



Public Health Data Standards Consortium

RESPONSE TO THE REQUEST FOR INFORMATION

**on the Development and Adoption of a National Health Information Network
from the Office of National Coordinator for Health Information Technology,**

Department of Health and Human Services;

Released on November 15, 2004

Baltimore, MD
2005

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Acknowledgements

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INTRODUCTION

The Public Health Data Standards Consortium (PHDSC) is enthusiastic about the opportunity to respond to the Request for Information (RFI) on a National Health Information Network (NHIN).

PHDSC is a national non-profit membership-based organization of federal, state and local health agencies; national and local professional associations; academia; public and private sector organizations; and individuals. PHDSC is dedicated to developing, promoting, and implementing data standards for public health practice and research through collaboration of local, state, federal, clinical and public and private organizations to ensure that these efforts are appropriately integrated with broader health care data standard development initiatives in the US. The PHDSC is committed to bring a common voice from the public health community to the national efforts of standardization of health care data and systems.

The PHDSC is comprised of public health professionals, health services researchers and private and public partners, working with all stakeholders in the health industry to expand educational resources, and inform and organize stakeholders to assure that health data and health data standards meet their needs and ultimately the health needs of the public, with appropriate privacy safeguards. The PHDSC has a unique role in promoting and developing standards for public health functions within the framework of standard development organizations (SDOs) and coordinating their development in tandem with standards for health care.

The PHDSC defines the NHIN as the policy framework and technical linkages between disparate health and health care information systems that allow patients, physicians, hospitals, public health agencies and other authorized users across the nation to share timely clinical information under stringent security, privacy and other protections. In the view of the PHDSC, the goal of the NHIN should be to effectively use information technology to improve the quality, efficiency, and safety of healthcare for all Americans through the widespread adoption of interoperable electronic health record systems (EHRS) within ten years and to enhance the health of the population.

The foundation of public health is to detect health events and assess health status trends in populations to assure timely intervention and prevention of disease, access to care and promotion of wellness. In fulfilling the population-based and patient-centric missions of public health, state and local health agencies and health care providers need to be capable of exchanging pertinent information about individuals. This should be an explicit NHIN interoperability goal.

If the primary focus of a NHIN is to achieve interoperability of health information technologies used in the health care delivery in America, the NHIN must include public health and research perspectives from the outset. For example, the NHIN should incorporate the CDC's National Public Health Information Network¹ (PHIN) in its initial design. It is through the mainstream delivery of health care in America that National Health Electronic Disease Surveillance System² (NEDSS) and other PHIN components will gather and analyze much of the information that will

¹ Public Health Information Network. URL: www.cdc.gov/phinf

² National Health Electronic Disease Surveillance System. URL: www.cdc.gov/nedss

improve our ability to identify and track emerging infectious diseases, disease outbreaks, chronic disease trends in populations and potential bioterrorism attacks.

Furthermore, the NHIN can serve as a vehicle to disseminate and monitor the Department of Health and Human Services (DHHS) Healthy People 2010 objectives and priorities³ that are mainstream healthcare goals in America for individual citizens. They are also our nation's aims for improving the health of populations. Health information technologies must be capable of reporting such data to health departments at state and local levels.

A goal of a national network must also include balancing concurrent and potentially conflicting needs to make public health data useful for the challenges facing our nation in the 21st century, while maintaining appropriate patient confidentiality. Public health's efforts to assess individual patients, provide services in a secure, timely, comprehensive, and cost-effective manner and analyze important trends in disease occurrence⁶ are often hindered by inaccessible and outdated information exchanged in old, non standards-based technology requiring the re-entering of information several times from the source. These limitations lead to morbidity and mortality that could be prevented and to disease outbreaks that go unrecognized too long. The design and function of the NHIN must enhance these public health efforts while keeping health information confidential except for authorized uses.

The NHIN should not constrain its initial thrust to the direct provision of healthcare to the exclusion of public health. The NHIN must include public health as a full partner in the emerging transformation of our nation's health care system through the adoption and use of information technology.

³ U.S. Department of Health and Human Services. Healthy People 2010, 2nd ed. Understanding and improving health and objectives for improving health (2 vols.). Washington, DC, 2000. URL: <http://www.healthypeople.gov>

⁶ U.S. Centers for Disease Control and Prevention. Public Health Information Network. URL: <http://www.cdc.gov/phinf>

RESPONSE TO THE REQUEST FOR INFORMATION

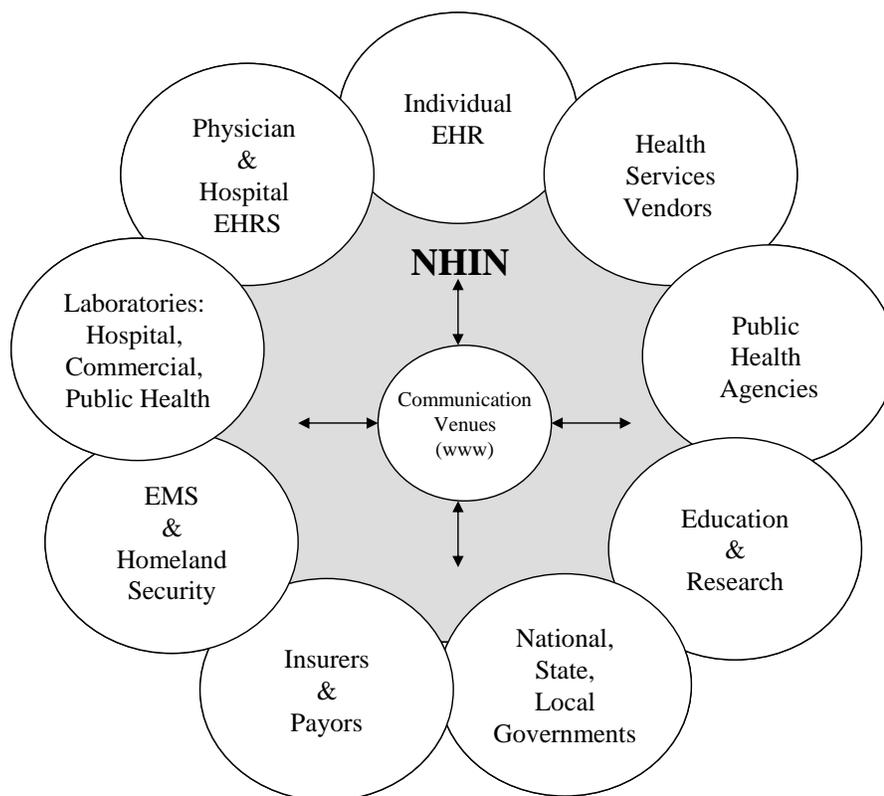
GENERAL

Q1. *The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of healthcare 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 PHDSC defines the NHIN as the policy framework and technical linkages between disparate health and health care information systems that allow patients, physicians, hospitals, public health agencies and other authorized users across the nation to share timely clinical information under stringent security, privacy and other protections. In the view of the PHDSC, the goal of the NHIN is to effectively use information technology to improve the quality, efficiency, and safety of healthcare for all Americans through the widespread adoption of interoperable electronic health record systems (EHRs) within ten years and to enhance the health of the population.

