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SYMPOSIUM

Disease Registries on the Nationwide Health Information Network

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Abstract

Background:

Donation by individuals of their protected health information (PHI) for evidence-based research potentially benefits all individuals with disease through improved understandings of disease patterns. In the future, a better understanding of how disease features combine into unique patterns of disease will generate new disease classifications, supporting greater specificity in health management techniques. However, without large numbers of people who donate their PHI to disease registries designed for research, it is difficult for researchers to discover the existence of complex patterns or to create more specific evidence-based management techniques. In order to identify new opportunities in disease registry design, an analysis of the current stage of maturity of the newly created U.S. Nationwide Health Information Network (NwHIN) related to large-scale consumer donation of PHI is presented.

Methods:

Utilizing a use–case analysis methodology, the consumer-centric designs of the policies and technologies created for the NwHIN were examined for the potential to support consumer donations of PHI to research.

Results:

The NwHIN design has placed the enforcement point for the policy-based release of PHI over the Internet into a specialized gateway accessible to consumer authorization. However, current NwHIN policies leave the final decision regarding release of PHI for research to the health care providers rather than to the consumers themselves.

Conclusions:

Should disease registries designed for research be established on the NwHIN, consumers might then directly authorize the donation of their PHI to these disease registries. However, under current NwHIN policies, consumer authorization does not guarantee release of PHI by health providers.

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Abbreviations: (DURSA) Data Use and Reciprocal Support Agreement, (HIE) health information exchange, (HIO) health information organizations, (HIPAA) Health Insurance Portability and Accountability Act, (HL7) Health Level Seven, (IHE) Integrating the Healthcare Enterprise, (NHS) National Health Service, (NwHIN) Nationwide Health Information Network, (OASIS) Organization for the Advancement of Structured Information Standards, (PHI) protected health information, (SAML) security assertion markup language, (TPO) treatment, payment, or operations, (XACML) extensible access control markup language, (XML) extensible markup language

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Introduction

At the 2010 workshop, *Advancing Rare Disease Research*,[1] Benjamin Greenberg, M.D., M.P.H., reminded us that the modern concept of "disease" has matured, saying, "Most diseases are the result of the following formula: disease = genetics + environment + timing." This certainly would include the very common syndrome known as "diabetes." For example, treatment of a patient for AIDS with protease inhibitors (an environmental factor) has introduced a new physiologic mechanism for the later development (a timing factor) of diabetes.[2] Common "diseases," such as diabetes, might actually comprise a collection of rare diseases characterized by unique combinations of genetic profiles, environmental influences, and timing of key events. For example, are protease inhibitors a new cause of the old disease "diabetes," or are protease inhibitors the cause of a new disease that "looks like diabetes in some laboratory tests"? In the future, we hope that a better understanding of how these disease features combine into patterns will generate new disease classifications, supporting greater specificity in health management techniques. Today, this trend toward greater specificity in health management based on detailed personal characteristics is commonly known as personalized health. However, without large numbers of people who donate their protected health information (PHI) to disease registries designed for research, researchers may not discover these rare patterns of disease or identify enough people to test more specific evidence-based management techniques. This donation of PHI benefits individuals who experience disease through improved understandings of disease patterns, first by researchers in evidence-based medicine, then by providers of care, and then by patients themselves via personalized health initiatives. In the rare disease workshop hosted by the National Institutes of Health, the author proposed that disease registries for research be established on the newly created Nationwide Health Information Network (NwHIN).[1]

Although the active, national exchange of PHI became established on the NwHIN in 2010, the NwHIN has roots that trace to the 1960s, with the first computerized medical records.[3] After experiencing the "silos of information" created by these early electronic medical records, not unlike prior experiences with the multiple paper records that electronic systems were designed to replace, physicians increasingly called for better communications between the new electronic systems. By the 1990s, these calls for better health information exchange (HIE) increased in scope and included plans for national health information networks as well as local networks. At the same time, the current, model-based, extensible markup language (XML) standards used in HIE were created by Health Level Seven (HL7), a health standards development organization,[4] as well as cross-industry Web service standards for business process management.[5] During this period, the National Health Service (NHS) in England and Infoway in Canada pioneered national health information networks using the new model-based HL7 XML standards and Web service implementations.

