HIT specialists should embrace privacy as an opportunity that, if addressed, can enhance the flow of information. Confronting this issue head-on by establishing an effective electronic process for consent—one that honors each patient's specific privacy needs and desires—can enhance patient participation in research, expand access to data and biological samples, reduce the costs and time associated with the recruitment of patients for clinical trials, and accelerate the discovery of new treatments.

In the era of EMRs, addressing privacy is essential both to encourage patient participation in research and to gain access to personal health information. Multiple studies (3, 4) have revealed that when individuals do not understand who is accessing their information or how their data might be used, they are less willing to share these valuable resources when the information is not being used directly for their care. These privacy concerns, although legitimate, have the potential to hinder

translational and clinical research if not properly addressed. One way to deal with privacy concerns and enhance participation in research is by establishing channels of consent that give stakeholders a way to verify that patient-privacy directives are followed and that approved requests are promptly and efficiently fulfilled.

In a recent study based on data from 20 focus groups across the United States, the majority of participants agreed that if medical data are to be stored electronically, health care consumers should have control over whether and how their data are shared and used (3). In addition, participants felt that they should be able to set limits on the use of their medical information individually rather than have use of their information be governed by general rules applied to all consumers. Overall, this demonstrates a general willingness by patients to share their health information if they feel that they are in control of how it is shared and with whom. With a proper consent process, patients may be comfortable with allowing their information to be accessed and analyzed for research purposes. This amassing of data collected in human subjects is an essential component of all translational and clinical research.

Newborn bloodspots provide an excellent example of what can happen when the privacy of personal health information and issues of consent have not been adequately addressed (Fig. 1). Most newborns in the United States are screened for various ge-

netic and metabolic disorders by using a small blood sample taken from a heel prick obtained at birth, known as a newborn bloodspot. The blood is dried and stored on a card by state departments of health and, depending on the states' laws, may or may not be destroyed after a certain period of time. Obviously, bloodspots are a versatile resource that can be used to ensure the quality of existing newborn blood tests as well as to drive the development of new tests or treatments for serious childhood diseases. However, over the past few years the collection, storage, and use of bloodspots for research have been the subject of harsh criticism in several states stemming from the privacy concerns of parents and privacy advocates. Typically, states have not required that parents provide consent for their newborn's bloodspot to be used in clinical research, and no states provide automated systems through which consents may be solicited should an interest arise in accessing the information.

In April 2010, objections over the lack of consent led to a court-administered settlement in which the Texas Department of State Health Services (DSHS) was required to destroy more than 5 million dried bloodspot specimens and implement a



Fig. 1. Heel pricks support healing. Collected by making a small puncture in a baby's heel at birth, newborn bloodspots are precious resources for the development of modern diagnostic tests and disease treatments.

costly consent process for the future collection of specimens. The potential of this vast and rich trove of data is now gone forever, despite the fact that if asked, the majority of parents would consent to allowing their newborn's bloodspot to be used in research. Indeed, if permission is obtained, 76.2% of parents in one survey have indicated that they would be “very or somewhat willing”

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to permit use of the newborn bloodspot sample for research, compared with only 28.2% if permission is not obtained (4). By nearly a three-to-one margin, parents would like to have control over whether their child's information is used, who uses it, and for what purpose. For the future, the bloodspot collection process needs to be improved so that patient privacy is better protected and consent is given for any future medical research on the samples. Better privacy technology—that which allows parents and the owners of the bloodspots in the United States to choose the disposition (how the samples will or will not be used) of the specimen and ensures patient privacy—is one of the keys to improving this process, as is educating parents and bloodspot owners on the process of consent and how the blood samples can be used for the public good.

Responding to these concerns, Private Access and other organizations such as the University of Michigan, Genetic Alliance, Patient Privacy Rights, The Lyndon B. Johnson School of Public Affairs at the University of Texas, and 5AM Solutions have developed advanced HIT infrastructures designed to deal with privacy issues and maximize the accumulation and use of patient data. Here, I describe Private Access's system (5) to illustrate basic principles behind this innovative medical movement.