NHIN will support the continuously changing flow of health information among authorized users intersecting with all forms of health communication, *e.g.*, messaging, data linkage, data integration, information queries by users, the world wide web communications, 911 communications, telephone, radio, facsimile, and mail/post transfer. NHIN will support all forms of recordable health-related interactions between stakeholders, *e.g.*, physician-patient, parent-child-pediatrician, EMS first responder-patient-hospital, physician-laboratory, physician-payor, physician-hospital administration, physician-insurer, physician-public health practitioner. In addition, it will provide data for research needs allowing for further understanding of relations between human-health, human-disease, and human-environment. NHIN will provide timely access to data and information through secure communication channels for the authorized users whose purpose is to promote human welfare, including emergency access to information for clearly delineated issues of Homeland Security while protecting privacy of individual information. Fig 1. depicts examples of NHIN stakeholders.

Fig. 1. NHIN Stakeholders



Key Barriers

To identify barriers we have to learn from past and current experiences with developing community networks. Why did nearly all Community Health Information Networks developed in the 1990's fail⁷ and what are the organizational barriers to their success?

Slow Process of Electronic Medical Record System Penetration. The EHR-based NHIN requires that each stakeholder has an electronic system to maintain its own patient- and/or community-related health records and be capable of sending/receiving data via electronic channels.

According to a 2003 survey with significant selection bias towards EMR-based providers, only 24% of family practitioners use a computer-based system to maintain patient record. In 2001, the Association of Public Health Laboratories reported that 78% of public health laboratories did not have the ability to produce or accept an electronic standardized HL7 messages.⁸

⁷ Lorenzi, Nancy M. Strategies for Creating Successful Local Health Information Infrastructure Initiatives, December 16, 2003 URL: <http://aspe.hhs.gov/sp/nhi/LHII-Lorenzi-12.16.03.pdf>

⁸ United States House of Representatives, Government Reform Committee, Subcommittee on Technology and Procurement Policy, Testimony of the Association of Public Health Laboratories. December 14, 2001 <http://aphl.org/docs/Advocacy/Testimonies/NEDSSTestimony.pdf>

Cost-Benefit Factors. A major portion of the cost associated with adoption and implementation of an EHRs, which includes purchasing, maintenance and most importantly, change in workflow, will fall on health care providers (HCPs). Similarly, efforts are needed to build technical capacities for NHIN in governmental agencies at the state and especially local level for their systems to be transitioned to EHRs standards for communication, interoperability and security. There is a need for governmental incentives and funding for EHRs implementation in HCP offices and public health agencies to enable EHR-based data interchange between clinical care and public health via an Electronic Health Record –Public Health (EHR-PH) system.⁹

Silos-based Infrastructure. The majority of current clinical and public health data systems are "silos." While clinical "silos" are mostly of an administrative nature, public health "silos" are of a knowledge-based (programmatic, disease-specific) nature and could be even more difficult to transition to integrated EHR-PH systems. Over the last 40 years, a categorical disease-specialized approach has been utilized in public health, that is, communicable diseases, lead poisoning, injury, community-based mental health, substance abuse, bioterrorism, etc.¹⁰ Programmatic fragmentation and organizational diversity of existing clinical, public health, pharmacies, and payors systems are the main challenges to the NHIN implementation. "*Public health and clinical medicine – prevention and treatment – must come together along an interactive, integrated continuum, rather than operating in isolated silos of public health professionals, doctors, hospitals, HMOs and insurers.*"¹¹

Privacy and Security Measures built into the NHIN using the existing HIPAA Privacy and Security Rules as a base, must allow access to data/information on a need-to-know basis only. A significant educational effort is needed to build both public knowledge and public trust about the value of clinical data exchange, with appropriate protections, not only for personal health care but for broader community health. Development of applications that have value for the consumer will facilitate this building of knowledge and trust.

Absence of the NHIN Model. Models for EHR-based Regional Health Information Organizations/Exchanges (RHIOs/RHIEs) within NHIN architecture are needed¹². Public health and other NHIN partners should participate in the development of the regional RHIE models to assure connectivity/integration of various components of NHIN.

Policy Context. Policies, laws and regulations on the local, state and federal levels that are needed to support NHIN development and deployment must be aligned across jurisdictions. For example, the Newborn Hearing Screening public health programs are required by law in more than 38 states. In the state of Iowa, the IT application must disclose demographic information at the state level. The same application in Texas is configured to mark records as confidential unless the infant needs additional care.

⁹ Public Health Data Standards Consortium. 2004. Electronic Health Record-Public Health Perspectives. White Paper. PHDSC Ad Hoc Task Force on the Electronic Health Record-Public Health. March 9: 27p. plus 9 Attachments. ULRs: <http://phdatastandards.info> and www.hl7.org/ehr

¹⁰ Lasker RD, editor. Medicine and public health: the power of collaboration. 1997. New York, NY.

¹¹ Harvard School of Public Health. 2003 Annual Report. Cambridge, Massachusetts.

¹² Thompson TG and Brailer DJ. The decade of health information technology: delivering consumer-centric and information-rich health care. Framework for Strategic Action. Department of Health and Human Services. July 21, 2004.

PHDSC has identified barriers for the implementation of EHR-PH systems¹³ and to adoption of standards by state and local public health departments, which also apply to other stakeholders¹⁴, and also is developing strategies to overcome these barriers.

Enablers

NHIN Stakeholders. The current mode of data collection and communication burdens every health care participant, *i.e.*, HCPs, public health practitioners, pharmacists, patients, payors, and caregivers. The NHII 2004 conference demonstrated the full support of the health care community to the NHIN in order to reduce this burden by eliminating duplication in data reporting and data management in every stakeholder setting. This would improve data quality, data access and data sharing. Newly forming regional health information exchanges/networks/organizations are the demonstration that NHIN stakeholders are ready to begin this process.

Government is currently funding several RHIOs/RHIEs development projects. They are mainly focused on HCP's needs and do not involve other stakeholders, *e.g.* public health, patients and caregivers, etc. Despite creating a Coordinating Resource Center, the main focus of its activities is HCP-needs driven. We do not have the luxury to develop a NHIN that serves the clinical community and only later adjust it to other stakeholders' needs. The model to be developed for NHIN should address interests of all stakeholders who need to be a part of the NHIN but who are beyond clinical encounters. The process to identify these stakeholders and to address their needs should happen now, simultaneously with RHIOs project development.

Public Health Data Standards Consortium (PHDSC, Consortium). ***There is a critical need for educating the workforce about NHIN development process.*** PHDSC is a national non-profit membership-based organization of federal, state and local health agencies; national and local professional associations; academia; public and private sector organizations; and individuals. PHDSC is dedicated to developing, promoting, and implementing data standards for public health practice and research through collaboration of local, state, federal, clinical and public and private organizations to ensure that these efforts are appropriately integrated with broader health care data standard development initiatives in the US. The PHDSC goal is to empower agents of health and health care with public health information standards to improve individual and community health. ***Our mission is to bring a common voice from the public health community to the national efforts of standardization of health and health care information.***¹⁵

As was noted in the cover letter accompanying this response, the PHDSC is actively involved in promoting the integrated clinical/public health EHR-PH systems under NHIN through work with standard development organizations SDOs, *e.g.*, HL7, ASC X12N, National Uniform Billing Committee (NUBC) and National Uniform Claim Committee (NUCC), etc. on standardized information collection, exchange and data sharing. The Consortium represents the interests and

¹³ Public Health Data Standards Consortium. 2004. Electronic Health Record-Public Health Perspectives. White Paper. PHDSC Ad Hoc Task Force on the Electronic Health Record-Public Health. March 9: 27p. plus 9 Attachments. ULRs: <http://phdatastandards.info> and www.hl7.org/ehr

¹⁴PHDSC Educational Strategy <http://63.107.122.208/archives/workgroups/ewg>

¹⁵ Public Health Data Standards Consortium. Strategic Action Plan. ULR: <http://phdatastandards.info>

needs of the public health community at these organizations so that the tasks of developers and the needs of public health community (users) will be addressed in a collaborative and timely manner.

