HEALTH INFORMATION EXCHANGES:

Potential for Unprecedented Public Health Applications

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Abstract

Health Information Exchanges (HIEs) are regional, state-wide, or federal systems designed to exchange patient health information across providers and treatment episodes. HIEs have the potential to dramatically alter the nation’s public health landscape by giving providers unprecedented access to patient health histories while enabling innovative new applications for state and federal public health agencies. The legal landscape has matured considerably, and legal conditions at the federal level are quite favorable for the establishment of HIEs. Recent amendments to the Health Insurance Portability Accountability Act (HIPAA) have increased the viability of HIEs, and historic new patient protection measures should go a long way in allaying consumer concerns. However, state laws are an inconsistent “patchwork” in need of reform. Until the federal government drives states to adopt minimum technological and usage standards, HIEs will remain state-specific silos of invaluable patient health histories. To realize the true potential of HIEs, federal and state governments should choose opt-out consent models, educate patients about advances in legal privacy protections, and coordinate regulatory efforts to ensure that HIEs are interoperable and functional across states.

Introduction

Health Information Exchanges are a quickly emerging reality. In 2009,
Congress passed the $780 billion American Recovery and Reinvestment Act, which includes the Health Information Technology for Economic and Clinical Health Act (HITECH). Congress allocated $20 billion in an effort to drive nationwide adoption of Health Information Technology (Health IT or HIT) and provided $2 billion to the Office of the National Coordinator for Health Information Technology (ONC) to support Health IT. As a result of these federal initiatives, states across the nation are in the midst of planning and initiating state-wide HIEs. This technology promises cost and quality of care advances that should prove attractive to both providers and patients. Providers that are able to access patient health histories will be empowered to make better clinical decisions. As a result, patients will avoid adverse drug interactions, experience fewer repeated tests and fewer hospital readmissions. These benefits could lead to enormous cost savings if HIE technology is adopted across the nation. The technology may provide one solution to dealing with America’s exploding cost of healthcare.

Despite promising substantial cost and quality improvements, HIE policies require further reform if the envisaged National Health Information Network is to be realized. This paper will first examine how potential HIEs may work. Next, public health benefits and potential applications will be examined. An analysis of consent models and their policy implications will follow. Then, legal impediments to viable HIEs will be discussed. Lastly, the focus will turn to recommendations to overcome the legal and implementation hurdles that will pave the way for an effective National Health Information Network.

What are Health Information Exchanges?

HIEs promise to revolutionize the healthcare industry by providing patient health histories and personal health information (PHI) in an electronic format. HIEs promise substantial benefits in terms of cost and quality. Through the digitization of patient records, providers will be able to avoid unwanted drug interactions and reduce repeated tests, among other quality of care improvements. HIEs will offer the opportunity for an authorized user, most often a health care provider, to electronically exchange information with other users. States will need to decide which entities will be given user privileges, but foreseeable users include medical providers and health plans. Some states might consider special access for “unauthorized” users during an emergency situation. More contentious user privileges include whether health plans, research organizations, or public health agencies should have access to the HIE. States may also decide to create patient portals wherein patients can
log in and see the instances where their information has been accessed.iv

In application, providers will have access to patient histories of varying comprehensiveness depending on each state’s decision on which functions to include. Some states will elect to retroactively input previous patient histories, while others might choose to start collecting patient histories at the beginning of the statewide HIE. Once the system is in place, providers will have access to information such as which doctors have treated a particular condition and what drugs have been prescribed from the pharmacy for particular symptoms. Access to such information promises to improve medical outcomes and reduce medical errors. For example, HIEs could identify potential adverse drug interactions.v The key innovation for Health Information Exchange is that it promises to reach all providers, rather than specific provider networks. This attribute ensures that a patient’s health history follows the patient, regardless of which provider he or she chooses. If HIE technologies are compatible across states, then patient histories will follow the patient across states as well. HIEs will then ensure that providers have access to a patient’s history anywhere in the country.

