Welcome to the Health IT Certification Course on Nationwide Health Information Network (NHIN), which is the last course in the Certified Professional in Health Information Exchange (CPHIE) track. Other courses in this track have covered:

- V – HIE Goals and Governance
- VI - HIE Architecture
- VII - Data Stewardship
- VIII - Personal Health Records
- IX - Telehealth and Home Monitoring
Introducing . . .

Margret Amatayakul, MBA, CPEHR, CPHIT, RHIA, CHPS, FHIMSS
President, Margret\A Consulting, LLC; Adjunct Faculty, College of St. Scholastica; formerly Executive Director CPRI, Associate Executive Director AHIMA; Associate Professor, University of Illinois. Schaumburg, IL

Jeffrey S. Blair, MBA
Director of Health Informatics, Lovelace Clinic Foundation, recipient of HHS Award Contract for Trial Implementations of the NHIN, formerly Vice President, Medical Records Institute; 30 years with IBM. Member, National Committee on Vital and Health Statistics, Albuquerque, NM

John D. Halamka, MS, MD
Chief Information Officer, CareGroup Health System and Harvard Clinical Research Institute, Chief Information Officer and Associate Dean for Educational Technology, Harvard Medical School, Chair, New England Health Electronic Data Interchange Network, Chair, Healthcare Information Technology Standards Panel, Boston, MA

Thomas E. Jeffry, JD
Partner, eHealth, HIPAA, HIT
Davis Wright Tremaine LLP
Los Angeles, CA
Objectives

• Upon completion of this course, participants should be able to:
  – Describe the concept of the nationwide health information network (NHIN)
  – Identify federal initiatives in support of the development of the NHIN
  – Track the progress of key federal initiatives for the NHIN
  – Compare and contrast HIE initiatives with NHIN directions

The objectives for the CPHIE program are to enable participants to become knowledgeable in all aspects of health information exchange (HIE), whether this is a new opportunity or an existing activity that could use a boost in some way. No discussion of HIE would be complete without including the conceptualization of a nationwide health information network (NHIN). The objectives of this course, then, are to describe the concept of NHIN as it stands at this point in time, identify federal initiatives that are helping to design the NHIN and what progress has been made, and to compare and contrast HIE initiatives with NHIN directions - which may help provide HIEs with direction or ideas for enhancement.
Topics

Part 1. NHIN Concepts
Part 2. Federal NHIN Initiatives
Part 3. Results of Federal Initiatives
Part 4. NHIN Case Study

Topics covered in this Course include information that is currently available – recognizing that much is “in the works.” Providing a general landscape, web site information, and information on other resources may help you keep up-to-date as you proceed to monitor NHIN activities in the future.
Nationwide Health Information Network

Part 1. NHIN Concepts

Just to ensure the proper perspective, the NHIN is still very much in the conceptual stage. Some liken the NHIN to the Internet, but for secure health care information exchange. Both may be described as a network of networks, both are grounded in the private sector but with significant federal government activity early on, and neither are a repository of data. However, differences between the NHIN and the Internet are striking and must be addressed to ensure the NHIN’s success. In fact, the federal government appears to make a special point of NOT drawing comparisons between the NHIN and the Internet because of the significant differences. One significant difference is the speed and sponsorship of the development life cycle – with the Internet taking at least 40 years to develop and heavily influenced by federal initiatives, such as ARPANET; whereas the NHIN is desired to take 10 years with a strong desire to ensure it is a largely private-sector driven activity. The Internet Society marks 1945 as the first step toward the Internet when the proto-hypertext computer, Memex, was conceived. Thereafter, a forty-year series of milestones began with ARPANET (Advanced Research Projects Agency Network) launched in 1969 by the U.S. Department of Defense which was the world’s first operational packet switching network, and the predecessor of the global Internet. The World Wide Web was created in 1989 and the age of e-Commerce is pegged at beginning in 1995. Continued development activities are occurring, such as Internet2 advancing high-performance network computing. In comparison, electronic health records may go back to as early as the mid-1960s, but the first concept of a national health information infrastructure (NHII) was not addressed formally until 2001, and interconnecting health care was only announced in 2004 as a goal for the U.S. to achieve in 2014.