PHDSC is leading the EHR development process from public health perspectives. In December 2003, at the request of the EHR Collaborative¹⁶, we launched the PHDSC Ad Hoc Task Force on Electronic Health Record – Public Health (EHR-PH) to evaluate the HL7 EHR functional model from public health perspectives. This effort engaged 65 representatives from various organizations and was the first opportunity for the public health community to actively participate in national efforts of developing EHR standards for integration of health care and public health systems. The validation demonstrated that the HL7 EHR functional model provides a foundation for integration of health care and public health services. Participants agreed that “electronic transmission of standardized data from the patient health record to public health agencies via EHRS is essential to support key public health functions and services, and supply public health data repositories.” They also agreed that “adopting the EHR would not only enhance the information, data, and communication systems within the public health infrastructure, but would also increase the capacity of the organizational and system components of the infrastructure”.¹⁷

We are currently working with the Health Resources and Services Administration’s Maternal and Child Health Bureau on the development of the pediatric EHR data standard from public health perspectives.¹⁸ These two projects led to the development of the EHR-PH System Prototype for Interoperability in 21st Century Health Care System (Fig.2) that PHDSC and its members¹⁹ will demonstrate at the HL7 HIMSS 2005 Conference in Dallas, TX in February 13-17, 2005. The Consortium also is working with the National Association for Public Health Statistics and Information Systems on a standard HL7 message to transmit birth vital statistics information.

Informatics Research. The needs for the model-based driven NHIN architecture and IT tools call for understanding (1) an organizational structure of every NHIN stakeholder and (2) commonalities of dataflow and workflow across NHIN stakeholders and the entire health care delivery system as key steps in integrating health-related data and systems. This will inform standardization efforts to allow the flow of relevant information via EHRS across stakeholders. In addition, a broader vision to the population health data model (which goes beyond the disease-

¹⁶ The EHR Collaborative is a joint collaboration involving American Health Information Management Association (AHIMA), American Medical Association (AMA), American Medical Informatics Association (AMIA), College of Health care Information Management Executives (CHIME), eHealth Initiative (eHI), Health care Information and Management Systems Society (HIMSS), and the National Alliance for Health Information Technology (NAHIT). The goal of the EHR Collaborative is to facilitate rapid input from the health care community in this and other development initiatives that advance the adoption of information standards for health care.

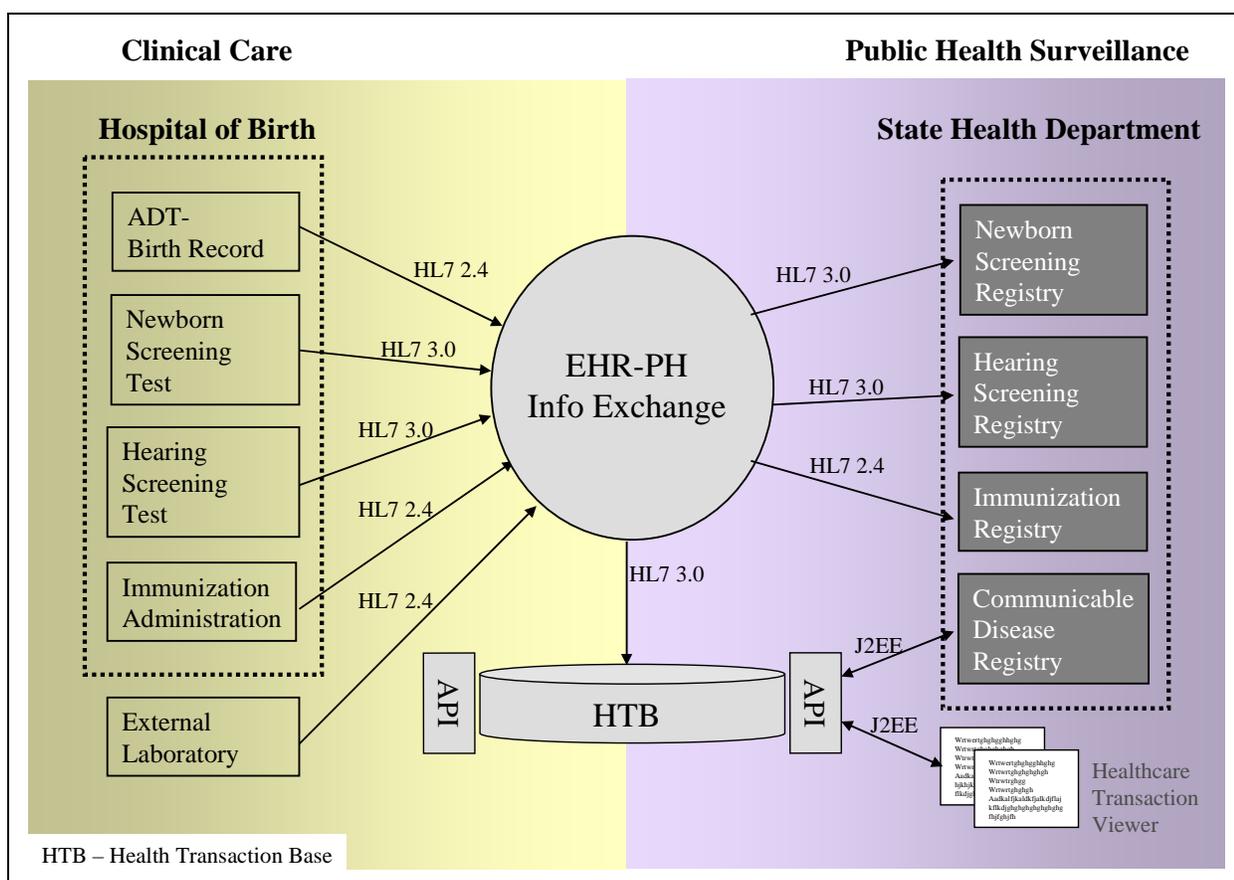
¹⁷ Public Health Data Standards Consortium. 2004. Electronic Health Record-Public Health Perspectives. White Paper. PHDSC Ad Hoc Task Force on the Electronic Health Record-Public Health. March 9: 27p. plus 9 Attachments. ULRs: <http://phdatastandards.info> and www.hl7.org/ehr

¹⁸ Public Health Data Standards Consortium. 2004. Pediatric Electronic Health Record-Public Health Perspectives. Report to Health Resources and Services Administration, December: 38p. plus 4 Attachments.