After examining efforts in England and in Canada, the United States embarked in 2004 on a series of iterative trials of national health information network design that used physical implementations for testing purposes.[6] The specifications for the NwHIN were finalized into a new network design for HIE. Unlike the NHS and Infoway designs, this network design did not require any central computer ownership by the government to run the network. All PHI, whether existing in federal agencies, state agencies, or private organizations, is isolated from the NwHIN by gateways. These gateways, which protect PHI within these organizations from the ravages of Internet-based events, are established as secure nodes on the Internet-based NwHIN.

Since the NwHIN is now running in a limited production mode, one might wonder whether the NwHIN is capable of supporting research HIE in addition to its primary purpose of patient treatment HIE. Specifically, in addition to the typical provider and federal organizations on the NwHIN, can other specialized organizations, such as disease registry organizations with an interest in research, also participate successfully on the NwHIN? (See **Figure 1**.) This analysis examines the policies and technologies of the NwHIN for the ability to support consumer donations of their PHI to disease registries designed for research.

Methods

A formal use–case analysis methodology, a kind of thought experiment used in computer science,[7] was applied to analyze new capabilities for consumer empowerment created for the NwHIN. Use–case analysis is helpful for adding clarity to the information structures and

transaction sequences in complex systems, in which business processes, policies, and technology often interact to muddy the domain. Frequently, use–case analysis precedes other more granular experimental methodologies in computer science that test specific components of the system and benefit from statistical analysis. Common examples of more granular studies in computer science important to actual implementations might include the addition of use–cases validated with market analysis techniques, usability studies to explore the human–computer interactions identified, performance studies to examine the requirements for speed and scalability, and algorithm research to improve the validity of the derived data. These kinds of studies could follow this NwHIN analysis as well.

The policies and technologies underlying the NwHIN were examined in order to explore the opportunities to make disease registries designed for research more effective in obtaining clinical data. Disease registries designed for research, a specialized type of patient registry, are more effective in identifying rare patterns of disease when they include data associations on larger numbers of people than they do today. In one use–case, inspired by consumer testimonials in the rare disease workshop,[1] the analysis focused on whether a diabetes patient with newly diagnosed diabetes might sign a consent form that allows the disease registry to collect PHI from the diagnosing physician in an automated fashion (see **Figures 2** and **3**). A second use–case (similar to **Figure 2**), also inspired by the rare disease workshop, focused on the question, "Could a diabetes patient who has enrolled with a specific diabetes disease registry easily sign a consent form with a diabetes disease registry that allows the diabetes registry to release PHI to a collaborating renal disease registry?" Not only do disease registries require large numbers of people with the targeted disease in order to be effective, but comparisons to people without the targeted disease and comparisons to people with comorbidity increase the value of the disease registry data. This observation led to discussions of collaborative disease registries by rare disease researchers at the same workshop.[8] These two use–cases formed the basis for the analysis of policies and technologies underlying the NwHIN related to using clinical data for research.

The original data sources examined were largely published on U.S. federal agency Web sites and the Web sites of standards development organizations. Both use–cases described represent release of PHI by two kinds of health information organization (HIO). The term HIO

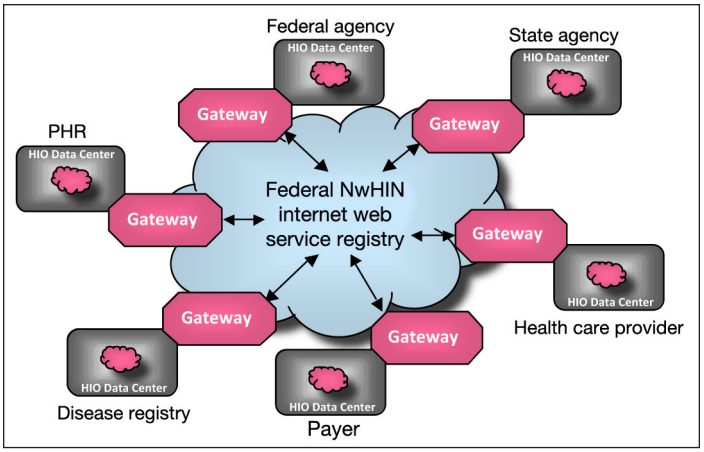

Figure 1. Schematic of the NwHIN, including a disease registry HIO, with gateways utilizing the federal web services registry and isolating HIO networks from the Internet. PHR, personal health record.

is used by the NwHIN to classify any organization that holds PHI, whether public, private,[9] for profit, not for profit, large, or small. One of the HIOs described in the first use–case is the traditional health care provider organization. Typically, a health care provider organization receives many release of information forms for PHI from other organizations. Examples of other organizations that request release of PHI from health care providers include other providers who request PHI for treatment purposes, such as the Social Security Administration for disability determination purposes and life insurance companies for coverage approval purposes. A disease registry organization might be another kind HIO established on the NwHIN. In the second use–case, the patient is directing the diabetes disease registry HIO to allow release of PHI to a renal disease registry HIO for purposes of research.

