



The Virtual Patient Record: A Vision for Integrated, Personal and Information-Rich Health Care Enabled by the NHIN

A response to the
National Health Information Network
Request for Information

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Introduction: The Challenges

The goals for the NHIN are clearly important and worth the substantial investment that will be required by all stakeholders. We applaud Dr. Brailer embarking on this difficult but ultimately very worthwhile endeavor, leading the industry a major step forward.

We see three primary challenges:

1. **Technical.** To the best of our knowledge, no industry in any region worldwide has ever successfully attempted information systems integration with the types of requirements and scale as required by a NHIN. The track record of software projects with a size above \$1 billion is appalling in any industry, and it needs to serve as a warning.

Further: Just applying the lessons from smaller-scale efforts will simply not work; a radically more capable software architecture is required to integrate across 1000's of organizations with often many dozens or more internal information islands each, working in real-time, while guaranteeing the necessary privacy and resilience against malfunctions as well as deliberate attacks. (Make no mistake: a NHIN will also be a prime target for electronic attacks from teenage hackers to foreign governments.)

2. **Organizational.** Operating, maintaining and evolving such a massively complex system as well as developing it and testing it in the first place is a substantial organizational problem. However, depending on which technical architecture has been chosen, the organizational challenge can easily be more than an order of magnitude larger or smaller.
3. **Financial.** The investment required to make NHIN operational will be substantial in absolute terms and in relative terms as percentage of industry revenue. However, the technical architecture chosen will have the single biggest impact on the financial resources required for the overall NHIN project. While it will be easy to waste billions on an NHIN with nothing to show after many years, if the right software architecture can be developed and agreed upon, it will be possible to bring the project to fruition and deliver a platform for further innovation in the future with comparatively moderate expenses.

Thus it is paramount that an evolvable, decentralized, innovation-encouraging, secure, resilient software architecture for the NHIN is chosen from the very beginning. While it clearly must leverage existing technologies and standards to the maximum extent possible, the requirements for the NHIN are one or two orders of magnitude more complex than anything that exists today in standards committees or commercial implementations. It needs to be driven by a full and complete list of all the use cases against that are expected to be required within the next at least 20 years of NHIN operation.

In our view, no other issue that we face at this juncture has a similar impact on the eventual outcome of the NHIN cause as good software architecture. Within the next year, this issue should be the number issue on the agenda of NHIN.

Our response focuses on this issue and those questions directly related to it.

NHIN Wiki

To support the NHIN cause, we operate a Wiki focused on the NHIN.

The Wiki is located at:

<http://nhin.netmesh.org/>

Our goal is to track industry's and government's thinking for an NHIN as it evolves, while enabling participation by anybody who is interested. This being a Wiki, anybody can register and contribute to all content on the Wiki.

As the tremendous success of Wikis such as the Wikipedia encyclopedia has shown, Wikis can bring out the best thinking from many stakeholders on complex subjects in a collaborative fashion, and we hope that will also be true for the NHIN. Such collaborative thinking will certainly will be required in order to make the NHIN successful.

NetMesh Technology Contributions

NetMesh has developed two technologies that fulfill a number of the requirements for a practical National Health Information Network. While we realize that technology selection cannot and should not be performed at this stage in the NHIN process, we list these technologies in order to convey the kinds of system architectures that are feasible today, as they have unique advantages that cannot be provided by older centralized or clearinghouse architectures. **Just like the internet itself, neither of them requires any central entity for operation.**

Extensible Protocol for Replicating, Integrating and Synchronizing Distributed Objects (X-PRISO™)

X-PRISO, developed as part of the NetMesh InfoGrid™ platform, is a modern web services technology that effectively and efficiently solves the problem of managing, in real-time, partially overlapping and redundant information that is held by many incompatible information systems in different organizations that are not under common technical or managerial control.

This problem lies at the heart of the technical NHIN challenges, and unless it is solved cleanly and elegantly for the NHIN, the NHIN will be unable to emerge in functional or affordable form. X-PRISO is model-driven and can be used with HL7 and other information models that will emerge as technology advances while the NHIN is operational.

For example, X-PRISO can be used to virtually integrate patient information across many provider EMR and other systems, in real-time. This establishes a virtual, 360-degree patient view that also can be easily shared in a collaborative fashion by all providers involved in the care for this patient. In addition, it provides for notification of new information and other events of interest as they occur in real time.

Lightweight Identity™ (LID™)

NetMesh Lightweight Identity (LID) is a decentralized, secure and private digital identity system that enables participants (e.g. patients and providers) on a network (such as the NHIN) to securely and safely identify each other. It enables organizations and individuals to manage their identifying information and control access to that information without them having to trust a third party, which is a highly desirable quality in a healthcare interoperability context.