¹⁹ EHR-PH System Prototype for Interoperability in 21st Century Health care System. PHDSC, Oracle, Medical Decision Logic, Inc., OZ Systems, Science Technology Corporation, Quest Diagnostics. HL7 HIMSS 2005 Conference, Dallas, TX, February 13-17, 2005.

based clinical model to include societal functioning and environmental factors²⁰) is needed to allow integration of other data and systems relevant to the public's health and quality of life, *e.g.*, environmental data, housing data, geographic data, ecological data, etc.²¹ These data are important for assessing and evaluating health status of populations as well as for identifying disease specific risks and clinical and public health interventions. Therefore, informatics research is an enabler of the NHIN development process.

Fig. 2. EHR-PH System Prototype for Interoperability in 21st Century Health Care System.



²⁰ World Health Organization. International Classification of Functioning, Disability and Health. Geneva, WHO, 2001.

²¹ Public Health Data Standards Consortium. 2004. Electronic Health Record-Public Health Perspectives. White Paper. PHDSC Ad Hoc Task Force on the Electronic Health Record-Public Health. March 9: 27p. plus 9 Attachments. ULRs: <http://phdatastandards.info> and www.hl7.org/ehr

Q2. *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 NHIN model should be built with the following elements in mind:

- An open, secure and reliable telecommunication network infrastructure (see *Question 4*);
- A set of electronic standards (data content and format) for data interchange, identified and adopted, through a national consensus process;
- Guidelines for the adoption of standards-based EHRS by health care providers;
- Information security standards including authorization, authentication, transaction and communications auditing, and other secure communications practices;
- A comprehensive health information privacy framework (already provided by HIPAA Privacy) to enable the adoption and use of interoperable EHRS
- Methods for uniquely identifying patients, providers, and other key individual and organization participants in the health care system;
- Clinical and public health knowledge-based applications to support medical/public health decision-making and good clinical/public health practices; and
- Operating policies and procedures among trading partners and health care organizations agreeing to exchange data and information.

We believe that NHIN participants (HCPs, payers, public health agencies and others) will need to be able to continue to exercise full control over the information that they are responsible for collecting and maintaining. We also believe that, as NHIN participants, these entities will have the responsibility of using interoperable systems and national data content and format standards to allow for the timely exchange of information, within the health information privacy and security framework already established under HIPAA.

Our EHR-PH system prototype (Fig.2) presents an example of a model for health information network that supports data exchange between a hospital, laboratory and public health programs. The approach accommodates multiple external data sources and every participant is the owner/custodian of its data system. These multiple data systems are interoperable through standards and technical linkages thus producing a virtual EHR. The network infrastructure provides securely encrypted transport of data from and to every participant through multiple firewalls so data can be updated/accessed/viewed/integrated as needed with audit tracking of accessions. Data that need to be exchanged via the network infrastructure must be defined in the health information network data content standard. User views can present more limited data requirements for specific uses based on what the specific user needs to see. These requirements are also defined in the network infrastructure and should cover the rights and responsibilities of participants to eliminate misuse and abuse of data and information.

This model allows the data to reside at the data source, *e.g.*, HCP office or Laboratory or Public health agency’s registry (Fig.2), to support the workflow at the source, while the network infrastructure allows the data transport and integration without any alteration whatsoever to existing uses. This model can be considered as distributed EHR-based RHIE/RHIN model.

This distributed health information network infrastructure approach places the user and usage at the center of the process rather than the data collection and storage, as it exists now. It takes full advantage of the “silo” platform independence derived from standards of communication and data exchange beyond that of merely transporting data for re-storage. It has the potential to enable and encourage a richer and broader involvement from all stakeholders including HCPs, vendors, academia, governmental agencies beyond public health and consumer (individual patient) as described in *section Q23 and Fig. 4* below.

Q3. *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.)*

Consistent with the NHIN model elements we highlighted in *section Q2*, we believe the following considerations should be made about the national/regional responsibilities related to the implementation of the NHIN:

Element	Federal	State/Regional
Network Infrastructure	<ul style="list-style-type: none"> * Adoption of Internet as NHIN infrastructure; * Investment in making internet more secure for health information 	<ul style="list-style-type: none"> * Build health information networks and exchanges; * Implement the Internet as the health information network backbone
Standards for Clinical Interchange	<ul style="list-style-type: none"> * Establishment/endorsement of formal process for adoption of standards; * Create regulatory framework for assuring use of standards 	<ul style="list-style-type: none"> * Participate in the development/testing of standards; * Adopt and use standards (require use by local members of RHIOs)
Guidelines for EHRs	<ul style="list-style-type: none"> * Establish and promote guidelines for the adoption of EHRs by HCPs; * Implement a National Education Effort on EHRs; * Use purchasing power to provide incentives to the use of EHRs by HCPs 	<ul style="list-style-type: none"> * Work locally with HCPs/payers/employers/ others to foster the adoption of EHRs by the industry; * Identify barriers, enablers, models, cost-benefits associated with the use of EHRs
Security Standards	<ul style="list-style-type: none"> * Regulatory and monitoring responsibilities for the adoption of standards by industry (HIPAA) 	<ul style="list-style-type: none"> * Continue facilitating local health care organizations with the implementation of standards
Privacy	<ul style="list-style-type: none"> * Regulatory and monitoring 	<ul style="list-style-type: none"> * Continue facilitating local health

Framework	responsibilities for the adoption of standards by industry (HIPAA)	care organizations with the implementation of standards
Unique Identifiers	<ul style="list-style-type: none"> * Establish regulatory framework for assuring that patients can be uniquely identified, and patient-identifiable information can be securely and accurately transferred; * Continue regulatory and monitoring responsibilities for the adoption of other identifiers 	<ul style="list-style-type: none"> * Identify barriers, enablers, models, cost-benefits associated with different approaches for uniquely identifying patients; * Continue facilitating local implementation of other identifiers
Knowledge-based applications and value-added services	<ul style="list-style-type: none"> * Forster the creation of knowledge-based applications for use in medical and public health decision-making 	<ul style="list-style-type: none"> * Perform R&D associated with these applications; * Test and implement applications across the region
Operating policies and procedures	<ul style="list-style-type: none"> * Establish a regulatory framework that assures health care organizations to adoption policies and procedures related to the NHIN, the use of EHRS, the exchange of clinical information via standard transactions, the use of privacy and security standards, and the involvement in a regional effort activity 	<ul style="list-style-type: none"> * Foster the adoption and use of operating policies and procedures related to the NHIN, the use of EHRS, the exchange of information via standard transactions, the use of privacy and security standards, and the involvement in a regional effort activity; * Ensure that participants at the regional level have in place these policies and procedures

ORGANIZATIONAL AND BUSINESS FRAMEWORK

Q4. *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?

(b) What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?

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

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

Framework

Regarding the technical infrastructure, an organized approach to a market-driven network, such as represented by the Internet, is one framework that should be seriously considered. In the future, the actual physical NHIN infrastructure would be no different than the Internet, and any investment should be towards enhancing the ability of the Internet to meet the security, privacy and reliability needs of population health and health care information. A totally separate network should not be built.

This will need to be developed in conjunction with regulatory guidance from the Department of Health and Human Services that will assure interoperability. The relationship between DHHS and the National Committee on Vital and Health Statistics (NCVHS) in recommending and adopting standards for administrative, clinical and public health data can serve as a prototype, with the NCVHS process allowing for the open and transparent exchange of information from various stakeholders on subjects of interest to understand their perspectives and to build a consensus.