Results

Within these use–cases, there is no indication that these disease registries designed for research fall under the safe harbor in Health Insurance Portability and Accountability Act (HIPAA) related to release of PHI for "treatment, payment, or operations" (TPO).[10] When TPO is not identified in a request for release of PHI, many HIOs require an authorization document signed by the patient. Typically, the requester provides this signed document to the responder before the responder releases the PHI to the requester. Therefore, for the use–cases in question, the successful diabetes registry HIO must be able to obtain a signed authorization from the patient for the release of PHI intended to populate the diabetes registry database designed for research. One could debate whether it is "easier" for the patient, as specified in the use–cases,

to sign a paper authorization form from the HIO or to sign an electronic form via an HIO Web application. Likely, both will occur. However, after assuming that the authorization form was received by the disease registry organization in some manner, the policies and the technology specifications of the NwHIN were examined for support of the next step. The next step is the communication between the diabetes registry HIO and the provider in the first use–case and between the diabetes disease registry and the renal disease registry in the second use–case. Since this is the initial step in both use–cases that introduces communication over the Internet, this is the first step in each activity section that actually falls under the policies of the NwHIN.

The contract for organizational participation in the NwHIN is named the Data Use and Reciprocal Support Agreement (DURSA). The version of the DURSA available for examination by the author was labeled "2009 Version for Production Pilots."[11] Note that a revised version of the DURSA or equivalent publication might become available prior to publication of this analysis. However, this version of the DURSA specifies specific duties of a responding participant, including the duty to respond to all information requested for treatment purposes. When the "purpose" is classified as a "permitted purposes other than treatment," the DURSA language gives the health provider more flexibility:

> DURSA Section 15. "***Specific Duties of a Responding Participant***. A Responding Participant shall be responsible for … 15.03. Responding to all authenticated Messages that seek Message Content for Treatment, in accordance with this Agreement, the NHIN

Title: Healthcare Consumer Authorizes Disease Registry to Collect PHI for Research

Purpose: To illustrate potential interactions between a Consumer, a Disease Registry, and a Healthcare Provider

Pre-condition: An individual Consumer with diabetes wishes to donate personal PHI to a Diabetes Disease Registry for purposes of research. A Diabetes Disease Registry owned by a private, non-profit organization has been established as an HIO on the NwHIN in order to be able to service consumers and researchers in pursuit of diabetic research. A Healthcare Provider has previously evaluated the Consumer for diabetes and is also established as an HIO on the NwHIN. The Consumer with a validated identity has signed on to a Consumer Application offered by the Diabetes Disease Registry

Activities:

1. Consumer Application displays a screen to the Consumer that allows the Consumer to learn about and authorize the collection of PHI from other HIOs for various "Purposes of Use" by the Diabetes Disease Registry HIO
2. Consumer selects "Research" from a list of potential Purposes For Use of the Consumer's PHI.
3. Consumer signs the human readable Access Consent (BPPC) document indicating both understanding of Access Consent and authorization for the use of PHI.
4. Consumer Application generates a computer readable Access Consent (XACML) document consistent with the BPPC.
5. Consumer Application binds both Access Consent documents into the same IHE XDS document set and sends the document set to a Document Storage Application located at the Diabetes Disease Registry
6. Time Elapses
7. Diabetes Disease Registry Researcher triggers a Document Request from the Requesting NwHIN Gateway identifying the Consumer and Purpose of Use from the Healthcare Provider HIO
8. Responding NwHIN Gateway for the Healthcare Provider HIO identifies request for PHI for Research.
9. Responding NwHIN Gateway for the Healthcare Provider HIO orchestrates the local search and then remote retrieval of the Access Consent Document Set for the Consumer from the Requesting Gateway
10. Responding NwHIN Gateway releases the Consumer's PHI to the Requesting NwHIN Gateway

Post-condition: The Consumer with diabetes has succeeded in donating personal PHI to a disease registry for purposes of research. The Diabetes Disease Registry has retrieved the PHI from a Healthcare Provider that has previously evaluated the Consumer for diabetes. In addition to copies of the Consumer's PHI located in both HIO's document storage, Access Consent documents signed by the Consumer exist in both document storage locations as well.