The most important difference might be best characterized, with no disrespect intended, as the difference between a top secret activity and the wild, wild west. There is a very high degree of concern about assuring privacy and confidentiality in the NHIN; while the Internet enables virtually any and all information to be exchanged without constraints. The ability, then, to execute the concept of a NHIN with appropriate privacy and security controls must be kept in mind as its development is promoted.
Part 1 describes premises upon which the concept of the NHIN is described today, provides definition of key terms, and identifies who is expected to participate in a NHIN and in what manner.
NHIN Premises

- A “network of networks”
  - to securely connect consumers, providers, and others who have or use health-related data
- Shared architecture (standards, services, and requirements), processes, and procedures
  - No national data store or centralized systems at the national level
  - No national patient identifier
- Connect:
  - Providers (EHRs)
  - Consumers (PHRs)
- Interconnect:
  - State, regional, and non-geographic health information exchanges
  - Networks oriented to specific functions
- Provide a secure foundation for growth & innovation

As noted, the federal government describes the NHIN as a “network of networks,” largely connecting HIE organizations. There will be no central database housing all health data and no national patient identifier. However, a variety of services will be provided through a shared and standards-driven architecture. Some services may exist throughout the NHIN, while others may be specific to a given HIE organization or other specific-function network.
NHIN Goals and Objectives

• Enable health information to follow the consumer
• Be available for clinical decision making,
• Support appropriate use of healthcare information beyond direct patient care so as to improve health
• Develop capabilities for standards-based, secure data exchange nationally
• Improve coordination of care information among hospitals, laboratories, physicians offices, pharmacies, and other providers
• Ensure appropriate information is available at time and place of care
• Ensure that consumers’ health information is secure and confidential
• Give consumers new capabilities for managing and controlling their personal health records as well as providing access to their health information from EHRs and other sources
• Reduce risks from medical errors and support delivery of appropriate, evidence-based medical care
• Lower healthcare costs resulting from inefficiencies, medical errors, and incomplete patient information
• Promote a more effective marketplace, greater competition, and increased choice through accessibility to accurate information on healthcare costs, quality, and outcomes

The Nationwide Health Information Network (NHIN) is intended to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. The NHIN is expected to enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care so as to improve health. The NHIN seeks to achieve these goals by a series of specific objectives.
Terminology

John W. Loonsk, MD, Director for Interoperability and Standards, Office of the National Coordinator for Health Information Technology, June 21, 2007

• **Health information exchange (HIE)**
  – An entity that enables the movement of health-related data among entities within a state, a region, or a non-jurisdictional participant group

• **NHIN HIE (NHIE)**
  – An HIE that implements the NHIN architecture, processes, and procedures and participates in the NHIN Cooperative

• **Health Information Service Provider (HSP)**
  – A company or other organization that supports one or more HIEs by providing them with operational and technical health exchange services

The Office of the National Coordinator for Health Information Technology (ONC) uses the terms health information exchange to broadly describe an organization that enables movement of health data; NHIE to refer to an HIE that implements the NHIN architecture, processes, and procedures – yet to be defined; and HSP to identify a company or other organization that supports HIE technology. An HSP enables the connection of NHIEs to form the NHIN.
Much as with HIEs themselves, the NHIN is anticipated to be used by care delivery organizations, consumer organizations, HIEs, and many specialized participants. There will be connections between EHRs and HIEs, PHRs and HIEs, as well as portals for those without EHRs or PHRs.

