

**Response to the ONCHIT
Request for Information**

By the OpenHRE Team

www.openhre.org

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About OpenHRE.org

www.openhre.org

Mission:

- To foster development, distribution and support of Master Patient Index and Health Record Exchange systems and components held as Free/Open Source Software
- To build a community to this aim
- To realize this goal via a self-sustaining business model and open collaboration among all stakeholders

Goal: To accelerate the National Health Information Network (NHIN) implementation by providing public domain tools to Regional Health Information Organization (RHIO) initiatives

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Executive Summary

This RFI response is from OpenHRE.org, a community fostering development, distribution and support of Master Patient Index and Health Record Exchange systems and components held as Free/Open Source Software.

The RFI asks questions to stimulate public response on the NHIN, how it can be created, grown, managed and sustained, and what are models, roles and responsibilities for this process. The RFI discussion is in the context of RHIOs, conceptual entities still to be realized, but which may be business entities created to deliver more cost effective and efficient health services, possibly regional in scope. In response to these questions, OpenHRE.org thinks:

- The NHIN is the set of standards for interoperability, connectivity and data exchange between RHIOs, the security for those exchanges and the definition of responsibilities and activities for RHIOs (or business entities exchanging health information).
- The Federal government, most likely ONCHIT, should initially charter organizations to set standards for interoperation, connectivity and the responsibilities for and between RHIOs. Standardization should focus on open-source “reference implementations” to deliver interoperability and interconnectivity between RHIOs and interoperability and interconnectivity with health records systems at the point of care.
- Subsequent to initial standardization and reference implementations, ONCHIT should foster and encourage private innovation for further growth in the NHIN.
- The government should not build the NHIN, only set it in motion by facilitating standards, including reference implementations, and then by encouraging innovation.
- Two models can be used to build the NHIN: the internet for interoperability and connectivity and the Federal banking system for financial sustainability. Of these:
 - The Internet was initiated by DARPA for secure communications, became a science research network, then was released to the private sector as it grew into the world wide web.
 - The federal banking system focused on efficiency and effectiveness by reducing transaction costs to become a model of secure global transactions at least cost.
- Adoption of the NHIN will follow business case and cost effectiveness from the top down, with large payers as the first likely users. Reducing transaction costs for payers will drive the NHIN.
- The Federal government is one of the most likely users of the NHIN as a major payer.
- The bottom levels, where health care is delivered to patients, will be the last adopters of interconnectivity and interoperability since the systemic and cultural maturity is lowest, even though the standards for interconnectivity are expected to be the same, though perhaps more detailed, as at the top levels.
- If NHIN adoption is encouraged by preferential payment or punitive measures by lesser payments, the safety net must be supported or subsidized as the least sophisticated yet key players serving the under- and uninsured.
- The NHIN will not happen swiftly.

ONCHIT Question #1:

The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned, and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this RFI regarding interoperability.

OpenHRE.org Response:

The NHIN is both the technology and governance infrastructure that enables three objectives:

- [1] Real-time point of care access to patient health information from all healthcare providers participating in Regional Health Information Organizations (participating providers)
- [2] Patient-centric aggregation of health information from all participating providers into a patient-owned model (e.g. virtual health record)
- [3] De-identified aggregation of health information for improvement of public health, including bio-terrorism surveillance.

The governance and technology models for these three objectives have various requirements:

Real-time point of care access supposes a model that is fully federalized, where providers who originate patient health information (PHI) are the only ones who own and hold that PHI (the PHI is not centrally owned by a RHIO or the NHIN). This PHI is accessible on a real time basis by another, unaffiliated provider (a requesting provider) assuming that both are affiliated with participating RHIOs (although not necessarily the same one). Originating providers for matters of convenience may choose to maintain PHI in shared databases, such as a database managed by the provider's RHIO, or an exchange within their RHIO, which might include data caches to permit real-time access, however the PHI remains nevertheless owned and controlled (through database administration and governance regulations) by the originating provider, not by the RHIO or NHIN. In this respect the originating provider maintains responsibility for the PHI, including under what circumstances the PHI may be shared with a requesting provider. The originating provider thus is the responsible link between the patient (who authorizes the originating provider to share the PHI) and the requesting provider.

The governance model for real-time point of care access must address sharing of trust between a requesting provider and originating provider regarding the veracity and authenticity of the PHI and the method for correct patient identification. The governance model must also address medical malpractice liabilities associated with the requesting provider's use of external data (data collected and categorized by others with whom the requesting provider has no legal relationship). An assumption is that personal verification between requesting and originating providers may not be practical because of the real time nature of the process, and therefore a governance framework is required.

The technology model must address issues of data format and Health Records Exchange standards to ensure proper interpretation of external data by the requesting EHR. Note the assumption that the external data is brought into the requesting EHR system, not simply displayed separately to the requesting provider. This process requires significant changes in EHR's such that external data can be tagged as external and displayed despite data format differences. The NHIN must establish a complete set of data standards (what the data is and how it is formatted) to facilitate this, but differences will exist wherever the data standards permit choices. For example, if an originating EHR collects body temperature in degrees Fahrenheit, while the requesting EHR only handles temperature in degrees Celsius, then a conversion process must be employed by either the provider, the requestor, or potentially a third-party conversion provider.

The NHIN should include recommended data format and exchange standards, to minimize the need for conversions.