Figure 2. A formal use–case expression for use–case 1 describes potential activities related to consumer signature and authorized release of information over the Internet from an HIO to a disease registry via the NwHIN for the purposes of research should a disease registry designed for research be established on the NwHIN.

> Performance and Service Specifications, and the NHIN Operating Polices and Procedures. The Participant may respond to Messages that seek Message Content for a Permitted Purpose other than Treatment, in accordance with this Agreement, the NHIN Performance and Service Specifications, and the NHIN Operating Polices and Procedures."[11]

Note that the term "may respond" allows the responding organization to decide whether to deny a permitted use other than "treatment," even if the request is authorized by the individual subject or such individual's personal representative under a more general clause in the DURSA:

> DURSA Section 1. "**Permitted Purposes** shall mean the following reasons for which Participant Users may legitimately exchange Message Content through the NHIN … cc.
>
> Uses and disclosures pursuant to an Authorization provided by the individual who is the subject of the Message or such individual's personal representative in accordance with 45 C.F.R. § 164.502(g) of the HIPAA Regulations."[11]

A second topic of importance to this use–case analysis is the technical design of the NwHIN, as documented in the NwHIN specifications[12] referenced in the DURSA.

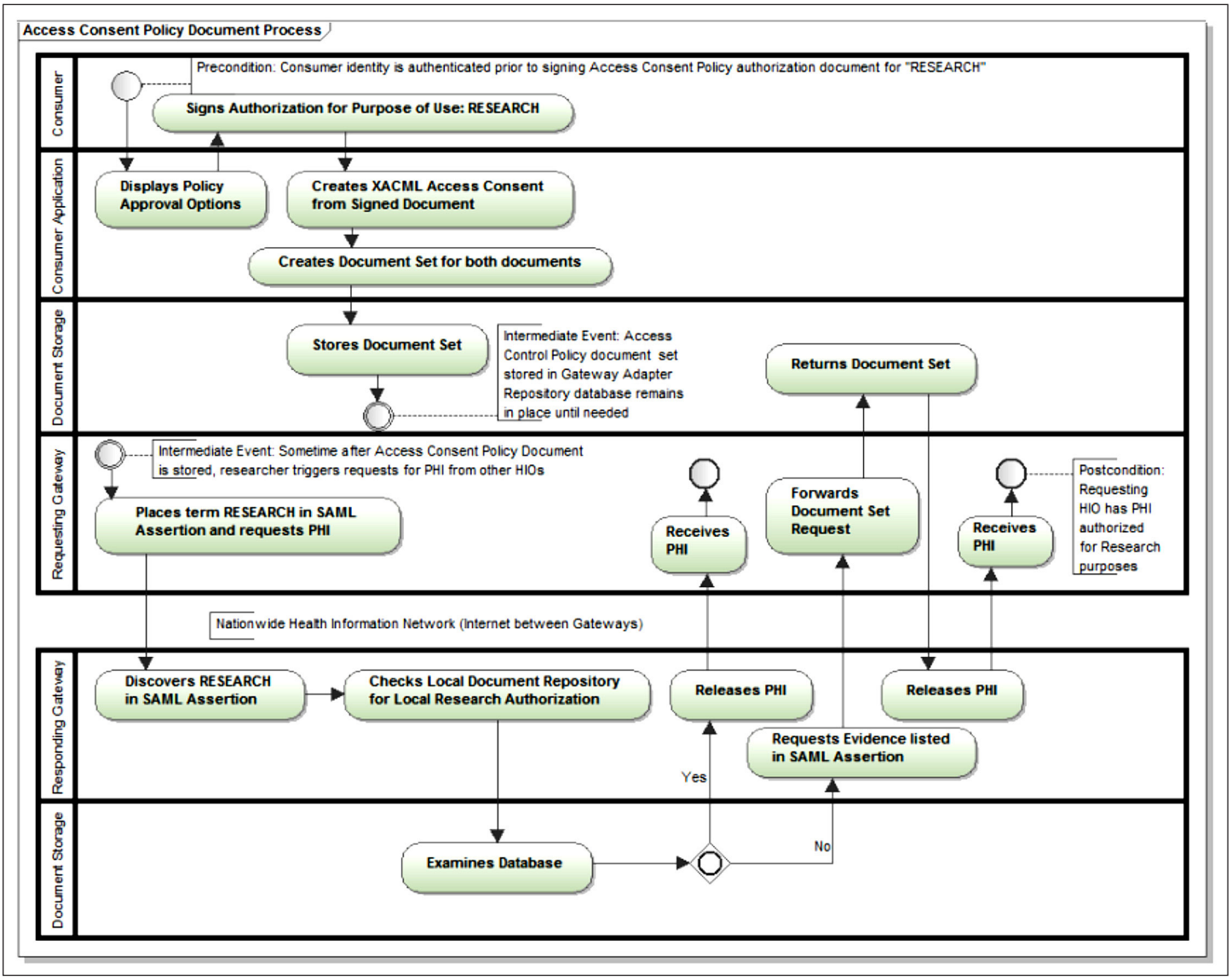

Figure 3. The formal use–case in Figure 2 executed in business process model notation demonstrates the potential workflow transaction sequence initiated by a consumer signing an access consent policy document set used in disease registry gateway transactions requesting PHI over the NwHIN for research purposes should a disease registry designed for research be established on the NwHIN.

This design has placed the policy enforcement point for the policy-based release of PHI over the Internet into a specialized gateway that manages the flow of information into and out-of an HIO. The term gateway is often used to describe a specialized kind of proxy server that is located at the periphery of a data center and protects the data center from unauthorized Internet traffic. In this design, the policy enforcement point for the release of PHI utilizes a policy engine that evaluates relevant Access Consent Policies and rules authored by the consumer or authored by the HIO for regulatory or for organizational policy reasons:

> "Access Consent Policies may be 'off-the-shelf' policies that are adopted by or apply to a consumer, or they may be policies that are customized by a consumer to grant or deny access to specific types of information by specific types of users. Access Consent policies may also be created by users other than consumers; for example, physicians may create policies that restrict access to health information they create."[13]

The result of an evaluation of relevant access consent policies by policy engine algorithms is typically either a "permit" that allows the release of PHI or a "deny" that prevents the release of PHI over the Internet.

