

REQUEST FOR INFORMATION:

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.

The National Health Information Network should be based on an open architecture that encourages innovation, information exchange and collaboration; assist in overcoming technical and organizational barriers to deploying and using next generation applications and networks throughout the nation including rural areas and underserved communities; and it should assist in the creation and deployment of network technologies and middleware that enable a continuously improving and evolving health network.

The National Health Information Network can be thought of as a grid or mesh of interconnected health resources throughout the United States. Like the Biomedical Information Resources Network (BIRN), these resources need not be consistent in their internal structures, operations, or data resources. Rather, each needs to be carefully mapped, through middleware resources, to a well defined open architecture that provides the infrastructure for the NHIN. The NHIN must address and improve the ongoing interaction between healthcare, research and education.

Models for the NHIN exist within the advanced networking and computing communities. BIRN and the caBIG (Cancer Biomedical Information Grid) project under development at NIH are examples. While no project of the magnitude of the proposed NHIN has been undertaken, these (and similar) projects have shown the feasibility and difficulties associated with an NHIN concept.

Organizational and operational barriers are significant as are issues of data representation, vocabularies, identification, security, authentication, authorization, allowable and appropriate uses and auditing requirements. However, significant enablers exist in existing and improving middleware that address security, authorization, and role based use. The body of standards available is increasingly comprehensive with examples such as the HL/7 Electronic Health Record and the National Library of Medicine's

recent acquisition of the rights to SNOMED.

Ultimately the NHIN should encourage national healthcare services, education and health sciences research collaboration so that companies like Johnson and Johnson, Nortel, IBM, Eli Lilly and small start-up companies are able to deliver their considerable capabilities via high-bandwidth secure links to hospitals and clinics throughout the country. This has the potential of creating a national marketplace for the next generation healthcare services, research and education.

These requirements drive an advanced network structure that will consist of a highly trusted network integrated with the Internet and sources of middleware that provide services such as the identification of a patient, role based security and privilege management. The middleware envisioned will allow individuals to find and access services and people. Key will be a patient identification service through regional or sub-network locator services. Local Health Organizations have so far found that they must have a method of correlating patient identity among systems.

Our vision is for patients anywhere (nationally and internationally) to be able to have high quality care and to promote national scale research collaboration and data resources to accelerate improvements in medical care.

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 Internet itself provides a model for meeting this goal. The Internet is the classic model of an open architecture success that can support either open source or proprietary applications. This model is proposed for the development of the NHIN.

An open architecture is one whose specifications are public. This includes officially approved standards as well as privately designed architectures whose specifications are made public by the designers. The opposite of open is closed or proprietary.

The great advantage of open architectures is that anyone can design add-

on products for it. By making the architecture public, however, one allows others to take advantage of the availability of the resource to enhance its utility and create and operate additional resources which may be either openly available or proprietary.

The challenge for the NHIN is to ensure that the open architecture does not diminish the trusted nature of the network. Service quality and security are additional critical factors that drive this architecture. The NHIN must interface with systems of varying trust/security including untrusted systems in order to be useful. We are today seeing, however that if the machines connected to the network cannot be trusted then we cannot trust or rely upon the network itself. Institutional border firewalls, while a necessity, have become largely ineffective due to worms and other malicious software finding their way through the firewalls via apparently trusted services, for example through Virtual Private Network (VPN) connections to infected machines, e-mail, laptops, and infected web sites. A solution is to adopt a trust hierarchy with at least four levels of trust:

0 – Anonymous Internet user, untrusted allowed to seek educational information and public directory services

1 – Authenticated users/machines allowed to access individual patient records

2 – Trusted users/machines allowed accessing, creating and changing individual records. Trusted machines should be scanned for current patches, infections and virus protection prior to admission to the network

3 – Trusted services and administrative access – systems and personnel responsible for hosting or administering services and applications require the highest level of trust. May not operate or access untrusted services or applications.

This network structure can operate in a highly secure manner by requiring level 2 and 3 machines within a trusted network with greater security and within which all machines and users must be positively identified, and privileges and services are strictly limited to those needed for authorized uses/services.

An advanced network has two important advantages. First, current institutional border firewalls make it difficult to reliably provision performance-sensitive applications like videoconferences end-to-end. The h.323 standard, for example requires several ports open on the firewall and videoconferences also tend to be quite sensitive to jitter, latency and bit loss that can be introduced or aggravated by firewalls and other security devices. Operating the network as a secure overlay provides a

good method to avoid these issues. Second, regulations require that electronic protected health information (EPHI) be secured (encrypted) when transmitted across public networks. While encryption programs are readily available today, the methods are not unfortunately standard and usually have to be set up in a pair-wise (user to user) manner, which is expensive and does not scale. One possibility is a secure overlay network, possibly encrypted, that would allow any to any access in a secure manner.

