Minnesota e-Health Initiative Steering Committee

Request for Information

Development and Adoption of a National Health Information Network

Office of the National Coordinator For Health Information Technology

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MINNESOTA
MDH
DEPARTMENT OF HEALTH

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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 Infrastructure should be as transforming for the healthcare industry as the ATM was to the banking industry. Consumers, healthcare professionals, and other involved in the healthcare industry should be able to sit down in front of their computer and access the information that they need to make the best possible healthcare decisions.

A National Health Information Network (NHIN) is essentially a public/private infrastructure (that is, a network of networks) used to effectively interconnect providers, payers, public health agencies and individual citizens in order to securely exchange standardized electronic health record (EHR) information. EHR information that can assure greater patient safety, improved quality of care, and increased efficiency, and decreased healthcare costs, while enabling individuals and communities to make the best possible health decisions. (For this document, EHR is understood as defined in the "Framework for Strategic Action" Glossary of Selected Terms, page 37. 7/21/04)

As a guiding principle, the NHIN should help to improve patient care and population health through reducing well-documented overuse, under use, and misuse of healthcare services. The NHIN should:

- Support information transparency, giving consumers tools and information to help consumers make appropriate and cost effective decisions about their medical care.

- Empower providers with information at the point of service, and support providers use of evidence-based medicine to help assure the highest possible quality and value for consumers.

- Support payers and purchasers across a broad range of administrative and clinical functions essential to administering benefits, adjudicating claims, and tracking and improving consumer satisfaction.

- Empower consumers with information and tools needed to ensure they can make informed decisions about their healthcare.

A prerequisite for the NHIN is a common framework that lays out the minimum necessary policies and specifications for achieving interoperability –based on technologies that are open, readily available, easy to use, and inexpensive to acquire (for example, XML and web services) – and a staged, multi-year implementation period that builds on existing processes and infrastructure. If certain core policies are not in place nationally before localities, states, or regions move forward, then there will be duplication, conflict and a subsequent necessity to retrofit a national solution onto a local system.

The NHIN governing body must provide the following:

- A minimum set of common semantic standards that specify:
    - what information is communicated;
    - where information is communicated (from whom and to whom);
    - how information is communicated (format);
    - who (role definition i.e. physicians, nurses, public health) is authorized to send and receive information (for example, role definitions such as physicians, nurses, public health); and
    - when information is communicated (batch, real time etc.);
- Interconnection standards for user authentication, authority verification, common web services architecture, data integrity, security technologies, and appropriate audit trails.
- Common networking and communication protocols to unify access and security;
- Mechanisms to ensure the sustainable operation of these components (for example, to oversee and manage adherence to public policy objectives).

Finally, some standardized method(s) to identify patients across the entire health system – perhaps certified by an NHIN mechanism – is essential to consolidating and accessing data. Success fundamentally comes down to identifying the patient. Without a certified means for identifying patients, we will most certainly introduce considerable risk of more, not less, medical errors.

Barriers:
- Lack adoption of the electronic health records by providers;
- Lack of standards and national roadmap to support exchange and interoperability (that is, no HIPAA- like definition for clinical data);
- There may not be adequate physical infrastructure in place at this time to support all clinical and health information requirements;
- Legacy/proprietary systems that cannot export data readable by other systems;
- Legal liabilities (for example: anti-trust, tort, anti-kick back);
- Privacy/security issues;
- No current method to uniquely and absolutely identify an individual;
- Lack of capital investment to develop and implement a national solution;
- No self-sustaining financial model;
- High cost to implement;
- Backbone exists, but there is a high cost to connect the "last mile" to rural providers.

Enablers:
- Financial and business incentives;
- Data and messaging standards;
- Sophisticated affordable technology;
- Consumer-driven healthcare;
- Quality and performance-based purchasing;
- Patient safety initiatives;
- Cost savings;
- Reliable, robust, secure infrastructure components;
- Internet model is a proven concept;
- Public health prevention practices are proven concepts.

2. What type of model could be needed to have a NHIN that:

Whereas the guiding principle for the NHIN is to improve health and health is a common good, the NHIN could be thought of as a public utility: It will set overall governance to give public accountability for private businesses.