On June 11, HHS announced the selection of 12 communities for the Medicare EHR Incentive Project, that would further promote the infrastructure needed to support the NHIN. The demonstration is designed to show that widespread adoption and use of interoperable EHRs will reduce medical errors and improve the quality of care for an estimated 3.6 million consumers. Over a five-year period, the project will provide financial incentives to as many as 1,200 physician practices that use CCHIT-certified EHRs to perform specific minimum core functionalities that can positively impact patient care processes. The functionalities include clinical documentation, ordering and recording lab tests, and recording prescriptions. The core incentive payment will be based on performance on quality measures. Additional bonus payments will be available, based on a standardized survey measuring the number of EHR functionalities a physician practice has incorporated. To further amplify the effect of this demonstration project, CMS is encouraging private and public payers to offer similar financial incentives consistent with applicable law.

In addition, the huge surge of interest by employers and payers, and the involvement of computer and Internet giants through their PHR offerings, are facilitating readiness for consumer engagement in the NHIN.
Nationwide Health Information Network

Part 2. Federal NHIN Initiatives

Consistent with the U.S. national HIT agenda, the federal government is sponsoring a number of initiatives aimed at determining the best design for the NHIN. These initiatives are largely guided by the Department of Health and Human Services (HHS) through several of its agencies and funding to organizations engaged in building and testing HIT systems, standards, and projects. HHS agencies involved in the initiatives include the American Health Information Community (AHIC), Office of the National Coordinator for Health Information Technology (ONC), Federal Health Architecture (FHA), Agency for Healthcare Research and Quality (AHRQ), Health Resources and Services Administration (HRSA), Indian Health Services (HIS), National Institutes of Health (NIH), and Centers for Medicaid and Medicare Services (CMS). In addition, the Department of Defense (DoD) and Department of Veterans Affairs are have well-advanced EHRs and are actively engaged in a project to develop a Joint Patient Electronic Health Record (JPEHR) that would enable complete transferability between the Departments’ systems. The DoD’s EHR, AHLTA, and the Department of Veterans Affairs, Veterans Health Administration (VHA) EHR, the Veterans Health Information Systems and Technology Architecture (VistA) and My HealtheVet, the gateway to veteran health benefits and services, are among the most advanced systems in the world.
Content Part 2.

- Role of Federal Government
- American Health Information Community (AHIC)
- Healthcare Information Technology Standards Panel (HITSP)
- Health Information Security and Confidentiality Collaboration (HISPC)
- Certification Commission for Health Information Technology
- NHIN Architecture Prototype Project
- NHIN Trial Implementations
- ONC-Coordinated Federal HIT Strategic Plan

Although many of the HIE activities described throughout the prior five courses in the CPHIE track also lay the groundwork for the NHIN, there are several specific projects focused on broadening the scope to a network of networks. These are enumerated in this Part of the Course, and their results described in Part 3.
Role of Federal Government

- From the National HIT Agenda:
  - Foster widely available services that facilitate the accurate, appropriate, timely, and secure exchange of health information
  - Information that follows the consumer and supports clinical decision making

- Federal NHIN initiatives:
  - AHIC Use Cases
  - HITSP, HISPC, CCHIT
  - NHIN Architecture Prototype Project
  - NHIN Trial Implementations
  - NHIN-Connect Gateway
  - NCVHS Functional Requirements, Privacy, Data Stewardship

The federal government has a very active role in developing an understanding of what the NHIN might look like and how it should be structured. It is unclear if the federal government anticipates that the NHIN will evolve, on its own, out of these activities, much as the Internet evolved over time; or if it is anticipated that one day someone will push a switch and, at least a mini-NHIN or first exchange will signal that the NHIN has been born. Although the former would seem to be more likely, the two most focused projects funded by the federal government – the architecture project and the trial implementations – appear to suggest that there is at least some intent to impose a more controlled roll out. Of course, only time will tell!