Private Access has developed an online system that can help to determine the disposition of individual bloodspots and to streamline the collection process. Currently in a pilot project implementation, the offered technology balances privacy, confidentiality, and consent with the need for access to bloodspots for research. Patients and families can set detailed privacy preferences concerning access to their medical information, including applying settings for specific parts of the information, such as the bloodspots themselves or the family health history (Fig. 2). Parents and other bloodspot owners are asked if they want their bloodspot card to be destroyed or if it may be used in the future. The individual can also decide if he or she wishes to be contacted before the specimen is used for a specific purpose. Lastly, all consent decisions can be updated or changed at any time. Consumer-empowered data-sharing projects using technology such as this are expected to demonstrate the importance of dynamic consent for access to personal health information for clinical research.

Who What's this?	Can researchers use your information? What's this?	Can researchers contact you? What's this?
Department of community health	Yes. Use my bloodspots and health data.	Notify me first so I can decide then.
Academic researchers	Yes. Use my bloodspots and health data.	Notify me first so I can decide then.
Industry researchers (for profit)	Yes. For my bloodspots only.	No. Prohibit all contact.
All other researchers	Yes. For my bloodspots only.	No. Prohibit all contact.

Check here if you wish to have your (or your child's) bloodspot destroyed What's this?

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Fig. 2. Privacy matters. The ability to make decisions about how their medical information can and cannot be used empowers patients and enhances their willingness to share health data for research purposes. Depicted here is a sample of the kinds of privacy decisions one can make when using the Private Access application. Users can set privacy preferences that regulate access to their medical information, and all consent decisions can be altered at any time. Such technology-driven data-sharing projects have been designed to assess the significance of dynamic consent in the quest for access to personal health information to be used for clinical research purposes. However, without an opportunity to effectively consent to such access, use of these data for clinical research raises significant concerns by some parents.

Although the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule addresses patient privacy relative to electronic records, many view its provisions as an impediment to clinical research (6). The Privacy Rule requires researchers to obtain written authorization from subjects before their personal health information can be used—or to demonstrate that their research meets certain requirements that exempt written authorization, such as the use of information that is not individually identifiable (for example, the birth date or social security number of the patient must be removed). Because the Privacy Rule limits researchers' access to information, translational scientists must work closely with health care providers, health plans, and other institutions to obtain robust and legally sound consent from patients that make their health data available for future use (7). Electronic platforms that provide a digital process for consent—one that allows users to very specifically identify what information they want to share and with whom—provides the unique opportunity to streamline and enhance the consent process while slashing its associated costs. These on-

line applications give researchers advance permission to conduct focused searches for patients who match a particular study's criteria (for example, clinical trial candidates); banked biospecimens; and a wide variety of patient-related data. Scientists also gain the ability to contact individual patients in order to clarify existing information, acquire new data, or request expanded access to medical records. Lastly, this technology can serve to improve the reach of disease-management programs and unlock the research potential of patient registries and tissue repositories.

Today, in the so-called Information Age it still takes months or years—and often thousands of dollars per patient—to locate individuals or biological samples for clinical trials that may save or improve lives. Many patients who could benefit from participation in clinical trials don't enroll because they are not aware of relevant trials, cannot locate trials that match their needs, or worry that their personal health information will not remain confidential. New Web-based privacy technology will allow patients to safely share personal health information with the people, organizations, and institutions they trust to advance perti-

ment research. By recognizing and responding to patient privacy concerns coupled with community-wide educational content, policy-makers, researchers, and information technology experts have the opportunity to transform clinical trial recruitment and make it safer to locate and convey sensitive health information electronically.

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10.1126/scitranslmed.3002037

Citation: R. H. Shelton, Electronic consent channels: Preserving patient privacy without handcuffing researchers. *Sci. Transl. Med.* **3**, 69cm4 (2011).

Science Translational Medicine

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Sci Transl Med 3, 69cm469cm4.
DOI: 10.1126/scitranslmed.3002037

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