Benefits and Public Health Applications

HIEs offer several broad public health benefits. First and foremost, quality of care will improve. Access to PHI will enable providers to better serve the patient by enabling a more complete picture of patient health. The provider can ensure that treatments do not interact adversely. If a patient forgets which medications he or she is taking, HIEs will ensure that a provider has access to that information and can prescribe new drugs without adverse drug interactions.vi

Quality and cost of care will be impacted by decreasing rates of duplication. For example, the patient’s history of test results will be available to a provider, thereby reducing the need for repeated x-rays and lab tests. This will reduce patient exposure to harmful tests while providing cost savings.vii Additional benefits include access to information during emergencies, when a patient may not be able to explain certain health conditions. During such emergencies, providers will be able to quickly access information about the patient’s medications, treatments, health issues, and tests, which will allow the provider to make better decisions.viii Furthermore, in the case of a natural disaster paper records might be destroyed, whereas HIE information will remain protected. Paper records are also more vulnerable to physical theft, wherein HIE data
may allow for increased protections, including the ability for a patient to view incidences of access to his PHI via web portal.

Specific Public Health Use: Public Health Registries

Public Health departments around the country already collect population-wide data, most frequently in the form of public health registries. These registries track public health threats, such as flu, bio-terrorism related diseases, or diabetes. Divisions of Public Health have often created relationships with hospitals across their respective states and come to an agreement to track specific diseases. For example, North Carolina’s Division of Public Health and the North Carolina Hospital Association agreed to create NC Detect to identify bio-terrorism threats, but have since expanded to track a number of issues, including hospital infections. With the onset of HIEs, the scope of data tracking could be expanded immensely.

Another potential public health application of HIEs will be to mandate reporting of laboratory and physician-based diagnoses. Public Health Agencies already collect data-sets from state laboratories and HIEs will broaden the source and substance of the information collected. Electronic laboratory results are already directly transmitted to state public health divisions, and this reporting allows for vital public health functions such as tracking communicable disease outbreaks in a state. However, in states where there have not been strong investments in lab reporting, difficulties in mapping of disparate systems and codes can occur due to varying technology vocabularies. HIEs would prove beneficial by standardized mapping for clinical exchanges and state reporting purposes; these standardizations would increase the efficiency and quality of public health surveillance by providing accurate, population-wide data.

For example, in many states physicians are required by law to report some diseases to local health departments, specifically communicable diseases such as HIV. However, physician compliance with these requirements is tenuous. Again, if all providers tap in to a state-wide HIE system, the issue of inconsistencies in reporting will be largely eradicated. State and federal public health agencies will also gain vast new population-wide data, which will increase the scope for tracking many more diseases. Physicians will no longer be tasked to report; rather the HIE technology can automatically take care of this burden, leading to increased accuracy and efficiency. Diseases and pathogens that are currently not under bio-surveillance will provide new options for treatment and research. The potential for public health tracking is truly unprecedented
and so are the quality, research and treatment implications. Never before have public health agencies had potential access to real, population-wide data sets.

**Other Uses: Syndromic Surveillance and Population-level Quality Monitoring**

Another specific and high potential public health benefit is syndromic surveillance, which uses population health indicators to monitor the health status of a community. Antibiotic resistant organism surveillance is an example of a potential syndromic surveillance capability, which can aid public health agencies in their fight against these deadly organisms. In this application, microbiology culture resistance patterns could potentially be sent through the HIE system directly to the health department. This information could then be used to construct community-wide antibiograms that could help focus antibiotic selection in target areas based on local resistance patterns. Additionally, HIE technology could notify clinicians when a patient with a previously diagnosed antibiotic resistant organism becomes present. This would potentially decrease the spread of antibiotic resistant organisms by localizing infected patients and alerting attending providers. An average hospital-acquired antibiotic-resistant infection can cost up to $30,000 per incidence, and this application demonstrates the potential benefits of investing in real-time syndromic surveillance technologies. This concept could be extended to flu, bioterrorism related incidences, and other emerging communicable diseases, providing state epidemiologists with unprecedented access to population-wide data.

Population-level quality monitoring will enable state and federal public health agencies to target conditions such as diabetes, obesity, and heart disease that have taken on epidemic-level proportions. National campaigns have been started that are aimed at prevention. Community-wide monitoring could arm state and national agencies with population and community-wide data to improve disease prevention initiatives. The information could also be used to target specific communities with higher incidences of testing to better control costs and ensure that quality of care is not affected by over-testing. State and national leaders can maximize the impact of prevention efforts by using these population-wide data sets to customize and target specific communities.