In addition to a formal statement in the national HIT agenda and the two focused projects for prototyping and testing, the federal government has also developed specific use cases for the NHIN; sponsored, in part, attention to standards recognition, collaboration of states in addressing security and privacy harmonization; and certification of HIT that achieves, at least at a rudimentary level, interoperability. Twenty federal agencies that generate and/or use health information and form the Federal Health Architecture are developing a HIE network that may be conceived as a mini-NHIN. The latest addition to the joint effort is the Social Security Administration that seeks to obtain between 15 and 20 million medical records each year in support of its disability determinations. The federal government has also sought the advice of its advisory bodies to take the pulse of the public on key issues.
The American Health Information Community has been active on a number of fronts to accelerate the development and adoption of HIT in general, and specifically use cases for the NHIN. Plans are underway to establish a successor to the AHIC which would be a public-private partnership based in the private sector by Fall 2008. A team comprised of the LMI Government Consulting and the Engelberg Center for Health Care Reform at the Brookings Institution, working under a cooperative agreement with HHS, is convening stakeholders to transition the nationwide focal point for health information interoperability from a government advisory group to a public-private organization. AHIC 2.0, as this has been dubbed, might be viewed as something like the Internet Society, although, once again, the federal government has avoided references to the Internet for fear of concerns surrounding privacy and security.
Healthcare Information Technology Standards Panel (HITSP)

- Multi-stakeholder coordinating body
- Provides process to identify, select, and harmonize standards
- Functions as a partnership of public and private sectors
- Operates with a neutral and inclusive governance model administered by American National Standards Institute (ANSI)
- Receives use cases and harmonization requests defining perspectives (scenarios), business actors, and functional/interoperability requirements as events and actions

- Once an interoperability specification is released, implementation testing occurs. This does not involve determination of a product’s “conformance.” HITSP is working with NIST, ONC, and CCHIT to define an overall integrated interoperability testing strategy

HITSP has been referenced through this entire program on CPHIE, with the process for creating interoperability specifications from AHIC use cases explored in depth in CPHIE Course VI HIE Architectures. This multi-stakeholder coordinating body, set in the private sector, while working with the National Institute for Standards and Technology (NIST) within the Department of Commerce, ONC, and CCHIT, holds the key to achieving health information exchange from a technical point of view.
Health Information Security and Privacy Collaboration (HISPC)

HISPC, a partnership consisting of a multi-disciplinary team of experts and the National Governor's Association (NGA) worked with approximately 40 states to assess and develop plans to address variations in organization-level business policies and state laws that affect privacy and security practices which may pose challenges to interoperable health information exchange.

• Other Initiatives
  – State Alliance for E-Health
  – Privacy and Security Solutions contract
  – Best Practices for State-level HIE Initiatives
  – Medical Identity Theft Assessment

As emphasized throughout, the assurance of privacy in general, and as it relates to interoperability, is not only critical to the success of the NHIN, but, if not attended to, could derail efforts to achieve the goals set forth for the NHIN. Regulations promulgated pursuant to HIPAA established baseline health care privacy requirements for protected health information (PHI) and established security requirements for ePHI. Many states have adopted policies that go beyond HIPAA. The manner in which hospitals, physicians and other health care organizations implement required security and privacy policies varies and is tailored to meet their individual organizations’ needs. These variations in policies present challenges for widespread electronic health information exchange. As such, the federal government is hoping to work through state governors and other initiatives to address greater uniformity. These initiatives include:

• State Alliance for E-Health that would form a collaborative body of Governors and Governor-named high-level executives of states and territories that enables states to increase the efficiency and effectiveness of the HIT initiatives they develop and to map ways to resolve state-level HIT issues that affect multiple states and pose challenges to interoperable electronic HIE.
• Privacy and Security Solutions is co-managed by ONC and AHRQ that would bring states and territories together to address privacy and security challenges posed by HIE in their states and to propose Privacy and Security Solutions and develop implementation plans for identified variations in organization-level business policies and state laws that affect HIE.
• Best Practices for State-level HIE Initiatives is a contract awarded by ONC to the Foundation of Research and Education (FORE) of the American Health Information Management Association (AHIMA) to gather information from existing state-level HIEs and define, through a consensus-based process, best practices that can be disseminated across a broad spectrum of health care and governmental organizations.
• Medical Identity Theft Assessment is a contract let by ONC to Booz Allen Hamilton to assess and evaluate the scope of the medical identity theft problem in the U.S. and to set forth possible next steps for the federal government and other stakeholders in order to work toward prevention, detection, and remediation of medical identity theft.
The CCHIT is another private-sector initiative actively working on assuring that the products to be used within the NHIN are, indeed, interoperable. Starting with certification of ambulatory EHRs in 2006 and inpatient EHRs in 2007, CCHIT is rapidly expanding its activities to support HIEs and specialty needs in a number of ways. Many pay-for-performance and other incentive programs for EHR acquisition require that the product acquired be CCHIT certified.
NHIN Architecture Prototype Project

• Four awardees to design and demonstrate a standards-based network prototype,
  – that will use existing resources to achieve interoperability among healthcare applications, particularly EHRs
• Demonstrate solution in three marketplaces/communities

The first focused project on the NHIN itself, was the architecture prototype project. An RFI was released on November 15, 2004, followed by an RFP on June 6, 2005. Awardees were consortia, led by a systems integrator that coordinated efforts with healthcare market organizations, including HIEs, providers, and technology partners and vendors. The awardees were announced November 11, 2005. The goal of the project was to design and demonstrate a standards-based network prototype (rather than a functional network). Each of the four awardees were to develop and evaluate prototypes of a NHIN architecture that maximized use of existing resources to achieve interoperability among health care applications, particularly EHRs. They were required to demonstrate their solution in three marketplaces, or communities, and via three of the AHIC use cases (EHR-Lab, Consumer Empowerment, and Biosurveillance). A summary of the contracts was developed by Gartner, Inc. and released on May 31, 2007, available at www.hhs.gov/healthit/healthnetwork/resources/summary_report_on_nhin Prototype_architectures.pdf
NHIN Trial Implementations

- State, regional, and non-geographic HIEs
- Focus on service interfaces:
  - Between health information service providers
  - Linking health information service providers and provider organizations/systems
  - With specialty networks and systems
  - With government health systems
- Products of 2006 guide 2007 trial implementations:
  - Seven AHIC use cases
  - HITSP standards
  - NHIN functional requirements (with NCVHS)
  - Privacy and security work (CPS, NCVHS)
  - Public input from forums
  - Prototype architectures
  - Core services and capabilities for an NHIE
  - Report on service interfaces

Contracts for trial implementations followed the finalization of the architecture prototype project. These contracts are intended to create a secure foundation for basic health information exchange between select HIEs upon which more complex functions will be possible over time. This work will advance the nation toward the goal of most Americans having access to secure electronic health records by 2014, by creating a secure foundation for health information exchange that can follow Americans throughout their lives.

The trial implementation contractors will participate in the NHIN Cooperative, which is designed to test and demonstrate the exchange of private and secure health information among providers, patients and other health care stakeholders. HHS’ Centers for Disease Control and Prevention is also expected to announce contracts that will complement these efforts to further develop the NHIN. This joint work will ensure that health information exchanges using the NHIN infrastructure can support the community-based activities of public health agencies.

Interim results of the trial implementations will be shared through public forums and other public demonstrations of real-time information exchange at the end of the first contract year (September 2008). Once created, the NHIN health information exchanges’ specifications and related testing materials will be placed in the public domain to facilitate widespread participation in the developing the NHIN.
The nine initial awards for trial implementations, totaling $22.5 million, were made to organizations representing broad-based state and regional HIEs. In addition, cooperative agreements totaling approximately $600,000 have been made to six organizations to expand participation in testing and demonstration in the trial implementations. Awardees of the cooperative agreements will demonstrate the “core” services to support four principal outcomes:

- Patient lookup and information retrieval
- Secure information routing and delivery (including, but not limited to a defined summary patient record)
- Provision of data for population uses
- Consumer managed access to appropriate information
On April 27, 2004, President Bush issued Executive Order (EO) 13335 “to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care.” This established the position of a National Coordinator for Health Information Technology within the Office of the Secretary of Health and Human Services. The National Coordinator was charged with coordinating federal health IT policies and programs and relevant executive branch agency outreach and consultation with public and private entities. As such, the National Coordinator provides the day-to-day leadership necessary for the development of a health IT infrastructure for the nation.