A NHIN should:
- Treat the consumer/patient as the "epicenter" of the architecture; all else revolves around him/her.
- Leverage existing health IT infrastructure and investments wherever possible – build upon industry standards, among them ANSIX12 and HL7.
- Create open systems, not tied to only one tool or vendor.
- Allow for sufficient pilot testing of the NHIN capabilities – NHIN developers should factor in system testing in going forward over the next ten years

As the NHIN evolves, there will inevitably be different interpretations on implementation requirements that must be reconciled, not "worked around." Some public or quasi-public body might be needed to referee disputes that are sure to arise as the NHIN develops. More broadly, there may be a need for some governing body/ies to coordinate the development of interconnection and interoperability strategies that may be taking place locally (perhaps by RHIOs). Local bodies such as RHIOs should not be pursuing competing interoperability/interconnection strategies that cause problems later.

- **Allows widely available access to information as it is produced and used across the health care continuum;**

To allow wide availability, the NHIN must use:
- open technology standards such as XML;
- open industry standards such as HL7; and
- an open networking model such as the Internet with significant improvements in order to handle the specific needs of the healthcare industry.

- **enables interoperability and clinical health information exchange broadly across most/all HIT solutions;**

There must be wide participation by all stakeholder groups in Standards Development Organizations (SDO's) to work out the minimum standards that are needed to achieve interoperability. These standards should:
- be necessary to achieve stakeholders' objectives;
- meet business requirements;
- be mandated for all stakeholders, not just one kind of stakeholder group;
- have a low risk of being dependent on obsolete technology; and
- meet strategy and goals in the most cost effective and efficient manner.

There should be broad agreement on what data to exchange as well as transport design standards.

The NHIN governance body will approve and issue mandatory minimum standards. (A good model process to emulate: The Consolidated Health Informatics (CHI) Council of the National Committee on Vital and Health Statistics (NCVHS) identifies appropriate, existing data standards and endorses them for use. NCVHS recommends the standards for adoption. The Secretary of Health and Human Services issues the standards after NCVHS endorses.)

To enforce the standards, an independent certification of interoperability will be given to software (whether developed by vendors or independently in-house) that is built using adopted standards.

- **protects patients' individually identifiable health information; and**

Develop strong identification management methodologies and technologies that absolutely identify a unique individual which also recognizes the highest level of privacy protection legislation (whether that be federal or state). For example, Minnesota law relating to access to health records is at times more stringent than federal law.

For more information about access rights to health records in Minnesota, please see:
http://www.health.state.mn.us/divs/hpsc/dap/notice.pdf.
For information about the Minnesota laws mandating these access rights, please see:
http://www.health.state.mn.us/divs/hpsc/dap/fnlntce3414.pdf.

Data should be de-centralized other than what is necessary to support Patient identification. If this is done well, it will bring together consumers, government, public health agencies, and private industry creating a collaborative model to meet the needs of all.

- **allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives?**

The national strategy for IT standards should balance the need to ensure interoperability with the need to foster competition and innovation for value added features, improvements in systems design, quality of care, and patient safety.

Please include considerations such as roles of various private- and public-sector entities in your response.

The model needs to embrace a federated architecture that clearly defines the standards, communication protocols and process for accessing/using the NHIN. The specifications should be developed by designated industry groups, then adopted and enforced by government agencies at local and national levels. Clear and concise specifications will allow the technology vendors to create solutions that support interoperability. In the long-term, vendors must view these specifications as a requirement to compete. Ultimately vendors will compete based upon add-on functionality and services, not on the ability to just deliver against a set of standards and protocols. Commercial tax preparation software (such as Turbo Tax and Tax Cut) is an example of how vendors worked with specifications from a governmental agency to develop the software, but compete based on ease of use and other functionality.

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.)

Government and the healthcare industry must work in collaboration to develop a national roadmap. Certain attributes of the NHIN are best addressed at a national level, while others are best suited to be addressed at a local level. A national network model should allow for local networks to be created and connected through a common agreement on what standard transactions will occur.

Items to be included in the national roadmap would include the following:
- NHIN vision and strategy;
- Clinical data standards;

- NHIN infrastructure requirements and design;
- Interoperability standards;
- Privacy requirements;
- Security access/authentication protocols;
- Network communication standards;
- Common framework for patient identification;
- Incentives for adoption and usage of NHIN;
- Stimulus and incentives for adequate access and bandwidth throughout the county (analogous to public utilities);
- Oversight and enforcement (including evaluation & monitoring of metrics);
- Software certification standards;
- RHIO certification standards;
- Oversight of local financial models, including a safety net to ensure that the system continues to work and vital networking information is not lost even if a RHIO fails;
- Disaster recovery and continuity plans with data replication standards; and
- Policy to address liability and other legal issues.