Stakeholders

NHIN stakeholders are those involved in health care, public health and all the groups that support health care and the health of the population. This includes health care providers, public health and other governmental agencies, payor organizations, health services vendors and, importantly, consumers (individual patients and caregivers) across the nation (Fig.1).

There are numerous entities within each stakeholder group that will be involved in NHIN. For example, from population health perspectives governmental agencies beyond traditional public health should be involved in building NHIN, *e.g.*, Department of Housing and Urban Development (housing safety), Department of Transportation (transportation safety and injury prevention), Department of Labor and Occupational Safety and Health Administration (employment and occupational safety), Department of Commerce (product safety), Department of Education (training and vocational and special education), Department of Energy (safety of nuclear energy production and waste disposal), Homeland Security (bioterrorism), Department of Defense (national security). These agencies and their local, state and regional branches should be involved in local/state/regional health information networks (HINs) and HIEs.

(a) How could a NHIN be developed? NHIN development should be based on a standard informatics methodology and should be done in a bottom-up fashion starting with the development of the local HINs/HIEs but using common data and messaging standards for interconnectivity. The key steps to develop local HIN prototypes are the ones that are traditionally described in the system specifications requirement documents and are similar to the routine project management steps. The example of such specification requirements are provided in Attachment 1.

(b) What could be key consideration in constructing NHIN? What could be a feasible model for accomplishing its construction? There are three key considerations in constructing NHIN as follows:

1. NHIN development should be based on local/state/regional HINs/HIEs developments by preserving and building upon local/state/regional functionality.
2. NHIN development should place the user perspectives and usage functions at the center of the process rather than the data collection and storage functions as it exists now.
3. NHIN development should allow all stakeholders and entities to be equally heard in the development process so their perspectives are communicated to be addressed.

Experiences and lessons learned including the ones from the international community should be shared across all stakeholders. An EHRS certification process should be established. This is currently under development by the AHIMA, PHDSC member, and HIMSS for the certification of EHRS in clinical care. Additional efforts are needed to engage other stakeholders in the certification process. For example, certification process for EHRS in public health settings, i.e., EHR-PH systems, should be developed. The latter, however, should be done in coordination with certification of clinical EHRS to assure interoperability and connectivity.

(c) How could policies and standards be set for the development, use and operation of a NHIN? NHIN policies and standards should be set via DHHS' NCVHS and Office of National Coordinator for Health Information Technology (ONCHIT) and its Consolidated Health Informatics (CHI) initiative and Federal Health Infrastructure (FHA) committee. The NCVHS and ONCHIT could serve as national facilitators for the adoption of the standards developed by Standard Development Organizations (SDOs), e.g. HL7, SNOMED, NCPDP, etc. NCVHS should engage local and state representatives to provide testimonies on local/state policies that support or present a challenge for system interoperability and connectivity under NHIN. So, national NHIN policies that are needed will address local/state perspectives.

Professional associations, and consortia such as the Public Health Data Standards Consortium, should work with NCVHS, ONCHIT, CHI, and FHA to conduct validation of these policies and standards by the communities they serve. The PHDSC Task Force on the validation of the HL7 EHR functional model from public health perspectives described in *section Q1- Enablers* is an excellent example of such needed validation.

(d) *How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care.* To guide the electronic integration of health care systems via NHIN there is a need to understand how rapidly the e-health transformation is taking place and what issues must be addressed to provide for continued evolution of EHR systems. Diffusion of innovation theory posits an "S" shaped logistic growth curve to explain how new innovations are tested and adopted by organizations, a classical Verhulst-Pearl curve that models the growth of populations and their stabilization, collapse, and/or oscillation over time and that has been used extensively in descriptions of ecological populations.^{22,23,24,25,26} This theory provides a useful way to organize the many needs associated with the testing, adoption and use of new EHR technologies. Fig.3 shows that early in the life cycle of a new technology only a few early adopters come forward to test and improve the innovation. Gradually, others view the progress of early adopters and enter as colonizers. Over time the rate of adoption of the innovation accelerates at an exponential rate, leaving only the laggards to finally adopt or be left behind.

While no hard survey data exist to chart where the health care and public health communities are on this classical Verhulst-Pearl logistic growth curve, professional judgment among informed informatics and health professionals is that as a country the U.S. is at the early lag stage prior to the rapid adoption. The diffusion of innovation perspective helps stage the various policy support informatics research actions to support analysis and creation of effective NHIN systems as follows:

- ❑ Specifying and quantifying benefits, costs, and return on investment to stakeholders involved, *e.g.*, HCPs and public health agencies, developers and patients.
- ❑ Defining goals, processes and data needs.
- ❑ Constructing, validating and endorsing data in standardized formats.
- ❑ Defining minimum requirements for NHIN system.
- ❑ Defining workflows that drive population health improvements.
- ❑ Validating specific use cases.
- ❑ Supporting creation of model / prototype systems.
- ❑ Constructing performance measures that can be field tested for practicality.

Addressing these issues will lead to the development of the EHR-PH architecture prototype. Key ingredients of this process will include the establishment and maintenance of strong partnerships among the key stakeholders, agreements on standards, and adherence to realistic set deadlines.

²² Bonabeau, E. (2002). Agent-based modeling: Methods and techniques for simulating human systems. *Proc. Natl. Acad. Sci. USA*, 99 (Suppl 3), 7280-7287.

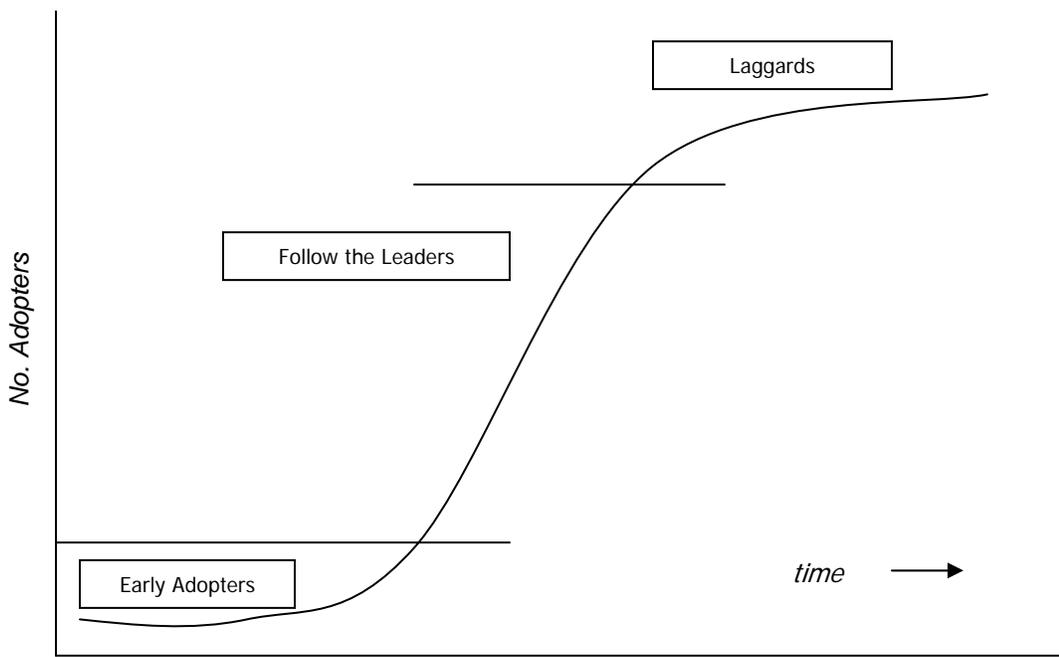
²³ Krebs, C. (1997). *Ecology: The experimental analysis of distribution and abundance*, 5th ed. NY: Addison-Wesley.