In support of the DURSA, the access consent policies authorizing the release of PHI should be available to the responding gateway, preferably both as a consumer-signed, human-readable Integrating the Healthcare Enterprise (IHE) basic patient privacy consent document[14] and as a computer-readable XML file that follows the extensible access control markup language (XACML) file standard for policies defined by the Organization for the Advancement of Structured Information Standards (OASIS) standards development organization.[15] In order to support automated processing of the request for PHI, the XACML file must be populated with data in accordance with the NwHIN specifications. Included in this requirement[13] is the use of a terminology value set for "Purpose of Use."[16] For the consumer granting authorization for release of PHI to a disease registry, "RESEARCH" is one of the terms available in the OASIS, "Purpose of Use" value set.

Although the responding Gateway may examine its own policy files for consumer authorization upon receiving requests for PHI, the NwHIN specifications also require the requesting Gateway to provide standards-based privacy and security information in the request using OASIS security assertion markup language (SAML).[17] An OASIS SAML assertion provides additional privacy and security data, such as an assertion of purpose of use, which can be utilized by the responding gateway. Within this SAML assertion is a section for evidence that may be used to validate the authorization of the request. Within this evidence section is a placeholder created by the NwHIN specifications for a record location that allows retrieval of an instance of the consumer-specific access consent policy validating authorization for the request.[18] If available from the requester, the responding gateway may retrieve the XACML file as well as the signed access consent policy file from the requesting gateway by using this record location information and standard NwHIN document retrieval Web services. By matching on "purpose of use" in the SAML assertion and "purpose of use" in the XACML file created by the consumer, the policy engine may generate a "permit" decision on the release of PHI.

The analysis of the second use–case builds upon the same results obtained for the first use–case. The complication of the second use–case is that it implies a sequence of two releases of the same PHI, first from a provider to a diabetes disease registry, then by the diabetes disease registry to a renal disease registry. This serial movement of the same PHI through different HIOs presents both a policy issue and a technical issue. The policy issue regards the common preference by health care provider HIOs that the PHI released to the first organization may not be released by the first organization to a second organization. This situation is only addressed in the DURSA within some other "permitted uses," such as "payment" and not included in "disclosures pursuant to an authorization provided by the individual."[11] The technical issue in both research use–cases and, incidentally, in "pay-for-performance" use–cases relates to the recording within the detailed clinical data of the identity of the organization where the data was first collected, an issue often referred to as "data provenance." Only some health data standards, e.g., HL7 reference information model, offer support for data provenance. However, NwHIN communications allow for a wide diversity of health data standards, some of which do not include support for data provenance.