The NHIN model recommended is one where

- The NHIN is a Health Records Exchange between RHIOs.
- Participating RHIOs are certified as abiding by interoperability standards, policies and operational guidelines promulgated by the federal government and chartered standards groups.
- EHR systems within federally certified RHIOs directly exchange health records with other such EHR's without requiring a NHIN application in the middle – the Internet model of direct server-to-server client exchange.
- As well as authorizing standards, the NHIN facilitates the provision of open Reference Software that clarifies the standards and also provides for a basic publicly-available implementation of the NHIN.
- The NHIN includes authentication services (for providers and provider organizations) and addressing services (unique identification for RHIOs, provider organizations, and providers) to support RHIO-to-RHIO interoperability.

The technology model must also address the issue of patient identification, such that a requesting provider will be able to determine with near 100% assurance that the data presented by an originating EHR does in fact belong to the patient at hand. The assumption here is that in many practical examples, such as a patient admitted to an hospital's emergency department, there will be no prior linkage of patient identity between the requesting EHR and external EHR and therefore the patient identification must be made on a real time basis, without necessarily the benefit of discussion between the requesting and originating provider. This places the burden of patient identification on the requesting provider, the patient, and the technology of the NHIN/RHIO patient identification model. RHIOs may evolve various patient identification models; it is critical that the NHIN institute interoperability standards between such models so that a requesting provider, using their RHIO, will be able to initiate a check against other RHIOs MPIs, hopefully without requiring an intermediary NHIN MPI translation application.

There are additional capabilities that might be required for real time point of care access of PHI that may result in elements of requirements for the NHIN, for instance there may be a requirement for secure messaging between requesting and originating provider, or tagging of requests for service (such as requesting specialty consultation) that would facilitate simplified sharing of resulting data with the requestor. Secure messaging and tagging might be two (of many) capabilities that the NHIN specifies supports for real-time point of care access.

Patient centric aggregation supposes a model where a patient can aggregate most (certain data will be excluded) of their PHI locally and permanently for their use. The authors assume that much responsibility will rest with the patient: the patient will initiate aggregation and will be required to request PHI from specific providers rather than requesting data from all possible sources. Such a patient-managed health record is an excellent opportunity for the patient to express what information may be shared, and what information may not be shared.

The technology model for patient centric aggregation should directly leverage the real-time point of care access model, described above. This should be possible given the federated, Internet-like model described above.

De-identified aggregation for public health requires a model that centralizes selected data on a regular basis, rather than the model of requesting PHI for specific patients on a real-time basis as described above. The NHIN network for de-identified aggregation will need to address additional difficult technical issues as well as new governance issues.

The primary governance question to be addressed is whether RHIOs will be required, as part of the operational guidelines, to perform regional de-identified aggregation such that public health organizations will work with regional data that has already been de-identified and aggregated. Alternatively, the NHIN could avoid requiring RHIO aggregation and instead allow for the collection, de-identification, and aggregation from all providers in the country – a decidedly much more difficult technical and operational task.

The technical issues to be addressed will depend on the above question of RHIO aggregation. If RHIOs are not required to aggregate, then the technical issues facing the NHIN will include

- [1] Determining an acceptable technical and operational burden of effort on each EHR in the country requiring each to establish a process for extracting PHI data and delivering to public health organizations via the NHIN. The data format and exchange standards defined for real-time point of care access should be acceptable.
- [2] Determining whether recipient or the originating EHR will be responsible for the method to be deployed to avoid duplicate data (while this might sound trivial, it is likely to be a significant effort).
- [3] Determining the mechanism for linking records from disparate systems to a single patient.

This correlation algorithm will likely be different from that used the real-time point of care access, since 100% assurance of correct linkage is not required and provider-to-provider verification would not be practical.

ONCHIT Question #2:

What type of model could be needed to have a NHIN that: allows widely available access to information as it is produced and used across the health care continuum; enables interoperability and clinical health information exchange broadly across most/all HIT solutions; protects patients' individually-identifiable health information; and allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives? Please include considerations such as roles of various private- and public- sector entities in your response.

OpenHRE.org Response:

As we look to best practices to help define a model that will in fact be adopted and result in the desired outcomes, there are successes and failures from which to learn. A most obvious success is the phenomenal use of the Internet, where key lessons include:

- [1] Establish bodies of authority to handle the need for standards.
- [2] Establish open (not proprietary) standards for all exchange and program interface. Http, https, html, xml, smtp, imap, etc. were set such that interoperability is readily achievable amongst proprietary as well as open source commercial applications that play a key role in the use of the Internet.
- [3] Recognize the need for addressability and from the beginning establish the means to ensure unique addressability. Email address uniqueness and URL uniqueness are two different models where uniqueness was a critical factor in the growth and use of the Internet. The NHIN might even build upon these two standards of addressability.
- [4] Tackle security issues by embedding security into lower layers of the process. Here the Internet model shows an example of doing it right (HTTPS was an early, well defined, yet flexible security protocol that kept the implementation relatively low in the protocol stack enabling commercial applications to readily use it), and an example of missing an opportunity to doing it right (email protocols came close to including requirements for secure/authenticated connections between mail servers, but did not implement this, to the delight of the spammers).
- [5] Keep the centralized infrastructure to a minimum; push as much “application work” to the edges (users and servers). The decision to have the Internet be just the connectivity, with applications “hung” on rather than embedded, has been a key reason for the rapid growth of applications by entrepreneurs. The rapid rise of Google is an excellent example of this – the Internet does have the low level IP address search capability necessary for interoperability, but does not have an (unnecessary) embedded application level search, leaving this “edge” function to be evolved (more effectively!) by others such as Google. The Internet model pushes as much to the edges as possible, while focusing its internal functions on enabling the edge players to prosper.