Items to be addressed at a local level should include:
- Establishment of Regional Health Information Organizations (RHIO) that includes participation of both local government and industry participants;
- Selection and implementation of governance model;
- Development and implementation of technical solutions with disaster recovery and continuity planning in place;
- Data Replication Governance;
- Access and authorization governance and management;
- Management and Administration;
- Marketing of Services;
- Financial sustainability;
- Interoperability oversight;
- Disaster recovery and business continuity plans with data replication standards (resilience must be built into the network); and
- Oversight of regional testing with end users to determine:
    - the feasibility of implementation;
    - impact on business processes and workflow changes and attainment of expected results; and
    - to validate integrity and function across the system.

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:

The oversight and management of the NHIN should include the following attributes:

- Local/Regional based approach – not-for-profit utility model
- Regulation through partnership of public and private sector
- National Oversight Board with the responsibility of financial planning, development planning, policy and procedure development and standards development. The National Oversight Board should have representation from the following stakeholders (no more than 15 member commission):
    1. ONCHIT
    2. RHIOs
    3. Health Plans
    4. Providers
    5. Public Health
    6. Technology Vendors
    7. Consumer

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?

Currently, there are numerous projects that are in development/implementation mode across the country. These projects, although focused on programs that support the vision of the NHIN strategy, lack the necessary rigor, a defined criteria for success, and adoption of technology/healthcare standards that can be pointed to as a model to be propagated across the country.

Before a full-scale NHIN is constructed and implemented at a national level, the federal government should conduct several pilot programs that are carefully scripted to include all the necessary attributes required for an initial phase of a national program. Each pilot program should be based on a common federated architecture. The scope of business functions and business applications should vary among the pilot programs. Each pilot program should include participation from key stakeholders in the designated geographic area. The minimum set of stakeholders should include providers, health plans and state/local government. The specific number of entities may vary depending upon the demographics of the geographic area.

Criteria for evaluation of the pilot programs should be established by ONCHIT at the outset of the pilot programs. Furthermore, it would be beneficial to allow each pilot program to establish a RHIO to manage the various implementation and operational activities. Various governance and financial model alternatives should be encouraged and evaluated as part of the pilot programs. The actual development and implementation activities associated with any pilot program could be managed by the designated RHIO.

ONCHIT could serve as the control point for awarding, monitoring, and evaluating the results of the pilot programs. Only under a prescribed and closely monitored set of experiments will we learn what really does and does not work. These pilot programs are necessary to manage the overall risks and costs of investment inherent with an initiative of this magnitude. The propagation of a full-scale NHIN should not be undertaken until there is some empirical evidence that predicts its success.

When the pilots have concluded, the National Oversight Board for the NHIN could establish baseline standards and guidelines for RHIO governance, financial model options, healthcare/technology standards, interoperability and functional capabilities that would be required within the NHIN. RHIO standards should be the minimum necessary for interoperability and should be overly burdensome or prescriptive.

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

Formal evaluations of pilot programs should be conducted. From this evaluation, a limited number of working models (2- 3) along with 'best practices' should be documented.

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

There are a number of options that could be considered. They include but are not limited to the following:

1. Creation of an 'Architecture Blue Print' that provides clarity around standards and required capabilities. This will enable the technology community to build products and services that are aligned with the vision and industry stakeholders to develop and implement at a regional solutions that ensure interoperability and based upon a common set of technology standards.
2. Low entry-fee for access to NHIN.
3. Establishment of criteria or procedures to certify healthcare software products that they meet certain standards in support of NHIN and identification of entities to perform the certification process.
4. Provide incentives to the vendor industry to provide low-cost solutions to small providers.
5. Fund the network 'backbone' that could be used by healthcare stakeholders.
6. Adoption of industry standards (ex. HL7, e Prescription, Electronic Health Records, etc.)

In addition, there needs to be a cost-sharing component among all parties no matter what the financing model. There needs to be value on investment for the entire industry. The price tag is big. All parties must assume a portion of the cost at one stage or another. Payers will need to pay for one part, provider pay for another, government pays for another. The financing model needs to evaluate the "value on investment" as there are many benefits to many different sectors, which may not appear in your standard "return on investment" model. In general there are three phases of financing along the path of realizing the long term vision of the NHIN.

1. Development
2. Adoption
3. Maintenance

For each phase above there would be very different financing models, standards, policies etc. The standards and models need to take into consideration the uniqueness of each phase and address them differently.