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 NHIN is envisioned as a GRID or MESH environment. Each node or resource on the GRID is a Regional Health Information entity or a health sub-network. It is understood that healthcare requirements and practice differ by location thus; it is unreasonable to expect that the organization models or the specifications will be the same between locations. Rather, the interactions and the transfer of information that occurs between locations must be understood. Thus, the roles of the RHIOs and sub-networks are to design, implement and operate inter-institutional systems that are appropriate to their specific environment. The RHIOs and sub-networks must in turn meet the requirements of the NHIN for at least the ability to identify, locate and move required information in a secure and appropriate manner.

The RHIOs and sub-networks can only accomplish this with the leadership and tools required to ensure that the inter-organizational sharing of information and resources can be successful. We believe this can be best accomplished by the development of an open and freely available NHIN architecture, an agreement upon a limited, essential set of standards and policies, and an identified and freely available catalog of middleware resources to enable appropriate access to the NHIN.

This will lead to the development of a toolkit for the RHIOs and sub-networks that will be used to ensure ease of development and compatibility with the NHIN. Initially at least, the toolkit will be dynamic and must be minimally disruptive to an RHIO's or sub-network's operating environment as will be the case with the use of middleware.

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?

The NHIN and the RHIOs and sub-networks will require investment and / or significant incentives initially. The model of the Internet which was funded as NSFnet and moved to commercial resources once it was proven as a financially viable concept is equally valid for the NHIN. The NHIN will require proof of concept activities which show (1) that it is feasible, (2) that it brings benefit to both the healthcare providers and the public, (3) that there is a significant marketplace that will result from the NHIN, and (4) that the government, public and commercial organizations are not compromised by the existence of the NHIN, RHIOs, or sub-networks.

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

A standards and policy entity needs to be created. The Internet Engineering Task Force (IETF) became a reasonably nimble, relatively conflict free, and a very effective means of establishing policies and standards for the Internet. During its emerging years the IETF was a very effective and objective force for the development, use and operation of the Internet and may be an excellent model for the NHIN.

The exact model of the standards and policy entity is a significant decision. It is strongly recommended that this be studied carefully by a credible and objective group such as the National Academy of Sciences Computer Science and Telecommunications Board (CSTB) in conjunction with the Institute of Medicine (IOM),

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

Acceleration in the adoption of the NHIN will come from the benefits are perceived by the users of the NHIN. A more narrowly defined NHIN of obvious (perceived or real) benefit to its users will be more quickly adopted than an more comprehensive but less beneficial environment.

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

Using the Internet or BIRN as an operational model for a future NHIN the environment will require at least an operations center that includes but is not limited to a network operations center. This could be modeled after the recent agreement with NORC as a coordination center or Internet2's network operations center at Indiana University. The NHIN should not, in our opinion, strive to build a NHIN staff. Development activities such as middleware resources or advances in standards are best achieved through a grants and contracts program that is both competitive and open. Any development undertaken by the government must remain open and available for re-use.

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.

Examples that have been successful of developing ongoing national resources include the Internet, which evolved from the NSFNET for which the National Science Foundation provided the initial funding, and the network of Comprehensive Cancer Centers which received certification and seed funding from NIH's National Cancer Institute. In both of these instances initial government seed funding was an important factor to prove the viability and the benefits of the established infrastructure.

It is anticipated that the NHIN and the regional networks can be successful if the same level of viability and proof of benefits is shown through a series of activities that involve a range of resources necessary to create an ongoing national infrastructure. Like both the Internet and the Comprehensive Cancer Centers, a business model evolved that led to the ongoing operational support of these resources without full direct support of the Federal Government.

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

The financial model will ultimately be based on the benefits derived from the utilization of the resource. These benefits have early indications from a few selected projects but are likely to evolve as the NHIN becomes operational. Thus, it may be early to project exactly what the ultimate benefits may be and thus risky to base a financial model on projected or perceived benefits.

However, it is clear that the financial model will include national, regional or sub-network, and end user components. It may also be that there will be a significant commercial component to the ultimate model for NHIN support and this will particularly require the ability to measure benefits associated with the NHIN.

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?

Privacy and security approaches were discussed in response to question #1 and will not be repeated here. Rather, it is recommended that the mature NHIN may be best served on an integrated lambda as represented by the emerging National Lambda Rail (www.nlr.net). The lambda may have the advantage of a network environment in which there is no competition for network bandwidth and with increased perceived security and with little overhead from the backbone network.

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

As indicated earlier, the NHIN must be predicated on an open architecture that promotes broad participation and a non-proprietary, interoperable infrastructure. This open architecture is most easily accomplished today through the use of the traditional Internet. However, the successful NHIN will quickly develop requirements for Quality of Service, QOS, bandwidth prioritization, additional capacity, additional security and privilege management. I.e. advanced networking resources and facilities that can be integrated with the existing Internet will become an integral issue of concern for the successful NHIN. It is strongly recommended that an advanced networking component be built into the NHIN strategy and that early implementation of activities and projects to meet the needs of the NHIN for ongoing advanced networking be established.

The integration of the advanced networking capabilities with the existing Internet will ensure that the benefits of the NHIN are available to the rural and underserved populations as well as the better served populations.