²⁴ Lotka, A.J. (1956). *Elements of mathematical biology*. NY: Dover.

²⁵ Pearl, R. & Reed, L.J. (1920). *Proc. Natl. Acad. Sci. USA*, 6, 275.

²⁶ Verhulst, P.F. (1844). *Memoirs of the Royal Academy of Brussels*, vol. 18, p. 1

Fig. 3. e-Health Activities Relevant to Phases in the Adoption of Innovation Curve



Early Adoption Phase	Rapid Growth Phase	Final Implementation Phase
<ul style="list-style-type: none"> ❑ Debate benefits and costs, i.e., Return on Investment (ROI) ❑ Define goal, process & data needs ❑ Define workflows ❑ Define minimum system requirements ❑ Validate use cases ❑ Build model / prototype systems ❑ Construct performance measures ❑ Agree on standards and standards setting governance 	<ul style="list-style-type: none"> ❑ Evaluate competing models to assess models that work ❑ Diffuse best practices associated with models that work ❑ Implement performance measures ❑ Identify best practices ❑ Identify which technical models work best ❑ Identify models for public-private governance ❑ Classify social change issues (e.g., need for additional privacy laws) ❑ Validate performance measures ❑ Publish results / benefits 	<ul style="list-style-type: none"> ❑ Establish standards of practice ❑ Establish performance metrics tied to reimbursement ❑ Maintain standards normalization activities

(d) How could the NHIN be operated? What are key considerations in operating a NHIN? The development and deployment of NHIN should be done under the overall guidance of the DHHS' ONCHIT. We believe the Office should play both a coordinating and advisory role (negotiating and ombudsman with federal agencies) during the developmental process and should work with local/regional/state HINs directors to develop the governing structure for NHIN operation in the future. ONCHIT should involve all NHIN stakeholders to participate in the development and validation process, so the needs of the NHIN constituents will be met. There should be considerable consumer/citizen oversight as well as representation from scientific, medical, ethical, and legal experts.

Q5. *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.*

Cost-benefit analysis conducted as a part of local HIN development process described in *section Q4a, Attachment 1* and *section Q4d* will help define the cost and the financial model to build NHIN components.

Federal financial resources that are currently channeled through various governmental agencies should be assessed to evaluate whether they can be used to finance coordinated NHIN development efforts. The inventory of programmatic funding by agency is needed to address duplication, if any.

The Congress, the Association of State Governors, representatives from state legislatures, the Conference of Mayors state and local health data organizations and consortia should be involved in NHIN development process by representing/advocating local, regional and state needs for HINs, so state and local funds will be identified to support/contribute to the NHIN development. For example, the State of Massachusetts has announced a 50 million dollar program to fund HIE.²⁷ The PHDSC member – Massachusetts Health Data Consortium – is a founding member of this initiative.

Funding strategy for the whole period of NHIN deployment should be developed based on the local HIN development cost-benefit assessments, to support the local/regional/state HINs steady integration into NHIN. Laws should be developed to secure this funding for the period of time needed for deployment

Accountability process should be institutionalized as a part of the funding allocation strategy.

Alternative data sources that can be integrated into NHIN based on the actual dataflow and not on the existing infrastructure developed in the past, should be considered. This may cause significant changes in the workflow, however, it will allow significant cost saving due to the reuse of already existing data sources that are ready for NHIN integration at minimal or no-cost.

²⁷ MA eHealth Collaborative. URL: http://www.maehc.org/documents/MAeHC_Request_for_Applications-6_Dec_04.doc

Q6. *What kind of financial model could be required to operate and sustain a functioning NHIN? Please describe the implications of various financing models.*

Public/private partnerships are critical to develop, operate and sustain a functioning NHIN. The public sector invests significant resources in the health care system through Medicare, Medicaid, Departments of Veterans Affairs and Defense programs. Numerous other agencies (e.g., Centers for Disease Control and Prevention, Health Resources and Services Administration) support health care delivery, disease prevention, health promotion and surveillance programs, as well as information technology implementation to support these programs. These resources should be leveraged, with appropriate incentives, so they support development of interoperable systems at the local community and provider levels. The ONCHIT should serve as a neutral convener to coordinate these multiple activities, assuring common standards and policies that assure interoperability.

NHIN and state/local HIN support also could continue with expansion of current federal IT funding for existing and new research and development projects. The strategic importance of the NHIN cannot be dependent on the state of the economy. The federal and state governments would need to provide a reserve fund to keep NHIN afloat at all times. In addition, vendors involved in building NHIN should contribute financial resources to this fund. A realistic cost assessment of NHIN and modeling of the system's requirements will be necessary to evaluate how these and other funding options could optimally support NHIN.

Q7. *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?*

ONCHIT work should be coordinated with NCVHS hearings on the implementation of the HIPAA privacy regulation at the local and state levels. With the inclusion of education records, the Family Educational Rights and Privacy Act (FERPA; Buckley Amendment Title IX of the Higher Education Amendments of 1972; (20 U.S.C. § 1232g; 34 CFR Part 99)) must be addressed for individual/parent/guardian permission to access education records. The impact of FERPA and HIPAA on NHIN must be assessed, as well as state laws going beyond HIPAA. These legal complexities will determine how the information flow throughout NHIN will be conducted.

Q8. *How could the framework for a NHIN address public policy objectives for broad participation, responsiveness, open and non-proprietary interoperable infrastructure?*

The RFI process is an excellent example of how public policies objectives for broad participation should be met. Validation of the adoption of all aspects of the NHIN, including regional HIN/RHIE models, should be conducted via an open process and broad participation of stakeholders with similar interests from other jurisdictions, so lessons learned through pilot HIN/HIE development projects can inform the development process in the other jurisdictions. This validation process should be conducted with participation of professional organizations and consortia such as PHDSC, as described in *section Q14* below.

National meetings such as EHR Summits, Connecting Communities for Better Health Learning Forum, NCHS Annual Data Uses Conference and CDC Public Health Information Network, and annual meetings of professional associations, *e.g.*, PHDSC, eHealth Initiative, Council for State and Territorial Epidemiologists (CSTE), National Association of City and County Health Officials (NACCHO), National Association of Health Data Organizations (NAHDO), Association of Public Health Laboratories (APHL), Association of State and Territorial Health Officers (ASTHO), American Public Health Association (APHA), American Immunization Registry Association (AIRA), should be used for educating communities about NHIN development process.