There should be a standard, and an implementation timeline that you have to meet to implement that standard, much along the same lines as the HIPAA implementation. The government should lead the way with Medicare and then encourage everyone else to do the same. This implies a phased-in approach with certain capabilities along the journey. This reduces risk, better manages the cost, and ensures a stronger likelihood of interoperability and adoption of standards across the industry.

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

The Internet should be the model. The Internet has evolved rapidly without being burdened with a high degree of direct management and controls. The NHIN could start as a business-to-business concept among some stakeholders, but evolve to a full-scale environment that would enable access/usage to the entire population.

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.

Much has been written on the topic of who should finance the development of an NHIN, RHIOs and EMR adoption. Funding will be required at a local level and the formula for each RHIO will depend upon market conditions, existing infrastructure, payer/provider composition, local regulations, and others. One approach will not fit all. In large part, we believe all stakeholders should participate at some level in the funding of the NHIN. The financing approach needs to evaluate the "value on investment" as there are many benefits to many different sectors, which may not appear in your standard "return on investment" model.

All stakeholders have a role to play in sharing the costs of building and supporting the NHIN because everyone will ultimately derive benefits. However, federal funding is critical. Initially, the federal government should take a leading role in providing grants to local/regional consortia to pilot-test NHIN capabilities.

The federal government should ensure that all federal healthcare programs (e.g., Medicare, the military healthcare system, the Veterans Health Administration) work together with the consortia. We envisage voluntary public-private consortia (hospitals, physicians, payers, vendors, employers, state governments, federal programs, and consumers) forming in states or regions to make productive use of federal funding. Consortia members would share the additional funds needed beyond federal funding to build required information infrastructures. Consortia members would have to conform to certain standards, set by the roadmap discussed in question number 1, to qualify for federal funds.

Federal funding is especially important because until we have accurate and reliable methods of collecting and analyzing data, calculating and documenting the extent of the system savings anticipated from implementing the NHIN is not possible. In fact, in the beginning stages, payers' costs may actually increase.

In addition, federal and state governments and private payers and purchasers should coordinate any efforts to promote providers' use of the NHIN. Whatever the approach different consortia choose, the federal government should be a major funder of programs to incent providers to adopt and use health IT.

Options to consider for funding the cost of building the NHIN include the following:
- Federal government as the largest purchaser of healthcare
- Government taxes (federal and/or state level)
- Government tax credits for those who will invest
- Technology vendors (e.g., telecom, hardware, software) possibly resulting in service fees, click charges, etc. in an operational mode
- Creation of a national impetus and urgency for construction (similar to what was done in the 1950s to build our Interstate highway system)
- Health Plans and Providers based on a variety of scenarios;
  a) Business size
  b) Revenue
  c) Health Plans and Providers each pay for specific components (ex. Health plans funds infrastructure: providers fund connectivity expenses and key applications such as EHR, CPOE, Decision Support, etc.)
  d) others

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

Ultimately, only a compelling business case will sustain a functioning NHIN. At every stage in the NHIN's development, from pilots through nationwide integration, stakeholders who are asked to bear the cost and

resource burdens of acquisition and implementation will question whether the NHIN supports each stakeholder's business case.

At this time, the benefits of an NHIN are speculative. Outside of a pilot or demonstration, stakeholders will be hesitant to provide sustained funding. When a network formed by a state or regional consortium is up and running, finances should be based in part on transactions and in part on a capitated, membership basis.

Other financing alternatives that consortium members may wish to consider include a fee schedule for using the NHIN, with fees based on the size, revenue, or value of the entity using the NHIN. Fees could be prorated based on the extent the entity is involved in operating and maintaining the NHIN, but all users would pay something.

The long-term financial sustainability of the NHIN will also depend on addressing data ownership issues. Theoretically, the value of the data flowing through the network could be tapped as a source of funding (for example, market researchers might be interested in obtaining data to analyze business prospects for different products in different areas). However, who owns which data to sell at what price? The issue is complex because various stakeholders will wish to protect their proprietary interests in their data.

Financing strategies for a NHIN will probably be somewhat different during the adoption phase vs. ongoing maintenance phase.