Management and Operational Considerations

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

An open architecture, such as the Internet, allows and promotes that participation of the private sector. The particular advantage of an open architecture is that it does not give an advantage to large or small corporate entities but rather provides an equal market presence to all who provide a beneficial resource.

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.

The NHIN can evolve from private investment when it is able to provide substantive examples of tangible benefit and market opportunity. We believe this is feasible and highly probable based on the exemplary models already in existence, e.g. Indianapolis Network for Patient Care. We believe the driving force for this investment will be the ease of entry into the marketplace achieved through the adoption of the open architecture. This has the added benefit of achieving the country wide interoperability and in fact rewards it by extending the market.

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?

The NHIN should be built upon existing infrastructure and not as an independent entity. The NHIN needs to allow connectivity for organizations and individuals with a low level of technical sophistication. However, it must also recognize and encourage advances in technology, particularly networking, that can improve the delivery of healthcare to consumers irrespective of their location or income. The use of incentives, grants and loans will drive the development and acceptance of the NHIN in underserved and rural communities.

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?

Existing community and regional health information exchange projects must become a part of the NHIN if it is to truly be a national resource. The NHIN should strive to build upon and share their accomplishments and not attempt to replace them. A common framework as proposed by the Thirteen Organization Collaborative Response (including Internet2) will provide an excellent foundation for this.

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?

Markets will be created as a direct result of a NHIN that improves the quality of healthcare by enhancing the exchange of health information. Care must be taken to not create undue barriers to entry nor stifle innovation or competition. An open architecture that allows and encourages adaptation, innovation and process improvement will promote this market development and not provide an advantage or raise a barrier for any specific commercial interest.

Standards and Policies to Achieve Interoperability

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?

Each RHIO or Subnet should provide strategic leadership and coordination to represent relevant stakeholders including consumers about the development and uses of the NHIN and collaborate in the identification and development of standards and policies.

Healthcare provider and professional organizations represent their constituencies on policies and standards relevant to their processes and / or timetables.

Healthcare Plan and Purchasers should participate and represent their practices and systems consistency with the proposed standards and policies.

Standards Development Organizations should develop new or modified standards as requirements become known.

Information Technology Industry should develop and promote cost-effective healthcare software and technologies that comply with the NHIN Common Framework.

Consumer and Patient Advocacy groups should work to ensure that its standards and policies improve the quality of service, decreases the rates of adverse effects, and increases access to health information and services for consumers and patients.

Academic and Research Organizations should participate with the NHIN should conduct research and integrate the NHIN infrastructure and

applications with other types of information infrastructure development (e.g. Internet2).

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.

The common framework is proposed as an integration point for the relevant standards and policies for the NHIN. Individual SDOs will benefit by taking responsibility for the development or modification of specific standards to meet NHIN requirements.

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?

Individual SDOs will benefit from participating with the NHIN and take responsibility for the development or modification of specific standards to meet NHIN requirements.

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?

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 decide on the process by which the basic set of standards and policies will be established and enforced at least initially. It must establish appropriate incentives for the use and maintenance of the NHIN and it must provide seed funding to bring the NHIN into existence.

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?

The success of the NHIN is dependent on financial incentives and the development of this marketplace. The ongoing success of the NHIN is dependent on the success of the marketplace that develops and the benefit that is perceived by the consumers, providers and payers. The financial model should be similar to the successful model used for the transition of the U.S.'s Internet which moved from government seed funding, NSF, to a new and self sustaining market.

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?

The incentives and investments for the regional health resources will need to be similar if not identical to the national financial model.

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?

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

Other

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

The National Health Information Network must be based on an open architecture that encourages innovation, information exchange and collaboration. It needs to assist all healthcare resources to overcome technical and organizational barriers to deploying and using next generation applications and networks throughout the nation including rural areas. It must assist in the creation and deployment of network technologies and middleware that enable a continuously improving and evolving health network.

The National Health Information Network will be a grid or mesh of interconnected health resources throughout the United States. Like the Biomedical Information Resources Network (BIRN), these resources need not be consistent in their internal structures, operations, or data resources. Rather, each needs to be carefully mapped, through middleware resources,

to a well defined open architecture that provides the infrastructure for the NHIN. These middleware resources will result in a common framework that ensures the interoperability of the interconnected resources that comprise the NHIN. The NHIN must address and improve the ongoing interaction between healthcare, research and education.

Models for the NHIN exist within the advanced networking and computing communities. BIRN and the caBIG (Cancer Biomedical Information Grid) project under development at NIH are examples. While no project of the magnitude of the proposed NHIN has been undertaken, these (and similar) projects have shown the feasibility and difficulties associated with an NHIN concept

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?

The ultimate measure of success of the NHIN will be the perceived value in the improved quality of healthcare through improved outcomes, improved processes and reductions or efficiencies in that result. A secondary but important measure will be in the value of the marketplace that develops around the NHIN. However, realistically the short term measures will be in the ratio of users to potential users, improved Healthcare Quality Indicators and the number and satisfaction of consumer and professional users of the resources the NHIN.