Opting for Opt Out: How One HIE Manages Patient Consent

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By Deb Bass

Every health information exchange must determine how it will gain consent from patients to share their information. The Nebraska Health Information Initiative chose opt out and with good communication and management has maintained a high rate of patient participation.

Even after technology, processes, and procedures are in place, health information exchange networks still require a crucial element: patient data. Without adequate data to exchange, HIEs offer little value. The challenge for start-up HIE efforts is how to obtain the data.

Providers have the data, but HIEs typically seek consent from patients to share their data within the network, either by actively seeking permission or by providing the opportunity to deny it. According to the latest survey from the eHealth Initiative, how HIEs obtain consent continues to be a mixed bag.[1]

Today the number of active HIEs in the US is approaching 250.[2] In the absence of national guidance on HIE-specific privacy and security policies, HIEs continue to develop their own. Several models have emerged, and policy makers at both state and federal levels are watching carefully to glean information for the statutory requirements that are sure to follow.

The Nebraska Health Information Initiative (NeHII) is Nebraska's statewide integrator for HIE. It faced the challenge of choosing a patient consent method in 2009, chose the "opt-out" model, and has been successfully managing the process for the past two years. The HIE learned a great deal about how complex and far-reaching the selection of a patient consent model can be, as well as the ongoing effort required to support it.

Balancing Patient Rights and HIE Operations

During NeHII's formative stages and into its implementation, the network spent significant hours and thousands of dollars reviewing the issues related to the rights of patients to make decisions about access to their health information. Concerns involved the electronic process used to manage the consent process, determination of which healthcare providers may access the data, and the specific data elements to be shared.

But the developing HIE first had to wrestle with the most basic and daunting of issues: the process for obtaining consent from 1.8 million Nebraska citizens that would allow providers to use their personal data to share their health data in a network of providers intended to improve the quality of their care. As this was taking place from 2007 to 2009, guidance was scarce.

In 2009 and earlier, as NeHII privacy and security experts sifted through existing policies and regulations and urged caution, the operational team provided a counter-balance. The challenge was to combine the rights of the patients with the practical necessities involved in implementing a robust HIE. One of the first accomplishments, however, was to disregard the obvious.

The "no consent" model-that is, including a patient's health information in the HIE without providing the patient the ability to determine his or her own participation-was quickly eliminated as an option. This approach was considered to fly in the face of the "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information," issued in December 2008 by the Office of the National Coordinator for Health IT.[3] The framework directs healthcare providers to give patients a "meaningful choice" in the control of their personal health information.

Having determined that it would require patient consent, NeHII was left with two general models to choose from, each with its own particular intricacies.

Opt-In: High Control, Big Challenges

The first model is generally referred to as the "opt-in" model. It prohibits the network from automatically including a patient's information in the data that is passed from the provider-such as a hospital or insurance company-to the HIE without the patient having provided direct consent for that express purpose. A more limiting counterpart to this model, "opt-in with restrictions," allows the patient to limit disclosure to a portion of his or her information.

Although the opt-in method ensures patients have maximum control of their data, it presented significant administrative obstacles to the NeHII implementation. To successfully oversee the process, each individual data provider would be required to collect consent from each patient, which burdens providers with another round of paperwork.

The opt-in with restrictions model presents additional burdens, requiring that portions of the patient's information be excluded from the scheduled data feed to the HIE. Ensuring those select restrictions requires development and implementation of a complex technical process. However, some stakeholders within the start-up HIE argued that with proper security in place, the information could simply be passed to the HIE and the consent determination made at that point, thereby relieving data providers of the burden.

As NeHII stakeholders debated the issues, the opt-in models presented overwhelming obstacles to provider buy-in. Implementing the processes to manage the restrictions was a task that could take months or even years to realize. In addition, the sheer volume of paperwork, consumer education, and community outreach required to implement an opt-in process would significantly slow the development and expansion of the HIE.

Because the value of HIE is directly related to the amount of information in the system, the slow and laborious process involved with the opt-in model presented significant barriers to the HIE's development and expansion.

Opt-Out: More Data, More Manageable

Even as the group realized the functional barriers of the opt-in process, it had concerns regarding the alternate model, "opt-out." Although the method offered an easier means to supplying the HIE with sufficient patient data, stakeholders worried that it would not give patients enough control over their information.

In an opt-out model, a data provider passes to the HIE all patient information that is not otherwise restricted. It is then the responsibility of the HIE to block access to the patient data if the patient chooses to opt out of the exchange.

In an "opt-out with exceptions" model, patients initially are included in the HIE but may exclude themselves entirely or include only specified or partial information. At the time of its development, NeHII was neither technically nor operationally ready to address the exclusion of specific information on a patient-by-patient basis.