> Options to consider for adoption of NHIN and supporting services include the following:
> - Health Plans – Pay for Performance, based on outcomes (ex. Disease management, etc.)
> - Required usage for State business/Federal Business based upon Medicare/Medicaid adoption strategy
> - Employer Groups – How can purchasers of healthcare incent adoption? Incorporate adoption standards in purchasing standards.
>
> Options to consider for ongoing maintenance and support:
> - Cost Sharing Model (i.e. Hwy System – Federal & State funding, tolls, tabs, auto sales tax)
> - Approach should not add any net cost to healthcare

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?

The minimum necessary standards of HIPAA are implicated by the NHIN. HIPAA set a floor of privacy regulation. Any state law (like Minnesota) that has more stringent privacy laws may have to develop new laws for national data exchange. State and federal laws related to privacy will need to be reconciles to promote interoperability.

Comprehensive access controls must be implemented to ensure protection of patient data. Audit logging, tracking and management reporting must be in place to track individual transactions (who authorized, who sent, who received, nature of transaction, etc.). Audit and control functions are critical.

Consumers must have confidence that the confidentiality of their individually identifiable health information is safeguarded –- as a result, privacy and security protections are an integral part of the NHIN. Significant

protections for health information are already provided through the Health Insurance Portability and Accountability Act (HIPAA) and corresponding regulations.

One issue is the extent to which entities that may use or disclose electronic health information as part of a NHIN should be required to institute privacy and security safeguards if they do not meet the definition of a "covered entity" for purposes of the HIPAA rules (*see*: 45 CFR §160.103). HHS should develop a regulatory strategy to ensure that these entities provide privacy and security protections as appropriate. This approach was recently taken by HHS in the proposed regulations for the Medicare Part D prescription drug benefit (*see*: Department of Health and Human Services, Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule, 69 Fed. Reg. 46632 *et seq*., August 3, 2004). Under the proposed rule, prescription drug program sponsors that do not otherwise meet the definition of a "covered entity" for purposes of the HIPAA privacy rule are required to meet the requirements of that rule (*see*: 69 Fed. Reg. 46666).

In addition, HHS should consider the interaction of other federal and state privacy laws and the national exchange of health information that would be permitted through a NHIN. There is a concern that some federal and state laws may serve as a barrier to implementation of the NHIN by unduly restricting the types of information that can be shared and the methods used to exchange information. For example, state laws that restrict the disclosure of information related to specific diseases or medical conditions may limit the ability of clinicians to participate in a NHIN.

HHS should work with Congress and other stakeholders to identify potential conflicts and consider whether such laws should be preempted. Congress has explicitly preempted state laws that conflict with the HIPAA requirements for security for certain electronic healthcare transactions.

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

Assuming an abstract of a Medical Record is developed, a common patient identification approach is implemented, and a standard query/retrieval process is defined it would be feasible for public health organizations to retrieve and build pertinent data repositories to support specific research projects. Much groundwork needs to be done to define the information requirements, retrieval processes, and technical standards to support public health including: guidelines for identification, guidelines for de-identification of health information for the purpose of research, guidelines and methodologies for data destruction for research groups, guidelines for health surveillance information. In addition, public health would need to define the processes to disseminate information from its studies to the healthcare industry via the NHIN.

Management and Operational Considerations

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

- While collaboration and shared vision for the community good and a community solution is essential, private sector competition is necessary in the development of the national network.
- The NHIN will set the minimum necessary or baseline standards and requirements and what set of information will need to be shared and the interoperability of the various systems.
- The competition in the private sector should not be stifled in the establishment of a NHIN.

- Many vendors will compete on the quality of their product, the ease of use, the functionality of the product and by price. Areas of competition include but are not limited to: electronic medical records (EMR), electronic health records (EHR), personal health records (PHR), computerized point of entry (CPOE), applications/technology, security software, transaction ,management systems and practice management systems.
- The competition should be around how organizations use the available information, not the data itself.

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

a. Evolves appropriately from private investment;

A National Health Information Network that evolves from private investment could be established if private parties doing the investing are involved or have a voice in the establishment of a NHIN – not exclusively setting the standards but having a voice. All stakeholders need to be considered.