LID also provides for distributed authentication. Each system participating in the NHIN will maintain its own authentication subsystem. The LID protocol enables existing and separately-maintained authentication systems to securely federate on an internet-wide basis. Unlike many other identity systems, LID is decentralized in nature and thus a good fit for an NHIN, which needs to integrate the respective security systems of many stakeholders.

LID is also highly resilient against identity attacks – something that is likely going to be a frequent occurrence on the NHIN – and compatible with the trend towards personal patient records, smart cards etc.

Answers to the Specific Questions

General

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.

Definition. The best definition for an NHIN does **not describe what it is, but what it does**, in a series of well-defined and measurable use cases that illustrate its value in each scenario.

This list of use cases must be defined collaboratively by the major stakeholders, including patient representatives. Before such a **list of use cases** exists, and unless it is agreed upon by the major stakeholders, any progress towards architecture, organization or financing must be considered tentative and highly uncertain, as no clear measuring stick will exist against which progress can be measured. In accord with virtually the entire modern literature on large-scale systems construction, we are strongly advocating a use-case driven approach to the entire NHIN project.

As an example, here are two use cases that may be part of an NHIN:

- 1) Person A is enrolled in health plan B through his employer C. While on vacation in a state that is not served by health plan B, person A becomes unconscious and arrives at hospital D. Through the NHIN, ED physician E can access Person A's current medication list within 90 seconds after A's admittance to hospital D. From that time, hospital D's EMR system automatically checks physician E's prescription for potential problems against Person A's record.
- 2) By providing a stolen medical record number, and address details but no driver's license, Person B attempts to impersonate Person A at hospital C that belongs to a different organization than Person A's regular health care provider. The NHIN detects the attempted impersonation and flags it before medical services are provided.

The core technical obstacle of the NHIN is the creation of a **single, dynamic, virtual patient record** that aggregates, securely and in real-time, all data elements known about the patient from the many information systems operated by all the health organizations that the patient has interacted with. It is clear that this must be accomplished without requiring radical changes to EMR and other systems in use already and the business processes for their use.

Construction of a national network that enables such a secure, virtual patient record poses many technical problems. The most challenging are:

- The network will connect a very large number of separate and disparate systems.

- These systems contain redundant and partially overlapping data (but see the discussion of X-PRISO™ in the previous section of this document).
- They are operated by many and diverse organizations.
- The software of these systems is provided by multiple software vendors.

These problems impose certain requirements on any NHIN software architecture:

- Federation, rather than central administration and control of the participating systems.
- Shared data model, or multiple models plus mappings between them.
- Shared data representation, or multiple plus conversion algorithms.
- Protocol for linking data about the same person in different systems.
- Protocol for ensuring or determining currency of data.
- Uniform interface to the disparate systems, or multiple plus gateways.

Equally challenging and of greatest concern to the public are the problems of privacy and security. The most challenging are:

- Identification of persons.
- Authentication of users of the network.
- Determination of who receives information and also who makes requests.
- Determination of who provides information as well as the information provided.

Security is required not only to ensure privacy for patients, but to protect payors from fraud.

The problems of privacy and security impose additional requirements on any NHIN software architecture:

- Capability to identify persons in the absence of a single namespace of identifiers (but see the discussion of LID™ in the previous section of this document).
- Distributed authentication.
- Non-repudiation by both providers and accessors of information.

To enable auditing of the NHIN, there must be authentication and non-repudiation on all distributed access.

The organizational challenges arise from both the very large number of organizations and the great disparities in nature, governance, size, capabilities and financial resources.

These problems posed by these disparities include:

- Barriers to cooperation.
- Challenges for regulation.
- Great difficulties for any attempt to establish central control, whether uniform or hierarchal.

However, as we have noted before, selecting a decentralized software architecture can sidestep many of these issues.

In our view, the often-used analogy with the banking/clearing system does not work: banks do not exchange, as a matter of course, the real-time financial status of any customer with other banks. They only exchange transactions. For the NHIN to be useful, it requires the establishment of a 360-degree, real-time view of the customer, which further includes data structures and relationships far more complex than in case of a financial transaction system. Therefore, a clearinghouse architecture is fundamentally inapplicable; a fully decentralized architecture is required.

A decentralized architecture is also highly advisable for privacy and security reasons as it does not have a single point at which failure or systematic attack would have catastrophic consequences. Just imagine the political fallout if, say, the clearinghouse of healthcare information in the Washington DC area was electronically broken into and monitored by a non-authorized entity, such as a foreign state actor.