An example of the distributed, rather than centralized, nature of the Internet is its DNS component, which translates between Domain Names and IP addresses. DNS is hosted on both private and public servers, spread across the Internet, all communicating according to an agreed-

upon specification. As an example for the NHIN, rather than building a Patient Index into a government-owned NHIN infrastructure, the NHIN should specify a distributed Patient Indexing Service that can be implemented across the NHIN as needed. If only one vendor chooses to implement this service, then they can surely charge for it. If some other vendor desires gratis use of the service, then they will contribute to its gratis implementation. Open Reference Software for the Patient Indexing Service will ensure its widespread use and uniform adoption.

Another example of a successful network between peers is the financial network within the United States, where banks and other financial institutions can freely interoperate to exchange financial information. Here again the network is standards based, privately funded and operated, and designed to minimize overall transaction cost.

There are numerous examples of attempts to build proprietary, data exchange capabilities; to the extent that they were successful (and many were) their ability to sustain themselves in the market has all too often depended on proprietary lock rather than value to the users. The lessons to be learned from these are for the most part the inverse of those above.

If we accept these notions of lessons learned, the NHIN will:

- Establish standards committees (or charter existing ones) to define complete (as in, nothing else is needed in order to...) standards for data format, exchange protocols, naming conventions, addressability protocols, de-identification processes, provider and user authentication (for within RHIO requests for PHI as well as RHIO-to-RHIO requests), and other topics as may be required.
- Establish governance models for NHIN behavior, including the topics of sharing of trust; managing medical liabilities; relationships between the NHIN and RHIO's, and federal agencies who use the NHIN such as CDC.
- Establish required activities of RHIO's, such as aggregation of de-identified health information (should it decide on this model), and acceptance of requests for PHI from providers outside of the RHIO participants.
- Engage the private sector and stakeholders in the federal, state and local governments and NGOs in the above deliverables. It is important in the authors' opinion to be certain that the stakeholders' business objectives be considered, but not viewed as primary objectives (the primary objectives are described in the July ONCHIT HIT Strategic Framework document). Had the Internet committees for example decided to consider Microsoft's and IBM's business objectives as primary, would the entrepreneurial/competitive spirit been engendered to the extent it has? Would Google be here today? Or Internet banking linked to QuickBooks? The fine line that needs to be walked is to include the private sector, to understand the impact of NHIN directions, solicit private sector support and position the private sector to respond quickly to NHIN needs, and at the same time not to confuse private sector objectives with the objectives driven by real-time point of care access, patient centric aggregation and de-identified aggregation for public health.
- Use private organizations/NGOs to build and deliver the physical NHIN, rather than have it be government-operated.

- Ensure that open Reference Software is made available for the NHIN, to clarify the specifications, and to allow basic access to the NHIN for all potential participants. OpenHRE.org is one organization dedicated to an open Reference for Health Records Exchange software.
- Utilize the Internet, including Internet connectivity, secure transport protocols and web services to minimize costs and complexity of implementation of the NHIN.

ONCHIT Question #3:

What aspects of a NHIN could be national in scope (i.e., centralized commonality or controlled at the national level), versus those that are local or regional in scope (i.e., decentralized commonality or controlled at the regional level)? Please describe the roles of entities at those levels. (Note: “national” and “regional” are not meant to imply federal or local governments in this context.)

OpenHRE.org Response:

At the national level, the NHIN should:

- [1] Establish and oversee, or charter existing, standards committees to design the NHIN.
- [2] Establish governance models for NHIN behavior, including the topics of sharing of trust; managing medical liabilities; relationships between the NHIN and RHIOs, and federal agencies who might use the NHIN.
- [3] Establish the required activities of RHIOs, such as aggregation of de-identified health information (should it decide on this model), and acceptance of requests for PHI from providers outside of the RHIO participants.
- [4] Engage the private sector and stakeholders in the federal, state and local governments and NGOs in the above deliverables.
- [5] Ensure that open Reference Software is made available for the NHIN, to clarify the specifications, and to allow basic access to the NHIN for all potential participants.
- [6] Charter entities that will test and certify compliance to NHIN standards.

The building and operation of the physical NHIN can be accomplished through private organizations/NGOs, operating within a free-market system.

ONCHIT Question #4:

What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Please describe the kinds of entities and stakeholders that could compose the framework and address the following components:

- (a) How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?*
- (b) How could policies and standards be set for the development, use and operation of a NHIN?*
- (c) How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?*
- (d) How could the NHIN be operated? What are key considerations in operating a NHIN?*

OpenHRE.org Response:

- 4 (a) How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?*

To develop the model for a NHIN, both NHIN and RHIO models should be developed in concert, so that the role of the RHIOs is to perform health records exchange through standards interoperability, while the role of the NHIN can be positioned as the organizational, governance, and lower level communications infrastructure, much as the Internet is to e-Commerce. To achieve this, stakeholders for both RHIOs and the NHIN must be included in the model development. A single location in the federal government (ONCHIT, presumably?) could have the responsibility/accountability for establishing these models and could do so through working groups comprised of representatives from:

- [1] RHIO-like pilots/projects such as MA-SHARE, the Regenstrief project and OpenHRE.org
- [2] The spectrum of healthcare providers (hospitals, HMO's, Specialty clinics, Safety Net clinics, lab services)
- [3] Public health agencies (CDC, FDA, AHQR, etc)
- [4] Appropriate current standards committees (ANSI, ASTM, W3C, etc)
- [5] Other parties, such as the Markle Foundation, which have interests in/knowledge of healthcare interoperability processes.