**Models of Consent**

States must choose to adopt either an “opt-in,” “opt-out,” or “no consent”
model for HIEs. “Opt-in” is the preferred choice for states with strong consumer protection concerns because it grants the greatest level of patient privacy. In this model, no patient’s health information is included in the HIE until the patient proactively gives consent. Upon consenting, the patient’s complete health data is included. In an “opt-in with restrictions” model, patients must give consent and can select which sub-sets of data are included. However, the health provider community largely prefers the “opt-out” model. “Opt-out,” models include all patient health information automatically, but the patient can then choose to opt out of the system completely. Finally, “no consent” models automatically include all health information, and patients are not given the choice to opt out.

In choosing a consent model, states must carefully consider the implications of each approach. Choosing a model with the option to restrict sub-sets of data can be clinically deceptive. For example, if a state decides that the patient can choose to withhold STD information, all such information must be purged from the record, including drugs that are specifically targeted at treating STDs. Yet providers across the country want access to the most complete possible patient history. Withholding certain subsets of information might actually confuse the provider into thinking that the patient is not affected by those conditions. For example, if a patient withholds a subset of mental health information the provider may mistakenly assume that the patient has no mental health history. The treatment could, therefore, be less effective or have adverse implications.

**Legal Challenges to Implementation**

There are a number of laws that complicate the successful implementation of HIEs, some at the federal level and many at the state level. A patchwork of state laws that protect privacy and sensitive health information creates a challenging and complex legal landscape. In many circumstances, there may be a need to change the legal landscape through legislative methods. Adapting state and federal law will ensure that HIEs protect patients’ privacy, while federal interoperability standards will ensure that the technology is useful on a nationwide scale.

*Patient Privacy Concerns: HITECH’s Expanded Civil Penalties and Enforcement*

Effective deterrents to fraud and abuse are essential for HIE’s to gain the public’s support. If patients do not trust that the technology will secure
their personal health information, they will choose not to participate and the benefits of HIEs will be compromised. Previously, HIPAA, the federal law designed to protect patients’ privacy during the transfer of personal health information, was criticized for civil penalties that were too low to be a truly effective deterrent. HIPAA civil monetary penalties, ranging from $100 to $25,000, will be amended under the HITECH Act. A tiered penalty structure based on the nature of the HIPAA violations will be instituted. HITECH will also allow DHHS to consider new evidence regarding the nature and extent of harm resulting from a violation in DHHS’ penalty determination. Whereas previous penalties were based solely on the existence of a violation, the new rules create a tiered penalty structure ranging from $100 to $1,500,000 for violations. Moreover, HIPAA covered entities (including providers, health plans, and healthcare clearing houses) can no longer plead two affirmative defenses (a tactic to mitigate damages) that were previously available prior to HITECH. A covered entity can no longer claim that it did not have knowledge of a HIPAA violation as a strategy to minimize culpability. Additionally, a covered entity cannot claim that its violation was due to reasonable cause, not willful neglect.

HITECH also expands enforcement incentives to the DHHS’ Office of Civil Rights (OCR). Most of the civil penalties collected under HIPAA privacy or security violations must now be turned over to OCR to expand enforcement efforts. Furthermore, HITECH grants explicit authority to state attorneys general to enforce HIPAA privacy and security rules, which adds another layer of enforcement. They may bring actions to enjoin violations and obtain statutory damages, although there is a $25,000 yearly damages cap. While the ability for attorneys general to enforce HIPAA was arguable implicit in that law, HITECH gives explicit authority for this added layer of enforcement.