Several approaches should be considered. They include the following:

1. The federal government will need to take an active role with regard to embracing and enforcement of standards. The creation and development of standard be set by the correct SDO.
2. Creation of incentives that allows entry-level access to the NHIN at low cost for rural, and small to mid-size providers.
3. Collaboration with private industry (vendors, healthcare organizations) in the development and strategic direction setting of NHIN. Give private industry a voice in the establishment and maintenance of NHIN. Collaboration is critical to overall success.

b. Is non-proprietary and available in the public domain;
A health information infrastructure that is non-proprietary depends on the charge to the NHIN to set national standards. If standards are set that all private parties must adhere to, then they would be non-proprietary.

c. Achieves country-wide interoperability; and
Interoperability would be assured nationally if national standards are set that must be adhered to if the private parties wish to do business. An example is the implementation of the HIPAA laws which all health entities have to follow. One significant exception to the HIPAA law would be the legislation of one version of one standard setting body. The creation and development of standards should be set by the correct SDO(s)   Follow the HIPAA model while implementing key learnings.

d. Fosters market innovation.
Market innovation depends on the quality of the software which the end user must decide on. The interoperability standards really are under the surface and should be invisible to the providers using the software. The provider will be primarily interested in the quality of the product, how it affects patient care and how it is able to improve outcomes and decrease medical errors.

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?

Local resources and regional entities should be used in the establishment of the NHIN. The creation of buying groups that small organizations can join is an example. A working model in Minnesota is the Sisu. Sisu (the

word is Finnish for "stamina, fortitude, mettle, stubborness, or perseverence") was started 20 years ago when several rural hospitals worked with Miller-Dwan Medical Center (now affiliated with Saint Mary's Duluth Clinic Health System) to get help with health information technology for the coalition. Sisu is now incorporated as a nonprofit corporation. By working together to share IT resources, the coalition is able to leverage the strength of the people, ask questions, and put dollars together to get a robust healthcare information system. For example, working collaboratively these facilities are able to purchase and implement robust software at significantly reduced cost. Individually, they could not have afforded such a robust system. St. Luke's uses this same system. St. Luke's will soon provide after hours pharmacy support that rural hospitals desperately need.

The Sisu model is important in that it showed how cooperation between hospitals and physicians and other healthcare providers could accomplish a success that could not be achieved with each group working alone. It is not just the infusion of capital, but the local and regional cooperation that are necessary. This is especially true on the rural level.

Federal government brings the NHIN to Sisu and Sisu connects all area entities. State government ensures and in some cases enables each county or Sisu like organization connects to the NHIN. The state governments role would also be to assure the continues development of reliable, accessible "broadband" capability to all communities. (Sewer, water & internet)

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?

Community and regional health information exchanges should seek to follow the roadmap or common framework, and transform into government-funded pilot sites (where and whenever possible) as part of a phased implementation approach for the NHIN.

Projects that start before the NHIN could be at risk. Additional investment to bring the early adopters back to where the NHIN is heading may be needed. The Minnesota Department of Health may need to coordinate early adopters and new projects in Minnesota. Educational effort for new projects to know where NHIN is going.

Products currently available to purchasers or developed independently may not be completely compliant with standards to be adopted.

A national information clearinghouse for NHIN, RHIOs, HIEI is needed.

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

The implementation of NHIN will be, should be, transforming to the healthcare industry, similar to the impact on the banking industry. This transformation will create new business opportunities while certain products and services will be eliminated.

Broad adoption of NHIN would spur competition among vendors to develop interoperable solutions in order to win contracts. With the new technology there is a lot of burden placed on the purchaser to help develop the technology jointly with the vendor. Vendors would have to take a more proactive role in developing solutions if they wanted to win big contracts. This in turn could bring developed products to the market quicker.

If funding is make available, the industry will develop creative and innovative solutions to combat healthcare deficiencies.

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

Yes, user, license, subscriber fees over time may exceed the up front capital investment, therefore there is incentive for technology and telecom vendors to invest in the development of NHIN.

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?

Telecom, ISPs, EMR vendors, software vendors will be the prime profit beneficiaries for the national adoption of the NHIN.

Providers could benefit by providing specialized services in a technological environment (e.g. lab, diagnostic, specialty physicians etc.)

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?

Multiple entities will be required because multiple standards will be necessary, as shown by the Consolidated Health Informatics Initiative (CHI). We see the need for a high-level, cross industry/government group – such as the Commission on Systemic Interoperability – to set policy and determine the need for standards based on business requirements.

A NCVHS like organization should be the overarching body to set a blueprint that can ensure interoperability of all standards or recreation of a group similar to the Joint Working Group for a Common Data Model (HL7, X12, DiCom) to ensure interoperability. Speed and predictability of development, adoption and modification as needed is critical.

This governing body would select and inform standards development organizations (SDOs) of high-level requirements. This group would organize and operate taking the following into consideration:

- There is a need to establish a voluntary core set of open standards that a free market would need to engage for whatever local/regional consortia emerge. This will ensure that local/regional organizations can be interoperable at a national level.