Accomplishing the construction of the NHIN will depend on the degree of success in establishing an interoperable model between RHIOs. Current vendors in the healthcare field, such as those providing EHR systems and insurance data exchange, should be consulted, but care should be taken not to consider their business objectives to the detriment of the three primary objectives of the NHIN. Rather, include their inputs as they relate to determining costs, degree of difficulty, and likelihood of success of implementing aspects of the models that impact their businesses. Include vendors to other markets as well, for example vendors providing

authentication services to the banking industry, in order to gauge feasibility of construction of new elements of the NHIN. A Reference Implementation of both the NHIN and RHIO, deployed to verify completeness and correctness of the model, protocols, etc will be an invaluable step in assuring success of the models, and will be an invaluable tool in qualifying software systems as interoperable.

4 (b) How could policies and standards be set for the development, use and operation of a NHIN?

Policies, standards and operational guidelines (for development, use and operation) could be set by working groups responsible for both the NHIN and RHIOs (combining the promulgation of both NHIN and RHIO policies and standards will maximize interoperability between RHIOs, as described earlier). Working groups could be established either within the domain of the federal government, or externally in existing standards groups if chartered by the federal government, where their charters will be to develop and maintain policies and standards for all aspects of NHIN including trust sharing, liability management, authentication services, data standards, etc.

Standards (or reams of good intentioned specifications) will continue to evolve and develop over time. These efforts are all worthwhile, and the more that information is available in standard forms, the better. Unfortunately, interpretations of how to implement these “standards” vary not only between software providers, but also within solutions delivered by the same software provider. The software community has learned from repeated negative experiences that standards are not sufficient to provide interoperability. At some point, the only remedy is to develop a reference implementation that all providers use for providing information exchange. Reference software is meant to be complete, available for use at no fee in basic form, and may be expanded or enhanced as market forces and evolving standards dictate. The collaborative open-source nature of this software allows all users the opportunity to participate in its development. Specifications can be incomplete or vague, but the building of a reference implementation using these specifications forces these issues to the surface where they are rectified.

4 (c) How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?

The best approach for accelerating the adoption of use of the NHIN, in the authors’ opinion, is to provide motivation to the users and at the same time simplify the effort required to use the NHIN and promote formation of RHIOs.

- To motivate users, an education effort could be effective in encouraging provider organizations to join their RHIO. Financial encouragement by the federal government where it is the health care payor (CMS and federal employee plans) could encourage provider organizations to join their RHIO.

- Implementing the recommended model should simplify the effort required to use the NHIN. The high degree of structure in the model for RHIOs to facilitate direct RHIO-to-RHIO interoperability should minimize or eliminate the amount of effort by RHIOs (and their users/providers) to extend their use of RHIO-based health records exchange across the NHIN. In this model, RHIO implementation de facto adds to the national deployment of the NHIN.
- The above-described model, which envisions a RHIO model with defined interoperability requirements, defined activities and a reference implementation against which to test RHIO piloting, will also promote formation of RHIOs by reducing risks, providing lessons learned, and enabling software and systems suppliers to develop standard, cost-effective offerings for the RHIO marketplace.

4 (d) How could the NHIN be operated? What are key considerations in operating a NHIN?

The recommended NHIN model requires only a modest amount of “operation” by the NHIN, for activities such as oversight and governance. These could be performed by private industry at the direction of the federal government, or at the direction of the chartered working groups.

A key component to the successful private operation of the NHIN is the economic component. The NHIN design should include the potential for service-for-pay. Perhaps the NHIN would define a structure that allows for micro-payments. For example, a vendor could build a great NHIN (inter-RHIO) conversion service, but to use it a RHIO might pay per transaction. The price would be driven by Quality Of Service and competitive pressures. Just as security needs to be built in from the start, flow of payments may also need to be built in.

ONCHIT Question #5:

What kind of financial model could be required to build a NHIN? Please describe potential sources of initial funding, relative levels of contribution among sources and the implications of various funding models.

OpenHRE.org Response:

Several financial models are possible during the building phase of the NHIN and RHIOs, including funding from:

- [1] Federal sources for the NHIN, and regional sources (from provider organizations, insurance carriers, state governments, etc.) for the RHIOs
- [2] Regional sources for both the NHIN and RHIOs, where the participants in RHIOs are required to fund the NHIN as well as their RHIO.

Much of the early work of designing the NHIN will be in standards setting, with various organizations, including private organizations/NGOs, participating. Dues collected, on a sliding scale, from the participants in these standards bodies could be used to defray the costs of setting the standards, including building the necessary Reference Software.

If the financial model for the operation of the NHIN allows for revenue opportunities for private industry, then build financing will take care of itself, because industry will be willing to invest with the promise of future profits.