It is critical that these forums will address perspectives of various NHIN stakeholders and not only the traditional audience that these organizations serve. For example, to inform the public health community about the NHIN development process in clinical care as well as the clinical community about public health perspectives on NHIN, the PHDSC is currently working with eHealth Initiative, PHDSC member, to organize the 2005 PHDSC Annual meeting as a joint meeting at the 2nd Connecting Communities for Better Health Learning Forum in May 2005.

MANAGEMENT AND OPERATIONAL CONSIDERATIONS

Q9. *How could private sector competition be appropriately addressed and/or encouraged in the construction and implementation of a NHIN?*

The private sector competition can be appropriately addressed via establishing national standard requirements for EHR and the EHRS certification process as described in *section Q4b*. NHIN development is an enormous task. In fact, we may lack vendors capable of delivering the model-driven, user-oriented IT products that are needed for this task. The NHIN is a multifaceted endeavor that will require both universal and specialized IT tools. The NHIN model will define the needs and therefore the requirements for IT tool and products needed.

Q10. *How could the NHIN be established to maintain a health information infrastructure that evolves appropriately from private investments?*

Currently, portions of the health information infrastructure (HII) development process are supported by federal funding, e.g., bioterrorism programs, 2005 AHRQ HIT grants and contracts, Medicaid and Medicare programs. Still, there are other parts of the HII that are being funded by private sector investment (the network infrastructure itself, including the use of the Internet for health information exchange; the development of new EHR applications; most of the security standards). In addition, vendors, e.g., the hospital information management systems developers, the pharmaceutical companies and the laboratory information management systems (LIMS) vendors are very much involved in creating portions of a HII. To assure that private investments will support the HII and will not be wasted, it is critical to continue to advance the establishment of national standard requirements for clinical data interchange transactions and the EHRS certification process. Requirements for electronic reporting imposed by the certification process would certainly “motivate” private sector efforts.

Q11. *How could a NHIN be established so that it will be utilized in the delivery of care by health care 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?*

- Use the Internet as the backbone of the health information network infrastructure;
- Invest in assisting rural and small providers to enhance their information technology capabilities (through grants and low-cost loans);
- Invest in expanding and facilitating access to the Internet-based infrastructure by rural providers;
- Invest in planning/pilot/implementation projects that demonstrate the cost-benefits of adopting and using EHRS and embracing the Internet for secure and reliable health information exchange.

Q12. *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?*

In *section Q1-Barriers* we describes “siloed” infrastructure of clinical and public health data systems created to support specific needs of HCP practice and public health program areas *i.e.*, *newborn screening, birth defects, immunization, communicable disease surveillance, injury prevention, etc.* These “siloed” clinical and public health data systems deploy certain software products that are often custom-made to serve particular HCP office or public health programmatic needs and are not interoperable across community or within setting, *e.g.*, hospital, health department, etc.. Lack of integration across system leads to the inefficient use of resources and frustration among families and HCPs asked to provide the same information, on multiple forms, with varying formats, to various entities and programs.

Automation of clinical data – inpatient and outpatient – via the EHRS under NHIN, puts both clinical and public health communities at the threshold of change in the way in which they can gather and exchange data. The EHRS is a pivotal instrument in integrating clinical and public health data systems (EHR-PH systems) (Fig.2), so public health authorities will have reliable, timely access to patient data to support public health practices and health policy decisions as well as HCP will gain access to aggregated data and information on the health status of the community he/she serves.

NHIN will dramatically affect the workflow of both sectors of health care (clinical and public health) in terms of data collection and data management because of the impetus towards integration of data systems. Even in the areas where there are already some forms of community or regional HIEs, *e.g.*, Michiana Health Information Exchange, Indianapolis Metropolitan Area, KIDSNET - integrated system of six maternal and child health programs at the Rhode Island Health department - NHIN will require broadened participation of other stakeholders (HCPs in other jurisdictions, other public health program systems, etc.) in these systems. This new level of collaboration will require a new level of transparency and trust among stakeholders and entities involved.

By adopting and using national standards for clinical data interchange and deploying certified EHRS, RHIE development projects may be able to address these “siloed” systems. The regional projects will also affect the development and implementation of a NHIN. By testing and piloting new approaches to performing clinical data interchange, these projects will inform the national process of the very type of standards that need to be adopted for implementation; in turn, the national adoption of standards will assist these regional initiatives to move forward with the local implementation of the NHIN.

What issues might arise? The main issue now is the awareness about NHIN. As we wrote in *section Q8*, first and foremost, communities have to be informed about NHIN development process. A strong educational awareness campaign, *i.e.*, National Education Program on EHRS and NHIN and the creation of Regional Resource Centers, with the support of the federal government, should be considered.

As of right now many local entities – the future backbone of NHIN - are still not fully aware about the NHIN. Moreover, efforts are needed to inform communities about differences between NHII and NHIN.

Standards are the foundation of NHIN. In parallel with the educational campaign on general awareness about NHIN, efforts are needed to educate both clinical and public health communities about the need of standards and standardization. Users have to be present at the standard development process with SDOs to assure successful implementation of standards. PHDSC views its role in bringing public health users' (practitioners and researchers) perspectives to the processes of developing terminology and messaging standards via participating in the HL7 Technical Committees on EHR, patient safety, Public Health and Emergency Response special interest group (SIG); ASC X12N, NUBC and NUCC.

To facilitate implementation of terminology, messaging, algorithms standards, they should be available at no or low cost with user-friendly implementation guidelines and training courses for personnel. Government funds used to develop applications need to require open source IT tools.

Q13. *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?*

PHDSC will not answer this question.

STANDARDS AND POLICIES TO ACHIEVE INTEROPERABILITY

Q14. *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?*

The entities to develop and diffuse interoperability standards can be divided in three groups:

1. Developers

- Standards Development Organizations (SDOs)
- Data Content Committees (DCCs)

2. Validators

- Professional organization and consortia that represent users interests in the standards development and implementation process

3. Facilitators

- National Committees and Initiatives

Developers are entities that develop various standards as follows:

- Clinical data content and terminology standards, *e.g.*, SNOMED, NCPDP, DICOM, LOINC, ACS X12, NUCC, NUBC;
- Messaging standard, *e.g.*, HL7;
- Procedure standards, *e.g.*, C-DISC – Clinical Trial - Data Interoperability Standard Consortium; and Public Health Informatics Institute’s specification standard for Laboratory Information Management Systems (LIMS).

In addition, the development of data processing standards algorithms is a critical component for community health assessment and evaluation of the effectiveness of clinical care and public health interventions. There is no entity today that develops algorithms standards, even this might be done in the future under HL7. For example, the HL7 Public Health and Emergency Response SIG formed with PHDSC participation can work on the algorithms standard development.

From population health perspectives, in addition to health care standards, local HINs/HIEs should utilize geographical standards to allow data integration and aggregation for community health assessments and services delivery. Zipcode or Census tract information may not be sufficient for these tasks, so resolution to the parcel level or geographical coordinates level is required. This in turn will help integrate housing data systems, law enforcement 911 systems, MTA driver license services in which address data systems are already being developed in many communities. For example, the technologies associated with implanted pacemakers and other health monitors as well as device miniaturization and wireless networks are already being merged with Global Positioning Systems, with health monitoring vendors linking with national, state, and local 911 systems to provide rapid, automated tracking and emergency responses to participating individuals who may experience a health emergency. Furthermore, local HIN developments should use adopted CHI standards and should be flexible enough to be modified for anticipated and unanticipated future advances in information technology.