Increased enforcement is a welcome addition to HIPAA, since lax enforcement of HIPAA might undermine the security of HIEs. The threat of substantial penalties, especially for repeat offenders, and the prospect of enforcement by state attorneys general will ensure that HIE operators will protect patient privacy. Hefty civil penalties will force providers and health plans to be careful with PHI and ensure that breaches are minimized. These added penalties should also allay patient concerns, especially concerning accountability.
Interoperability: HIPAA and State Laws

A patchwork of state laws will make compliance quite difficult for potential HIEs and RHIOs. In particular, laws that protect sensitive health information, such as those regarding STDs, HIV/AIDS, mental health, and substance abuse are often preempted by state laws that are more stringent than HIPAA regulations. Each state will need to carefully weigh policy considerations while determining which types of information to include in an HIE. Providers usually favor a robust exchange with the most complete patient medical histories. Sequestering specific information may result in an incomplete record. If patients are given the choice to exclude sensitive health information there can be important implications for treatment. For example, without knowing a patient’s mental health history, a provider might prescribe a drug that could negatively affect the patient’s mental health.

Policy considerations must be made in light of existing state laws. There may be a need to reform those laws to achieve the goals of a state’s HIE, especially for states that pursue opt-out consent models. An example of the interplay between state objectives and existing laws can be found in North Carolina. In this state, some laws were more stringent than HIPAA and proved to be challenging to the state’s HIE policy. Specifically, NC GS 130A-143 posed a major challenge to the implementation of policy goals. The statute states that all information and records “whether publicly or privately maintained, that identify a person who has AIDS virus infection” will be kept strictly confidential, although an exception exists when the patient is receiving medical treatment.

In effect, the statute implies that communicable disease information in North Carolina should be kept confidential unless it meets the criteria for certain exceptions. HIEs would provide health information upon receiving written consent from the person or persons identified. From the standpoint of many providers, “opt-out” consent features are most desirable because they ensure that a maximum number of people are enrolled in an HIE. Due to these policy concerns, North Carolina decided to pursue legislative changes that would bring G.S. 130A-143 more in line with federal HIPAA regulations. Thereby, the optimum policy goal of “opt-out” consent could be achieved while also keeping patient histories as complete as possible.

The example of North Carolina demonstrates the patchwork of laws that permeate various states. Depending on the policy objectives of each state, obstructive laws could require legislative changes to ensure that HIEs operate...
effectively. Those state laws that are more stringent than HIPAA are not preempted by the federal regulation. The DHHS Secretary has determined that state laws related to the privacy of individually identifiable health information would escape preemption. This implies that states will have to solve the legal patchwork problem themselves. This might pose problems for interoperability of HIEs, leading to incompatible standards and hindering a Nationwide Health Information Network (NHIN).

Perhaps the most challenging legal aspect of HIEs will be coordinating with other states and their laws. Mental health and substance abuse disclosure laws, for instance, vary from state to state, creating legal hurdles for the exchange of PHI across states and the establishment of a NHIN. Records must be interoperable in content, technology and legal compliance. Uniform laws will ensure that patient histories are exchanged across states without requiring adjustment to specific state laws. However, reconciling PHI across state boundaries will present huge challenges. Consequently, there must be national leadership on this crucial issue. True interoperability will expand the scope of HIEs and achieve the vision of a nationwide NHIN.

Recommendations

The issue of interoperability between records is becoming the defining challenge in creating a nationwide health information network due to the wide variety of policy choices being made by states. Each state is devising unique exchanges. States must first make the choice of adopting opt-in, opt-out, or mixed consent models. They then must decide on a timeline for setting up the exchange and decide on what types of information to include. They must decide which entities should have access to the information, whether public health officials or health plans. They must decide on a technology vendor and what if any special technology solutions should be provided to consumers, such as patient portals. The huge amount of discretion that states exercise threatens to derail the vision of a uniform, nationwide interoperable standard.

Consent Recommendations

In terms of an “opt-in” consent model, while such a model affords a great deal of patient control it also diminishes the potential benefits of a state-wide HIE, simply because the success of getting population-wide data depends on the HIE’s ability to convince patients to give consent. If the HIE is unsuccessful in convincing patients it will not achieve its true cost and quality potential. “No
“consent” is most favorable in achieving HIE’s potential, yet this model can seem draconian and create public and political outcry. Ultimately, HIEs will be subject to the political process and must be practical enough to survive public scrutiny. These considerations point to the “opt-out” model as the most favorable. With opt-out, consumers who have deep privacy concerns are given the opportunity to forgo the benefits of the system. Providers gain access to complete patient histories. State and federal agencies can access population-wide data since the whole state population will be in the system, and it may be unlikely that many patients will proactively opt out.