ONCHIT should take immediate action to market and incentivize state and/or private foundations to encourage NHIN-compliant HRE implementation grants within RHIOs. Part of ONCHIT's incentive could include matching grant dollars with ONCHIT related awards, reviewed and authorized in part by ONCHIT. At a bare minimum, a selective educational campaign on the benefits of a NHIN should commence. We are aware of over \$600,000,000 in 2 new set-asides for state health care improvements that are just now forming. After contacting both directors, we quickly learned that neither had any awareness of the potential returns associated with HRE, any knowledge of ONCHIT or the NHIN or a RHIO, or any inclination to fund any such efforts - at least at this point.

Again we can refer to the Internet for a model. The initial network was government funded and developed, as the DARPA net. The NSF then took over the network as wider academic uses for the network were discovered. Ultimately the Internet was able to be supported and operated without government assistance.

ONCHIT Question #6:

*What kind of financial model could be required to operate and sustain a functioning NHIN?
Please describe the implications of various financing models.*

OpenHRE.org Response:

It is critically important to minimize the operations duties of the NHIN by designing the NHIN to be little more than communications between RHIOs.

In the cases where inter-RHIO infrastructure and services are required, allow them to be provided, potentially for a fee under a free-market model, by private industry.

The NHIN should be designed from the start to include payment and micro-payment services, and brokerage services between requestors and providers.

Continued government oversight of the NHIN will be required throughout its operation. Grants for special projects to stimulate creativity may also be required.

ONCHIT Question #7:

What privacy and security considerations, including compliance with relevant rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are implicated by the NHIN, and how could they be addressed?

OpenHRE.org Response:

Privacy and security considerations will be of paramount concern for the working groups chartered with developing the interoperability standards for RHIOs and the NHIN. Privacy and security will have to be designed into the NHIN from the very beginning, because by its very nature, Health Records Exchange seems to fly in the face of Privacy. These working groups should develop, in addition to the standards, a set of privacy and security operational guidelines for both the RHIO and NHIN models, where the operational guidelines have the federal government (ONCHIT?) sanction for meeting the requirements of federal regulations (HIPAA, and other pertinent regulations). Providing such sanctioned operational guidelines will provide a major benefit to RHIOs and all participating health care providers by reducing the variability and guesswork (and legal expense and delay) that is currently an unnecessary part of compliance to HIPAA regulations.

It will be necessary for the NHIN to include federated Authentication services, Authorization services, and services that allow for the federation of Trust across the NHIN. A preliminary investigation into the sorts of Security services that are required may be found at <http://www.openhre.org/local/SecurityArchitecture.pdf>

One of the challenges of a Health Records Exchange is to transmit information without losing control of that information. Digital Rights Management technologies may help to solve this challenge.

ONCHIT Question #8:

How could the framework for a NHIN address public policy objectives for broad participation, responsiveness, open and non-proprietary interoperable infrastructure?

OpenHRE.org Response:

Broad participation: Use financial incentives. Increased efficiencies should lower costs. A portion of the surplus could go to NHIN support. The government is the largest payer, and can mandate participation for the transactions that they support. Make sure that there is a micro-payment infrastructure as part of the NHIN specifications, to encourage private vendors to provide the hardware and software needed for the NHIN.

Open Reference Implementations will help to lower the cost of entry for safety-net organizations and encourage their broad participation.

Responsiveness: Vendors will compete in real time on the network to bid on requests for services based on Price and Quality of Service(QoS). Include QoS measurements as part of the NHIN specifications, and have chartered vendors maintain blacklists of vendors who do not meet their QoS promises. Alternatively, the chartered vendors could measure and publish actual QoS performance, and bidding could be based on past, rather than promised, performance.

Secure data caches, perhaps at the RHIO level, may be needed to allow for rapid data access where in-house systems are not capable of the required performance.

Open and non-proprietary: Make sure that there is an open source Reference Implementation available for all the key components of the NHIN. Invest federal funds and dues paid into the standards organizations to support this in the areas where the open implementations are not forthcoming. In this way vendors will compete based on value-add and service, rather than proprietary lock.

ONCHIT Question #9:

How could private sector competition be appropriately addressed and/or encouraged in the construction and implementation of a NHIN?

OpenHRE.org Response:

The NHIN opportunity for the private sector is significant and can be encouraged by:

- [1] Including representation from the private sector in the working groups
- [2] Developing the model for the NHIN and for RHIO's whereby existing private sector activities are incorporated (with the public standards requirement as stated above), such as use of commercially available digital certificates and authentication servers based on open standards
- [3] Establishing clear data/protocol/operating standards for commercial suppliers so that these suppliers will be able to develop profitable, replicable, supportable "edge" applications that connect into the RHIO/NHIN infrastructure.

The NHIN framework design must enable:

- Access to structured clinical data via a vendor neutral core protocol or suite of protocols ("NHIN Core") based on Open Standards
- Robust opportunities to innovate and compete outside the NHIN Core, such as vertically within a market category (e.g., e-Prescribing) or horizontally across the NHIN Core (e.g, integration by a single vendor within an enterprise HIT installation)
- As a corollary, the NHIN framework must be complete enough to not enable proprietary "embrace and extend" attacks on the open standards of the NHIN Core.

Construction and implementation of the NHIN will offer substantial opportunities for private sector participation, but it is too early in the development process to forecast specific operations tasks. Hardware and "plumbing" infrastructure details that may be required for secure NHIN operations are unknown, as are administrative staffing requirements. This question will be better answered with results in-hand from the 9 Connecting Communities for Better Health (CCBH) demonstration projects.