Constructing such a decentralized, secure and resilient architecture will be the top technical challenge for an NHIN. Once it has been accomplished, the major technology risk has passed, funding requirements become fairly definite and large-scale implementation can commence.

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.

The operation of the NHIN has to be a completely decentralized and self-organizing model. See also our answer to question 24.

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.)

The specifications for the architecture, conformance tests, as well as organizational oversight must reside on the national level.

Implementation projects should be performed by regional cooperatives that are driven by the statistically more frequent execution of many NHIN use cases, thereby producing visible ROI as quickly as possible.

Organizational and Business Framework

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?

See also our answer to question 15.

We have extensive experience with functional and dysfunctional industry and standards organizations in several industries. Based on that experience, we suggest the following:

It may be advantageous for the federal government to invite the top 15 chief architects of healthcare technology provider and user organizations (as identified by peer vote) to take a one year leave from their employers, and develop the NHIN architecture off-site, but with real-time visibility and feedback on the internet. With some staff support, an investment of less than \$5m may well produce breathtaking results that cannot be accomplished in any other way.

Setting the technical architecture "by committee" is almost certainly doomed to failure. Given the best and brightest free reign to come up with the best architecture is far more likely to produce something that will work.

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

Answering this question should be attempted several years from now, not earlier.

c. No response.

d. How could the NHIN be operated? What are key considerations in operating a NHIN?

If, as we recommend, an entirely decentralized architecture was chosen, there would be no such thing as an NHIN that needed to be operated.

By analogy: there is no such thing as "the internet" that needs to be operated. "The internet" operates itself by the behavior of the organizations that connect to it, in conjunction with some fairly light-weight, and self-organizing industry bodies such as the World Wide Web Consortium and the Internet Engineering Task Force that are invoked by the market participants when they feel a need to do so. (ICANN is government-chartered as it is largely the only point of centralization in the internet architecture. We do not believe that the NHIN requires a similar central organization beyond what ICANN does already.)

We believe it would serve the NHIN well to use the internet as an example for governance and operation.

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.

See our answer to question 19.

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

See our answer to question 19.

7. No response.

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

See our answer to question 15.

Management and Operational Considerations

9. No response.

10. No response.

11. No response.

12. No response.

13. What effect could the implementation and broad adoption of a NHIN have on the health information technology market at large?

It will stimulate the market substantially in many foreseeable and unforeseeable ways. NHIN will be the healthcare's equivalent of the national highway system, whose benefits have been immeasurable.

As new personal healthcare technologies proliferate (in particular the expected onslaught of mobile but connected healthcare devices worn by the patient, over the next 10 years), the NHIN will also provide the avenue by which these devices can plug into all EMR systems in the same way, thereby enabling this market as well. The protocols for plugging in a new device and plugging in a new EMR by another provider organizations can and should be the same.

Could the ensuing market opportunities be significant enough to merit the investment in a NHIN by the industry?

Absolutely.

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?

All participants will benefit.

Given current imbalances in the US healthcare industry, some stakeholders will initially benefit more than others; but as market forces come to bear, the NHIN will also be a catalyst for some necessary realignments in the way care is procured, provided and paid for, which is a considerable beneficial side effect of an NHIN.

Standards and Policies To Achieve Interoperability

(Question 4b above asks how standards and policy setting for a NHIN could be considered and achieved. The questions below focus more specifically on standards and policy requirements.)

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?

We argue strongly in favor of an open process with full disclosure and full participation, preferably supported by the web (see also our answer to question 15).

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.

For a system the size of the NHIN, with as many stakeholders (many of them are not even known: lots will happen in the next 20 years) as the NHIN, and so many existing technologies in use in the market, there is only one approach that will be effective: full disclosure of all discussion and all information to the general public as it is being created, and the ability for all interested parties to participate at any time. Closing any part of the development procedures will likely turn out to be an almost certain guarantor for disaster.

We recommend using an open source development process (as exemplified by successful open source projects such as Linux, the Apache webserver and others) as a template: open source development is unique in human organizational history in that it successfully balances the conflicting requirements of often thousands of contributors, and delivers excellent results without any organizational structure that can apply traditional management methods.

The stakeholders in an NHIN are as diverse, and as difficult to govern as the stakeholders in an open source project.

Separate from the issue of organization, we believe it would also be advantageous from a public policy perspective, as well as from a security perspective, if the core elements of the NHIN infrastructure were available as open source. This would reduce the barrier to entry for additional participants in the NHIN, which would be in everybody's interest.

16. No response.

17. No response.

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?