**Privacy Recommendations**

Patients may have innate fears that their sensitive conditions will become public. To allay these and general privacy concerns, patients must be educated about the protections provided by HIPAA. In particular, they should receive instruction on HIPAA’s new, stricter enforcement capabilities and its enhanced penalty system. They should also learn about changes to the HIPAA Security Rule, which will ensure that minimum technological safeguards are in place. Most importantly, they need to understand how HIEs will affect their lives by reducing over-treatment and adverse drug interactions. When a patient understands that he or she will be able to avoid duplicate tests, he or she will understand the argument that HIEs will cut costs in the healthcare system. He or she will understand that he or she will personally benefit from the technology. Most patients will likely “buy in” to the innovative new applications of HIE information. A strong education and marketing campaign will be a requisite part of any HIE effort because the system will fail without patient “buy in.”

**Interoperability Recommendations**

Apart from consumer outreach and education, the national government has important work to do to achieve its envisioned nationwide NHIN. The federal government needs to push states to adopt standard technologies so that records can be made compatible across states. HIE policies are being planned. Many HIEs are moving into the implementation stages and next, states will award huge contracts to technology vendors. The national government has paid for policy creation thus far and may aid in funding the creation of this technology in the future. It is currently the chief source of funding for this endeavor and has the power of the purse. It needs to fervently push the adoption of standards that will result in interoperability. The national
government should also push states to reform laws that will lead to uniform legal compliance across the country, ensuring that a provider can access a patient’s history anywhere in the country. In order to ensure compliance by states, the federal government should consider minimum guidelines attached to future federal healthcare grants. In the current economic context, states will likely continue to depend on federal funds to invest in HIE technologies. Stringent minimum guidelines regarding legal reforms and technology compliance will ensure that state efforts are not fragmented and that records move towards interoperability. Lastly, the federal government should push all states to grant local, state and federal public health agencies access to HIE information. The resulting applications will revolutionize public health and create tremendous improvements in cost and quality. State policies are currently being created. The federal government needs to take the lead and act urgently and ensure that its vision of this technology is fully realized.

Conclusions

Ultimately, the current federal legal landscape greatly favors the creation and adoption of HIEs. HIPAA and recent changes enacted in the HITECH act allow, even encourage, the freer flow of health information. The federal government has committed unprecedented funds to initiate this process. However, at the state level, the situation can be described as chaotic at best. There remains a patchwork of state laws that threaten to impede the creation of interoperable health records - records that could potentially pave the way for a Nationwide Health Information Network (NHIN). State laws concerning communicable diseases, mental health, and substance abuse histories are particularly fragmented and in need of state-level reform. NHIN envisions the ability to access records anywhere in the country and also to give federal public health agencies access to nationwide health data. For this to happen, the federal government should make a stronger push for ONC to set interoperable standards and also to clarify minimum requirements for state HIEs. Moreover, the ongoing policy debate concerning individual privacy concerns must be resolved. To truly harness the potential of HIEs, patient privacy concerns should not keep HIEs from adopting opt-out models - models that would provide public health agencies with unprecedented volumes of PHI. With a concerted education campaign, which would explain HIPAA protections and the benefits of HIE, patient concerns can be allayed and the true potential of HIE realized.
Endnotes


ii. Ibid.


v. Ibid.


vii. Ibid.

viii. Ibid.


x. Centers for Disease Control and Prevention, “Nationally Notifiable Infectious Diseases” (June 2007).


xvi. Ibid.


xviii. Ibid.
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xiv. Ibid.
xx. Ibid.
xxi. Ibid.
xxii. 42. U.S.C. § 1320d-5(c)
xxiii. Ibid.
xxiv. Ibid.
xxv. Ibid.
xxvi. Ibid.
xxvii. 45 C.F.R. § 164.302
xxviii. Ibid.
xxix. Ibid.
xxxiv. NC G.S. 130A-143
xxxvi. Ibid.
xxxviii. 45 C.F.R. §160.203