Using the Internet as a model for the NHIN implementation, it is entirely possible for almost all of the NHIN to be constructed by and operated by the private sector. The Government still has an important role to play for oversight, standards setting and administration. Encouragement of open source implementations of NHIN components will remove the possibility of inclusion of proprietary technologies in the NHIN. Certification of open source Reference Implementations will provide concrete clarifications of specifications, and relegate the private sector to competition based on price, scalability, and reliability, rather than through the inclusion of proprietary features and technologies affecting interoperability.

ONCHIT Question #10:

How could the NHIN be established to maintain a health information infrastructure that:

- (a) evolves appropriately from private investment;*
- (b) is non-proprietary and available in the public domain;*
- (c) achieves country-wide interoperability; and*
- (d) fosters market innovation.*

OpenHRE.org Response:

10 (a) evolves appropriately from private investment:

Private investment should be used as much as possible to fund the implementation and operation of the NHIN, just as with the Internet and the US financial network. What must be kept out are proprietary Core features. By having open source Reference Implementations of all Core NHIN components, private industry is relegated to “doing it better” rather than “doing it different.” Opportunities for income from the operation and use of the NHIN should be sufficient to encourage the initial private investment needed.

10 (b) is non-proprietary and available in the public domain:

The NHIN Core Specifications and Reference Implementations should be available to the public. Vendors are free to produce their own implementations, as long as they meet the Standards and are certified to inter-operate with the Reference Implementations. If the Reference Implementations are found to be incorrect or inadequate, then they should be modified under a consensus process, with the results also being made public.

10 (c) achieves country-wide interoperability:

Let the NHIN standards development process operate under an informed and unified consensus process, as with the IETF. Connecting for Health (CFH) is exemplary in the convening of relevant participants necessary to succeed at establishing the open standards of the NHIN Core and a likely road map to get it deployed. Having concrete open Reference Implementations will greatly aid interoperability, as the Reference Implementations become the “gold standard” to which all other implementations must be certified. In areas of the country lacking funds to purchase high-powered proprietary solutions, the Reference Implementations become a sufficient low-cost solution to allow for connectivity and interoperability.

10 (d) fosters market innovation:

Outside the NHIN Core, vendors are free to innovate and produce new technologies. Inside the NHIN Core, vendors are free to produce more robust and efficient implementations. Inside the NHIN Core there is also the possibility of patented technologies, as long as the consensus process that leads to the Core specifications agree to the inclusion of these patented technologies. Free-market payment structures within the NHIN will encourage innovation.

ONCHIT Question #11:

How could a NHIN be established so that it will be utilized in the delivery of care by healthcare providers, regardless of their size and location, and also achieve enough national coverage to ensure that lower income rural and urban areas could be sufficiently served?

OpenHRE.org Response:

An assumption of the recommended model is that healthcare providers use their RHIO to access PHI from other providers. Therefore, in order for the NHIN to achieve national coverage and sufficiently serve the lower income areas and patients, including those who have no health insurance and rely on community safety net clinics, the NHIN should focus on:

- [1] Promoting widespread adoption of RHIOs, including establishing the RHIO framework of interoperability described above
- [2] Assuring that the RHIO “coverage map” of the country does not exclude rural areas
- [3] Assuring that the requirements of the safety net environment are included in the detailed development of the NHIN architecture, standards and operational guidelines.

RHIOs should be large enough to have the resources to connect to the NHIN, and be small enough to efficiently serve their constituents. Open Reference Implementations of the Core NHIN components will assure that software licensing costs do not stand in the way of intra- and inter-RHIO Health Records Exchange.

Although the NHIN will be a network for inter-RHIO communications, the standards that are set at the NHIN level will also be able to benefit intra-RHIO communications, with the ultimate benefit of increasing the efficiencies available to actual healthcare providers.

Increased visibility into medical histories should increase patient safety and save lives. Practitioners who regularly use the NHIN should have a lowered incidence of errors, and thus should be rewarded with decreased malpractice insurance payments. This sort of incentive, coupled with ease of use and a low cost of entry, should encourage use of the NHIN.

ONCHIT Question #12:

How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?

OpenHRE.org Response:

RHIO Health Record Exchange projects will, if the model described here is followed, be required to follow a considerable degree of standardization of operation in order that RHIO-to-RHIO interoperability is obtained with a minimal need for conversion services. Another assumption is that Health Record Exchange projects (other than for RHIOs) must join a RHIO in order to participate in the NHIN.

As a unit within a RHIO, these projects should abide by most of the same interoperability standards – this may require some re-engineering on the part of existing projects. It is critically important that the NHIN establish the RHIO interoperability standards as quickly as possible to minimize the deployment of exchange projects prior to promulgation of these standards to minimize re-engineering requirements.

A successful NHIN will render many greatly impact some current Health Records Exchange (HRE) demonstration projects obsolete, which is not unexpected because taken as a whole they are part of a larger iterative discovery process.

HRE solutions that enable facile, ubiquitous, and secure access to patient health data without compromising the needs of the clinical decision making process will “win” the NHIN paradigm design contest.

A robust and inclusive national technical dialog (e.g. CFH) combined with a series of creative demonstration projects (e.g. CCBH) and with an emerging certification process (e.g. CCHIT) will advance the process of identifying the likeliest “best practice” for an NHIN Core capable of adapting to every conceivable HIT niche.