While the opt-out method is often considered to ignore patient control, if implemented properly, it can be a solution that eases administrative burden while still allowing patients to exercise their choice regarding the sharing of their own data.

Opting for Opt Out

Ultimately NeHII selected the opt-out model, providing patients multiple avenues to opt out, along with a carefully developed consumer education plan to ensure that both patients and providers understood the patient's rights and the provider's obligations.

"We concluded that the opt-out model was entirely consistent with both current health information management practice and HIPAA in that there would be no change in what patient information was shared or why; only the means by which that information would be shared would change," explains Sara Juster, NeHII's privacy officer.

The HIE worked with each hospital to train staff on how to inform patients of their options prior to visiting with the physician. At the point of care, patients would be able to decide whether their treating physicians who participated in NeHII would have the ability to access their information.

The model was implemented with the NeHII pilot, which began in March 2009. A consumer advisory council, created by the NeHII board of directors, approved educational materials that had been developed by the NeHII privacy and security committee and the operational team. Training was provided at data provider sites to ensure that consumers would be provided with adequate information to make an informed decision regarding access to their data. Patients were provided with multiple options at the point of care to modify their consent status. When the pilot ended in June 2009, the opt-out rate stood at a low 1.3 percent.

How the Process Works for Patients

Today, each time patients visit providers participating in the NeHII network they are given the opportunity to change their consent status. Patients receive an educational brochure containing a form they can complete if they elect not to participate. Additionally, individuals can visit the NeHII Web site or call the support line at any time to opt out.

Regardless of the method, all requests are routed directly to NeHII system administrators. Once received, the opt-out is processed within one business day, placing a block on the patient's information.

NeHII retains access to minimal patient demographic information, but no clinical information or further personal data are accessible. The small amount of data that remains visible-name, gender, birth date, and consent status-allows physicians to effectively and accurately search for patients to determine if their data are accessible in NeHII.

How the Process Works for the HIE

Each Friday NeHII mails a confirmation letter to all individuals who have opted out during the previous week. The letter confirms their opt-out status and provides information regarding NeHII and the benefits of participation. Also provided are instructions on how the patient can reverse his or her consent status. Patients who decide to opt back into NeHII are called at the phone numbers on record to confirm that they do indeed intend to opt in. Once NeHII staff confirm the request, the patients are mailed a letter of confirmation.

NeHII tracks the reasons consumers give for their status changes. Sometimes patients inadvertently opt out, mistakenly signing the opt-out form as they work their way through the score of other papers they must complete.

In some cases, patients opt out because they do not fully understand the benefits of HIE or the precautions that are taken to protect patient information. Because staff at the provider sites are the primary people through whom patients learn about the HIE, their rights, and its benefits, NeHII tracks the opt-out requests by provider location so that communications specialists can address the need for further education. Staff turnover at the provider sites warrants regular training to emphasize the importance of informing patients of their rights and the benefits of participation.

Adding to the complexity is the fact that providers use a variety of office workflow processes for obtaining opt-out requests, none of which are mandated by the HIE. Different methods work for different providers, but NeHII must help each facility blend HIE awareness and education into the workflow in a way that results in a patient's full understanding of the impact of their consent choice and, importantly, how to communicate that choice.

Given the Chance, Few Opt Out

Since NeHII became operational in 2009, the percentage of patients electing to opt out has ranged from 1.5 to 2.6 percent. Of those who have opted out, approximately 7 percent elect to opt back in when provided with further education about the HIE's benefits, security, and how information is accessed and used.

A patient's ability to allow or restrict access to his or her records is only one side of the consent model equation, however. Increasingly, providers are seeing the benefits of, and incentives for, sharing more information with patients.

The meaningful use EHR incentive program requires that providers participating in the program give patients greater access to their health information. In January of this year, the Health IT Policy Committee released a preliminary draft of stage 2 meaningful use criteria. One proposed objective would require that 80 percent of patients are offered the "ability to view and download via a Web-based portal, within 36 hours of discharge, relevant information contained in the record about inpatient encounters."[4] Providers that participate in an HIE could turn to the network to provide such services.

Ten years ago, HIPAA granted patients new rights over their health information. Now in 2011 HIEs and their providers grapple with how to provide vital and sensitive information safely and securely to a demanding and discerning public.

Notes

1. eHealth Initiative. "The State of Health Information Exchange in 2010." July 2010. www.ehealthinitiative.org. (Access restricted to members.)
2. Ibid.
3. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology. "The Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information." December 15, 2008. http://healthit.hhs.gov.
4. Heubusch, Kevin. "HITPC Floats Preliminary Stage 2 Meaningful Use Criteria." January 12, 2011. *Journal of AHIMA*. http://journal.ahima.org/2011/01/12/hitpc-floats-preliminary-stage-2-criteria.

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