The federal government must “own” the definition of the use cases that the NHIN is supposed to address. It does not need to assemble this list, but must own it once it is assembled. It must further “own” the definition of the scores (see answer to question 24) by which success is measured. It should further solicit and promote public statements of support for the NHIN goals of market participants.

It should not be a participant in the technical (including standardization) and organizational details of how to accomplish the NHIN goals, other than to the extent of which departments of the federal government are providers, payors or consumers of health care.

Financial and/or Regulatory Incentives and Legal Considerations

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?

Absolutely. However, it is not clear to us that an incentive system could not be developed whose net cost to the taxpayer over, say, 20 years, would be zero. Carrots would be handed out towards the beginning of the overall project, and sticks towards the end.

An additional reputation system (such as by publishing scores for various stakeholders according to our answer to question 24) may, at minimal financial expense, have a decisive impact on market participants.

We further recommend a sizable marketing and public outreach budget that informs the general public about the goals of the NHIN and why it is valuable, creating an additional feedback channel for the success of NHIN.

20. No response.

21. No response.

22. No response.

Other

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

- a) A core protocol for assembling the virtual patient record in real time from N existing information systems maintained by N organizations. We suggest the X-PRISO™ protocol, developed at NetMesh and referenced elsewhere in this document, in conjunction with information models from HL7.
- b) A distributed identity system that securely identifies individuals across the information islands coming together under the NHIN umbrella. We suggest the Light-Weight Identity (LID™) system developed by NetMesh.

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?

One of the major benefits of employing a use-case driven approach to the definition of a NHIN is that it produces a list of measurable objectives. Success can easily be measured against whether or not specific use cases are and aren't supported, and to which degree.

For example, in the first use case discussed above, Person A's medication information either is or is not available at the bedside in hospital D within the time frame specified. As each use case describes a particular scenario whose support by the NHIN has value, such an approach clearly communicates status as well helps with directing decisions towards those alternatives that show the highest ROI.

It can also be used effectively to communicate status, accomplishments and importance of next steps to political oversight.

By aggregating over all scenarios, an overall score can be obtained for any subset of stakeholders of interest. As such a score is fairly objective, it can also be immediately used as an input variable into a financial incentive system.

Candidate solutions

Technical

The technical solutions proposed here are based on the assumption that the architecture must enable a distributed, federated system. An effort to use a centralized architecture is doomed to failure.

It should go without saying that any solution should use existing standards technologies wherever they meet the requirements.

Sharing data across multiple systems

A shared data model (the HL7 models are an excellent candidate), plus mappings from the model of each existing system to the shared model.

A shared standard for data representation, plus conversion algorithms as required by each existing system.

A protocol for linking data about the same person stored in different systems. This protocol will have the capability to:

- Send identifying information
- Negotiate for more identifying information
- Negotiation for confirmation of identity

It is not practical for NHIN to rely on a single space of personal identifiers. At present millions of people receive health care, but have not been issued a personal identifier in any comprehensive system (infants, immigrants, visitors). This situation will not change in the foreseeable future. The identification protocol must be based on a variety of kinds of identifying information:

- name, sex, address, date of birth, place of birth, parent's names
- the pair, <identification document identifier, person identifier>
- the pair, < record system identifier, person identifier>
- telephone number, credit card number, ...
- providers, ...

A uniform interface for access to systems via NHIN and gateways to systems that do not support that interface.

Privacy and security

For authentication and authorization, two approaches will enable identification of participants: For persons, the subject of health data, the identification protocol above. For providers, the identification techniques of the existing systems those providers use.

These two approaches can be integrated and enhanced by use of a distributed identity protocol.

There is no widely adopted standard that enables authentication in a distributed system. An agreed distributed authentication protocol is an essential component of NHIN.

Standard techniques will ensure non-repudiation.

Organizational

The nature and extent of organizational problems depend on the structure chosen. Three candidate solutions are:

- a central authority
- hierarchical authority relationships
- a decentralized system

Adopting decentralization as a technical solution removes the organizational challenges of the other solutions. Once the technical problems are solved using an architecture that enables decentralization and federation, essentially no changes are needed to existing organizational structures, except for establishing a forum for agreement on the technical solutions.

Financial

Candidate solutions for the financial challenges include:

- government funding
- legal mandate
- felt benefit

Choosing the third is a real possibility if a federated software architecture and organizational structure are chosen. The financial impact then becomes one of the cost of implementing and maintaining a set of interfaces to existing systems or use of a gateway. The primary responsibility for building and maintaining these interfaces will largely rest with the vendors of EMR software. Where vendors do not provide interfaces, others will step in and provide gateways. These will be available to smaller providers as a service subscription.