ONCHIT Question #13:

What effect could the implementation and broad adoption of a NHIN have on the health information technology market at large? Could the ensuing market opportunities be significant enough to merit the investment in a NHIN by the industry? To what entities could the benefits of these market opportunities accrue, and what implication (if any) does that have for the level of investment and/or role required from those beneficiaries in the establishment and perpetuation of a NHIN?

OpenHRE.org Response:

Adoption of an NHIN that focuses on direct RHIO-to-RHIO interoperability and the required enabling standards would have a positive effect on the health information technology market by:

- [1] Establishing an open standards approach for all of the edge technology players (EHR systems, Hospital IT systems, etc) where suppliers compete on value provided within their applications rather than on proprietary interfaces
- [2] The significant IT human resources required to implement US-wide RHIO deployment will benefit from having increased consistency of skills needed and
- [3] Increased ability of IT vendors to sell into multiple markets, driving benefits for both the suppliers of IT systems (larger, more structured and predictable markets for software and services) and the provider organizations (more competition in those larger markets).

The majority of the market will be for the edge products; the actual costs of establishing and perpetuating the NHIN should be minimized with the inter-RHIO model leveraging on the existing deployment of the Internet.

Adoption of an NHIN will increase the dependency upon IT in the health care sector. HIT expenditures will increase from their current minimal level as a percent of overall sector spending, as increased efficiencies are discovered to offset these expenses. This transition will present dramatic opportunities for nimble private sector players to profit from emerging opportunities by delivering the next generation of digital clinical solutions. The service sector will be a big winner. Redundant and failover solutions will become common. Application Service Providers (ASPs) and Managed Service Providers (MSPs) will surge as a business category in order to deliver 24x7 on-site HIT support to the point of care.

The opportunities for overall savings are already there. The Insurance Industry spends billions of dollars paying for lab tests that have already been done. The true costs for prescribing conflicting medications is in lives, but here again another win is for the insurance companies. By rights the insurance companies should already be building an NHIN.

Doctors complain that the insurance companies benefit from these new technologies that the doctors have to pay for. Legislation may be needed to set up the proper economic system such that the NHIN will flourish. Insurance companies would probably be glad to charge doctors more for malpractice insurance if they do not subscribe to the NHIN. Perhaps legislation could require insurance companies to charge more to doctors who don't, and give back to doctors who do use and fund the NHIN.

ONCHIT Question #14:

What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

OpenHRE.org Response:

The most important entity is a designated agency/office (ONCHIT?) within the federal government which will be responsible for:

- Chartering existing or new working groups to develop NHIN and RHIO interoperability standards, and define governance solutions (shared trust models, solutions to liability issues,
- Approving the resulting standards, policies and operational guidelines of the working groups to promote clear rules for deploying RHIOs and interoperability between RHIOs
- Chartering organizations for certifying NHIN compliance
- Assessing needs within the broad healthcare IT environment so that federal resources can be marshaled effectively

Many entities exist today that could participate in the development and diffusion of these standards and policies, including industry data standards committees such as ANSI and ASTM and organizations focused on healthcare IT. These entities should share the goal of open standards. Private industry representation should be encouraged, provided there is agreement to the open standards model. Standards that are not in the public domain should not be used, unless absolutely necessary; the use of CPT codes for instance is a necessity, although these are not in the public domain.

The Internet is a great model for the sorts of entities that could help to develop the NHIN. The IETF is one example, as is W3C. As a matter of fact, the NHIN could be thought of as an extension to the Internet, so some of the Internet entities might consider helping out with the NHIN.

Other existing groups with much to contribute are CFH, CCBH, and CCHIT.

Comparing the interoperability success of the Internet, and J2EE, with the comparative failure of the Object Management Group regarding CORBA, one sees that specifications alone are not sufficient. Free open source Reference Implementations, and certification of proprietary implementations, are required to assure true interoperability. OpenHRE.org is already working towards this end.

ONCHIT Question #15:

How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA? How can these standards be protected from proprietary bias so that no vendors or organizations have undue influence or advantage? Examples of such standards and policies include: secure connectivity, mobile authentication, patient identification management and information exchange.

OpenHRE.org Response:

There will be several working groups and standards committees required to develop the interoperability standards, policies and operational guidelines; each must be given a charter and direction from the federal government, and the federal government must be the final approving authority, so that objectives can be met. A clear chain of accountability for these standards, policies and operational guidelines must be in place, with the federal government the final authority.

Free open source Reference Implementations are required to fully define the NHIN standards and protect them from proprietary bias. By removing "private features" from consideration, vendors will have to rely on attributes such as scalability and reliability to develop products for the NHIN Core. ONCHIT should consider securing funding for these initiatives where they are not forthcoming.

ONCHIT Question #16:

How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

OpenHRE.org Response:

The federal government, as the chartering and final authority on the standards, policies and operational guidelines, should charter existing SDOs wherever appropriate to perform the functions of the working groups.

A new SDO should be established, perhaps by ONCHIT, to develop and disseminate the official NHIN standards. This SDO would delegate work to the existing SDOs whenever possible, but would maintain the final say. This NHIN SDO would also be ultimately responsible for the shepherding of the Open Source Reference Implementations.

ONCHIT Question #17:

What type of management and business rules could be required to promote and produce widespread adoption of interoperability standards and the diffusion of such standards into practice?

OpenHRE.org Response:

Widespread adoption will be a function of financial opportunity, which should be built into the NHIN from the start.