In summary, this analysis finds that DURSA policies support the ability for individual consumers or their representatives to authorize release of PHI for "research" and for responding participants on the NwHIN to honor this authorization by executing the release of PHI. Consumers must utilize the term "research" within the access consents in order to explicitly authorize the

disease registry to use their PHI for research purposes. However, according to the DURSA, a health care provider HIO may elect *not* to honor authorizations for permitted purposes other than treatment, which would then effectively negate consumers' efforts to donate PHI.

Discussion

This analysis of the policies and technologies designed for the NwHIN validated that disease registries could become participants on the NwHIN and enable consumers to donate their information to research.

This empowerment of consumers by policy assumes that both the disease registry organization and the health care provider have signed the DURSA, have passed the NWHIN test approach requirements, and comply with the NwHIN specifications:

> DURSA Section 1. "u. **NHIN Performance and Service Specifications** shall mean the NHIN Test Approach and the NHIN Specifications.
>
> v. **NHIN Specifications** shall mean the specifications adopted by the NHIN Technical Committee to prescribe the data content, technical, and security requirements necessary to support information exchange among NHIN Participants. The NHIN Specifications are attached hereto as Attachment 1, and as amended from time to time in accordance with Sections 11.02 and 11.03.
>
> w. **NHIN Test Approach** shall mean the framework for Testing and demonstrations for parties seeking to participate in the NHIN. The NHIN Test Approach is attached hereto as Attachment 2, and as amended from time to time in accordance with Sections 11.02 and 11.03."[11]

However, from the viewpoint of the consumer wishing to donate PHI to a disease registry designed for research, the analysis of the DURSA revealed some weaknesses. Health care providers need not honor the consumer authorization and need not support the data provenance standards needed for good research.

To allow full automation, this empowerment of consumers assumes that the disease registry has the technical capability to collect an authorization signature from the consumer and create a standardized XACML policy file authorizing the release of PHI for the purpose of research. Further, a copy of that signature document and that specific XACML policy file for an individual consumer should be available to the responding HIO when the responding HIO receives a request for release of PHI from the disease registry or when the disease registry receives a request for PHI from another HIO on the NwHIN. Of course, this analysis also assumes that the disease registry is able to analyze the standards-based PHI data it receives from other HIOs over the NwHIN. Disease registry organizations should undertake an examination of their own internal systems for the ability to analyze standards-based data.

All HIO transactions must generate audit trails. However, when a consumer has authorized release of PHI for research purposes and a responding HIO has permitted or denied the request, a HIO might also desire an automated mechanism that notifies the consumer. Electronic health care notification standards exist for this purpose in IHE and the NwHIN secure health email specifications.

Together, these many assumptions could represent a daunting barrier to disease registry organizations. Fortunately, in parallel with the development of the NwHIN, an open-source community was created called "CONNECT" to create a NwHIN gateway.[19] This software gateway simplifies the complexity of implementing the NwHIN specifications. Increasing experience with implementing CONNECT gateways has led to an expanding number of human resources available to help organizations participating on the NwHIN. In addition, multiple open-source software vendors have announced support for installation and maintenance of CONNECT gateways.[20] A subsequent analysis that examines the cost of implementing NwHIN gateways might be helpful to registry organizations contemplating strategies to extend their research capabilities.

Conclusions

This analysis of current NwHIN technology and policy allows several deductions. Disease registry organizations with interests in research may decide to participate in the NwHIN by utilizing gateway technology. By supporting this kind of research HIE, they also empower consumers who wish to create access consent policies for release of PHI for research. Viable technologies that allow more patients to easily donate their PHI to disease registries create the opportunity for viable strategies that allow disease registry organizations to increase the size of their research databases.

By extension, more capable disease registries enabled by this technology create new opportunities for researchers in evidence-based medicine. However, this extended conclusion should be exercised with caution. Better use of disease registries may depend as much on improved DURSA policies and better-trained and motivated researchers and providers familiar with this technology as much as on empowered consumers who can participate by utilizing this technology.

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