Validators are entities that provide input in the development and validation of developed standards and develop policy recommendations for standard implementation and diffusion. These organizations usually serve certain stakeholder groups and have been active recently via the EHRS standard development process. They include the following:

- Clinical community, *e.g.* EHR Collaborative that includes two PHDSC members – eHealth Initiative and AHIMA;
- Public health community, *e.g.*, PHDSC (EHRS standards); NAHDO, PHDSC member, (hospital discharge data standards); Association of Public Health Laboratories (APHL), PHDSC member (public health LIMS); Environmental Council of States (ECOS) (environmental data)

Facilitators are entities that enable implementation of standards via policy development. These are NCVHS, ONCHIT and its Federal Health Architecture (FHA) Committee and CHI.

To assure the development and diffusion of interoperability standards and policies these three types of entities should work in coordinated fashion. ***Funding is needed to support validators that represent interests of users in the standards development and validation process.***

Q15. *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.*

It is our opinion that the national health information privacy and security framework established under the final HIPAA Privacy and Security Rules provide the legal and policy bases for the establishment of the NHIN. While there might be a need to adjust certain elements of the Privacy and Security Rules, as more and more experience is gained with the exchange of administrative and clinical information, and new technology is developed that pose new, unforeseen privacy and security challenges to the exchange of health information, the current comprehensive set of national standards should cover the initial and ongoing development of the NHIN.

Regional health information organizations should be supported to establish mechanisms that help monitor the implementation of the NHIN and its impact on privacy and security. Privacy Officers and Security Officers Advisory Boards should be considered to assist ONCHIT and the NHIN identify new issues and recommend mechanisms to address them.

Q16. *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?*

Validators should represent interest of communities they serve at the SDO to provide input in the standard development process.

PHDSC is actively involved in the EHRS standard development process by representing public health community at various SDOs as described in *section Q1-Enablers* and *Q12* above.

Q17. *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?*

A System Specification Standard Document that describes management and business rules for each HIN/HIE should be required under NHIN. The Association of Public Health Laboratories and the Public Health Informatics Institute's specifications for common requirements for Laboratory Information Management Systems can be considered as a prototype of such a document.²⁸ The outline of such document is provided in the Attachment 1.

Q18. *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 continue to play an active role as participant and facilitator, as described in *section Q14* above, to enable policy development for the implementation of standards. The federal government is an active partner in the current national standards development process for health information transactions. This could be enhanced with the active involvement of existing interagency entities such as NCVHS and ONCHIT with its FHA committee and CHI initiative and new groups established by ONCHIT. Their work will guide the development of financial and/or regulatory incentives and regulation to develop NHIN. These committees should work with validators and representatives from local and state government to assure that interests and needs of all stakeholders are addressed.

The federal government should refrain from taking a role of a standard development organization.

Q19. *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*

²⁸ "Requirements for Public Health Laboratory Information Management Systems: A Collaboration of State Public Health Laboratories, the Association of Public Health Laboratories and the Public Health Informatics Institute", September 2003 URL: <http://www.aphl.org/docs/RPHLIMS.file.pdf>

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 are required to drive the development of a marketplace for interoperable health information. We will be discussing this issues with our members - vendors in the future.

Q20. *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?*

PHDSC will not answer this question.

Q21. *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?*

This question was answered in *section Q3*.

Q22. *How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g., data privacy and security, antitrust constraints and tax issues)?*

This question was answered in *section Q3*.

Q23. *Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.*

Part of this question was responded under *sections Q3 and 4*.

Additionally, we believe RHIEs/RHIOs are principal elements for a potential technical architecture for a NHIN. Some of the more critical elements of a potential technical architecture for a RHIE are presented on Fig. 4. It is based on the PHDSC's EHR-PH system prototype (Fig. 2). This model (1) represents a distributed, federated, decentralized approach, which can, however, be easily converted into monolithic architecture; (2) combines data from all relevant heterogeneous sources: clinical, public health, geographic, environmental, ecological, housing, etc.; (3) addresses access control and privacy issues and enforces non-repudiation; (4) is not vendor-specific, but instead, it utilizes more general approach, based on simple object access protocol (SOAP) and web services description language (WSDL); (5) uses text-messages as oppose to hardcoded low-level Application Programming Interface (API); and (6) offers framework for true semantic interoperability of local HIT systems, whatever they are.

Q24. *How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?*

Continuing evaluation of how NHIN responds to the original goals for which it was designed should be institutionalized. Usability studies should be conducted regularly to assure that NHIN supports users' workflow, so revisions to the design will be made if needed.

We believe that establishing realistic, achievable and measurable goals is a key aspect of the planning and development of the NHIN. An excellent example of this approach is the one used by public health agencies nationally, to measure progress towards established "Healthy People" objectives (Healthy People 2000; Healthy People 2010).

RHIEs/RHIOs should be encouraged and supported by the federal government and other means to establish their local measurable goals and objectives, and should be expected to report periodically their progress.

The need to invest in assessing and evaluating progress (data collection; monitoring and evaluation) should also be kept in mind.

Measurable outcomes should include all levels, components and aspects of the NHIN, from the extent to which the telecommunications network infrastructure is being established/used, to the adoption of standards, the adoption and use of EHR by various types of providers, the use of privacy and security standards, and the adoption and use of knowledge-base clinical support systems and medical decision making applications.

All measurable outcomes should also be directly connected to the ultimate consumer-centric goal of NHIN: improving the quality and efficiency of the health care services and enhancing population health.

ATTACHMENT 1. Example of Steps for a Local HIN Development

- I. Define the purpose for which the HIN will be created in this jurisdiction.
- II. Conduct an inventory of all stakeholders to be included in the HIN for this jurisdiction. For example, the inventory for the local HIN will include all HCPs that serve this jurisdiction, all programs of the local health department that require data reporting from HCPs; all programs at the state health department that require reporting directly from HCP and/or through local health department's programs; all pharmacies that operate within this jurisdiction; all payor groups that serve this jurisdiction; all other stakeholders that can have potential to contribute/benefit from health-related information, such as, schools, fire departments, housing department, libraries, private sector, e.g., restaurants).
- III. Conduct cost-benefit analysis documenting resources (human, technical and financial) needed.
- IV. Develop coalition necessary to pursue the HIN idea; engage coalition actively and continuously.
- V. Develop governance structure
- VI. Map dataflow and data exchange across identified stakeholders.
- VII. Describe workflow that supports dataflow and data exchange.
- VIII. Describe technical capacities of each stakeholder.
- IX. Set up a timeline for integrating stakeholders into HIN.
- X. Develop an evaluation plan for HIN implementation process.
- XI. Design HIN model.
- XII. Develop HIN prototype and conduct pilot testing.
- XIII. Finalize HIN development.
- XIV. Develop user documentation on each step (I-IX).
- XV. Finalize HIN development and documentation.
- XVI. Train personnel to use HIN system.
- XVII. Deploy NHIN.
- XVIII. Repeat steps I-XVII for the regional and state HINs.
- XIX. Validate this approach across several local jurisdictions.
- XX. Develop specification requirements for local/regional/state HINs.
- XXI. Begin HINs implementation across the nation.

These activities will guide the development of national NHIN model.