- All stakeholders that are required to engage in interoperability of clinical data

exchange need to be well represented. Stakeholders must have the opportunity to state their positions.

- Care must be taken to assure that vendors can engage in the process of interoperability development, but are not in leadership positions to control the direction and/or outcome. Conflicts of interest could easily emerge because vendors have strong financial incentive to leverage the outcome of standards development to their personal products/services benefits.

- SDOs with some dedicated full-time staffing can generally be more responsive than those that consist entirely of part-time volunteers

Interoperability standards need to be moved along a pathway common to the end users it is targeting. Using CMS to encourage early adoption of standards creates an impetus that incents all providers to embrace usage of standards. The use of CMS or its intermediaries provides a conduit to nearly every practicing physician in the US. An alternate method would be through commercial insurers, again, utilizing the connection that each provider has with a payer source.

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.

All aspects of the HIPAA privacy and security rules will be a challenge, regardless of the solution implemented. To avoid problems with permitting access to NHIN data outside healthcare operations, we recommend that the enforcement arms for HIPAA review and assess the ultimate NHIN design.

More restrictive state laws governing the use and protection of sensitive health information must be taken into consideration. *We support federal pre-emption of state privacy laws to facilitate data exchange across state and other legal entity boundaries, thus avoiding the need to operate under 50 plus different sets of rules.*

In addition, lessons learned from experience with HIPAA lead us to suggest the following:

- Concentrate new security efforts associated with the exchange between organizations as opposed to additional requirements within organizations.

- Avoid requirements that are dependent on specific products and or technologies.

- When possible security standards should be addressable allowing for alternatives to be deployed to obtain required objectives.

Security must be reasonable taking into consideration the size of the participant; the scale being from individuals to large national organizations.

Evaluate what SDOs are in place today. Are there any standards needed that are not covered? Do we need to create a new SDO or is the "missing link" assigned to an existing SDO. An appropriate oversight group to triage these types of issues might be NCVHS to act as a clearinghouse of standards information. The issues related to missing or inadequate standards would be identified within the RHIO.

The establishment of the policies and standards must be developed from collaborative resources including vendors, providers, and consumers. The construction of an oversight group may be needed to create a framework independent of proprietary bias that might develop if there were no formal oversight for the activities. It may be in the best interest of efficient development to give an organization a non patentable advantage. While one organization may stand to benefit initially, it will be the need of the industry to match the standard in order to continue to compete.

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?

We endorse the use of SDOs as a vehicle for establishing and maintaining standards (including version management) for data interchange within the healthcare industry.
Standards must be set in a structured way with oversight. A passive approach leads to chaos.

Existing SDOs need to have a common oversight group or council that
establishes policy, direction and priority across the industry. Collaborative agreements
among SDOs and any oversight group should be established prior to SDO final
selection. Existing processes for developing and maintaining standards need to be
revised to be timelier.

There should be wide participation from all stakeholders in setting the standards, with final endorsement by the NHIN. A good process to emulate: The Consolidated Health Informatics (CHI) Council of the National Committee on Vital and Health Statistics (NCVHS) identifies appropriate, existing data standards (X12, HL7, SNOMED, LOINC, etc.) and endorses them for use. NCVHS recommends the standards for adoption. The Secretary of Health and Human Services issues the standards after NCVHS.

Software should be certified to ensure it follows interoperability standards.

RHIO's should be credentialed to ensure they follow policies.

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?

We support a free-market driven incentive environment, where funding for adoption of technology would require the use of specific standards, and where incentives for continuing use would require continued adherence to the standards. The federal government should encourage consistency between federal programs and the private sector, and facilitate educational and outreach programs.

A certification process for vendors, as is currently being developed by HIMSS and URAC, would be a method by which business rules can be required and promoted. This will encourage vendors to develop in order to compete. Without any incentive to write to a common standard, the vendors continue to develop in a proprietary methodology. The model for this could be HL7.

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 should actively contribute intellectual and financial capital in the same fashion as other stakeholders. The government should refrain from using the rulemaking process to identify specific standards.

The Federal Government can also lead by example and establish de-facto standards for some aspects of interoperability, as in the government's Consolidated Health Informatics initiative. In addition, CMS adoption of interoperability standards for Medicare and Medicaid programs would also lend credibility and supply momentum for this strategic initiative.