Clarification of standards, and diffusion into practice, will be greatly helped by the availability of Open Source Reference Implementations. These low-cost alternatives to proprietary systems will also help the penetration of the NHIN into rural areas.

The federal government (ONCHIT or its designee) should certify each RHIO as meeting the standards, policies and operational guidelines; a RHIO Reference Implementation could be effective against which to test compliance. Organizations that do not gain this certification should not be permitted to participate in the NHIN without intermediaries. Periodic re-certification should be built into the process

ONCHIT Question #18:

What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

OpenHRE.org Response:

The federal government should take on the role of shepherding the NHIN through its initial phases until private industry can fully take over its operation. The federal government can also set up legal and incentive structures to ensure the success of the NHIN.

The federal government should refrain from implementation or operation of the NHIN, except as may be needed in its initial stages.

The federal government should charter and oversee the organizations that are responsible for NHIN standards, certification bodies, and reference implementations.

ONCHIT Question #19:

Are financial incentives required to drive the development of a marketplace for interoperable health information, so that relevant private industry companies will participate in the development of a broadly available, open and interoperable NHIN? If so, what types of incentives could gain the maximum benefit for the least investment? What restrictions or limitation should these incentives carry to ensure that the public interest is advanced?

OpenHRE.org Response:

Financial incentives are key to the success of the NHIN. Ideally the opportunities for savings that are already present, e.g. duplicate labs and duplicate meds, will be sufficient to insure success. Artificial incentives may be needed at first.

Incentives may be needed for two organizations: health care providers and RHIOs. Health care providers may need incentives to help build the business case for joining their RHIO and funding the IT and other changes needed for health information exchange. The federal government, as the largest single payer for health care, could initiate an incentive by instituting a two tiered reimbursement fee structure for Medicare, Medicaid and federal employee health care, with a higher reimbursement for providers who participate in certified RHIOs. This could be considered a form of a “pay for performance” fee structure, since higher quality healthcare will be a result of health information exchange. RHIOs would be the beneficiaries of this two tiered reimbursement; providers will be more willing to fund the sustainability of their RHIO knowing that the RHIO is needed to gain the benefit of the higher reimbursement.

Other means of incentives should be explored to promote provider organizations joining RHIOs and for the formation and sustainability of RHIOs.

An oversight Commission should be established to monitor the financial workings of the NHIN to ensure that the public interest is advanced.

Potential federal funding of Open Source Reference Implementations may be required to insure that standards are well-defined and that "proprietary locks" may be avoided.

ONCHIT Question #20:

What kind of incentives should be available to regional stakeholders (e.g., health care providers, physicians, employers that purchase health insurance, payers) to use a health information exchange architecture based on a NHIN?

OpenHRE.org Response:

Free market forces should ensure continuing incentives for all stakeholders once the NHII Core is established.

Start-up incentives should be limited. Competitive projects should be funded to discover best practices. Once identified, best practice pilot implementations should be funded, but once the benefits of the NHIN are apparent the subsidies can be tapered off or removed entirely

ONCHIT Question #21:

Are there statutory or regulatory requirements or prohibitions that might be perceived as barriers to the formation and operation of a NHIN, or to support it with critical functions?

OpenHRE.org Response:

Unfortunately, government regulations, particularly HIPAA security and privacy, are perceived as barriers, in large part due to the lack of federally approved operational guidelines. Currently each provider organization must develop its guidelines and gain agreement from their legal counsel and corporate leadership. This process is particularly difficult because of the new nature of the regulations and the risks associated with failure to meet their intent. If the federal government were to issue guidelines on how provider organizations could meet the intent of these regulations when participating in a certified RHIO, this perceived barrier would be dramatically reduced resulting in the more rapid adoption of use of the RHIO/NHIN model.

The ability for patients to manage their own Virtual Medical History will aid in the implementation of HIPAA-compliant privacy.

ONCHIT Question #22:

How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g., data privacy and security, antitrust constraints and tax issues)?

OpenHRE.org Response:

RHIOs could shoulder the bulk of new governance approaches needed to address these issues by establishing legal agreements between provider organizations (information sharing agreements, trust sharing agreements, etc) and by meeting the operational guidelines set forth by the chartered working groups.

A federally-managed oversight organization may be needed to monitor compliance.

ONCHIT Question #23:

Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.

OpenHRE.org Response:

The overriding technical architecture is the same as for the Internet: A “lightweight” decentralized network between providers and users. As many functions as is possible should be provided by the private sector, with standards and reference implementations shepherded by the public sector. Services are provided on a distributed basis. Payments, micro-payments, security, and Quality of Service infrastructure need to be part of the basic NHIN design.

For example, instead of a central, federal, Master Patient Index, the NHIN design should allow for federated identity queries to sweep over the NHIN, looking for matches. Regional consolidation of patient indexes would be done as a performance improvement, not an operational requirement.

ONCHIT Question #24:

How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?

OpenHRE.org Response:

NHIN System Readiness success could be measured by an 80% achievement of

- [1] Healthcare providers participating in NHIN-certified RHIOs
- [2] Population covered by certified RHIOs.

NHIN utilization could be measured by number of requests made for the exchange of health records, and success would be declared when 80% of all patient visits include utilization of RHIO and/or NHIN network services.

Another measure of success would be when 80% of all medical records are available over the NHIN, instead of locked up on paper or in closed legacy Electronic Health Record systems.

True success will be measured by the lives saved and cost efficiencies realized by the NHIN.