The most important role the federal government can play is in mandating a methodology to uniquely identify all individuals. Without an identification methodology either an agreed upon algorithm or unique numerical identification, than the opportunity to share medical record information will always run the risk of compromise. With compromise comes insecurity and consumer resistance. The federal government can also legislate timelines for interoperability with positive financial incentive tied to implementation. We should strive for a benefit to integrating as opposed to a penalty for not integrating.

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?

Financial incentives with time-line restrictions from the federal government, as a healthcare payer and a governing body, are required to drive the development and adoption of a national model.

The federal government needs to formulate an architecture blue print at a level that gives enough guidance for vendors to develop products/services that meet the vision. The adoption of standards is mandatory.

Financial incentives for vendors may not be required if vendors understand the requirements.

Industry stakeholders (providers, payers, state government) would be willing to invest if the risk was minimized. Organizations are looking for clearer direction to avoid costly re-engineering of technical solutions and business processes. Large providers are already investing in EHRs, CPOE, etc. The problem is that nothing is being done in a coordinated effort to ensure interoperability. Large providers may need to be incented to share information.

Incentives will be needed for smaller providers.

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?

To take a page from building the federal interstate highway system, the government needs a national impetus that creates a sense of urgency that something must be done.

The federal government should offer tax incentives to build various parts of the NHIN, and matching funds to states that participate in building the NHIN. In addition, the federal government could also align the conditions of participation in Medicare with use of the NHIN by providers.

The interoperable exchange of standards based health information is an incentive. This should be based on consumer demand for quality healthcare. There should be incentives for the patient.

Any financial incentives should exist only for a short period of time.

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?

The variation in rules and regulations from state to state could pose an unacceptably high barrier to full implementation of the NHIN. The most important variation concerns privacy: a national network needs a national approach to privacy, but some states have privacy rules that are more stringent than HIPAA. With information traveling from network to network across states with different privacy and security standards, users may be forced to adopt the most stringent of the state standards to ensure compliance, regardless of that state's population. Other significant variations occur in state laws that concern such issues as data, terminology, and prohibitions on e-prescribing. As the NHIN grows, liability issues will assume greater importance.

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

This should be addressed by the national governance v. local governance. The answer to this question can be found under Question 3.

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 NHIN will require:
- The ability to uniquely identify all individuals
- Providers will need to be able to access the infrastructure from land line connections or cellular based connections
- Authentication of requestors and data sources

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? Identify baseline measurements that are consistent with recommendations being made for improving the healthcare delivery system by the IOM Report. Ensure that metrics are monitored, evaluated and adjusted to reflect improvements in medicine, technology and best practices throughout the industry.

Measurement is essential to the successful deployment and operation of a NHIN. The measurements should address issues relating to the system and to health outcomes that the NHIN supports. These could include:

Operational issues such as:

A. Use of the NHIN.
Actual hands-on use of the NHIN systems by patients, providers, and those involved in population health, as they care for patients. Example measurements we might be able to make here include:
- The percentage of patients in a region whose data was accessed by someone other than the originator of the data.
- The percentage of clinicians who actually logged-in to the system
- The percentage of healthcare institutions that submitted data to the RHIO

B. NHIN Systems Availability
These Measures include NHIN availability, to access the requisite technology to collect, store, display and transmit patient-identifiable, structured, clinical data in electronic formats. Possible measurements could include:

- The percent coverage (i.e., patients in a region who have copies of their data available through the RHIO of patient's in a community?
- Use of US census data for a geographic region covered to estimate denominator.
- The percentage of clinicians with an RHIO login?
- Estimate of total clinicians in region eligible for NHIN access
- The percentage of healthcare organizations in a geographic region with a signed data exchange agreements with the RHIO in place.

Outcome and other Measures:

Measurement of NHIN progress should also include outcome metrics and qualitative reviews of the current context for the implementation of the NHIN.

Outcome Examples Include:

Individual and community health status indicators affecting quality and safety issues including the six aims identified by the Institute of Medicine: Healthcare being:
- Safe
- Effective
- Patient centered
- Timely
- Efficient
- Equitable

Other Measures:

Qualitative reviews of organization and context issues should also be addressed. These might include:
- Qualitative assessment of the organizational and legal climate in each state to support NHIN
- Patient privacy protections
- Legal restrictions on sending/receiving various data types
- Electronic signatures
- Prescription transmission to pharmacies
- Legal restrictions on sending laboratory results to patients
- Requirements to submit data in electronic format to local, state, federal payers
- Availability of unique provider ID at federal level