The EO required the National Coordinator to deliver a report on progress toward a strategic plan within 90 days of appointment. On July 21, 2004, the nation’s first National Coordinator, David J. Brailer, MD, PhD, and then Secretary of HHS Tommy G. Thompson, issued such a report, entitled, “The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care.” This Framework for Strategic Action outlined 12 strategies focused on four goals: to inform clinical practice, interconnect clinicians, personalize care, and improve population health.

The executive order also charged the National Coordinator with developing, maintaining, and directing “... the implementation of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures.” The Office of the National Coordinator (ONC), now under the direction of Robert M. Kolodner, MD, and reporting to Secretary of HHS Michael O. Leavitt, has worked across the federal government to develop the ONC-coordinated Federal Health IT Strategic Plan, which identifies the federal activities necessary to achieve the nationwide implementation of this technology infrastructure throughout both the public and private sectors. The timeframe of the Plan is 2008-2012. The Plan has two goals, Patient-focused Health Care and Population Health, with four objectives under each goal. The themes of privacy and security, interoperability, IT adoption, and collaborative governance recur across the goals, but they apply in different ways to health care and population health.
Obviously, the federal government is moving rapidly to achieve a standards-based network for health information exchange that will improve the health and care of individuals and communities and continue to modernize health care delivery. Part 3 looks at the results of the federal initiatives to date – recognizing that many of the initiatives are just getting underway.
Content Part 3.

• AHIC Use Cases
• HITSP Standards Recognition
• HISPC Observations and Results
• CCHIT Progress and Plans
• NHIN Prototype: Core Services and Capabilities
• NHIN Trial Implementation Activities and Challenges
• NCVHS: Functional Requirements, Privacy and Confidentiality, Data Stewardship

Part 3, then, looks at the use cases developed by AHIC, recognition for HITSP interoperability specifications, HISPC accomplishments, CCHIT progress and plans for the future, the core services and capabilities generated by the NHIN architecture prototype project, the NHIN trial implementation activities and challenges, and recommendations of the National Committee on Vital and Health Statistics (NCVHS) relating to the NHIN.
AHIC Use Cases

• NHIN Prototype Architectures addressed AHIC priority areas:
  – EHR-Laboratory Result Reporting
  – Consumer Empowerment-Registration and Medication History
  – Biosurveillance – Connecting Clinical Care to Public Health

• NHIN Trial Implementations to address new AHIC priority areas:
  – Emergency Responder-EHR
  – Consumer Empowerment-Consumer Access to Clinical Information
  – Medication Management
  – Quality
  – Remote Monitoring
  – Remote Consultation
  – Personalized Healthcare
  – Referrals and Transfer of Care
  – Public Health Case Reporting
  – Response Management
  – Patient Authorization to Release Electronic Records to Social Security Administration (for Disability Benefits Determination)

The first three of the AHIC use cases were incorporated into the NHIN prototype architecture project. EHR-Lab and Consumer Empowerment use cases/HITSP Interoperability Specifications were studied in depth in CPHIE Courses VI and VIII respectively. The Biosurveillance Use Case relates to connecting clinical care to public health – an important goal for the NHIN. The NHIN Trial Implementations must address the EHR-Lab, Consumer Empowerment-Registration and Medication History, and Biosurveillance uses cases, as well as Emergency Responder-EHR, Consumer Empowerment-Consumer Access to Clinical Information, Medication Management, and Quality use cases. An eighth use case was added relating to Patient Authorization to Release Electronic Records to Social Security Administration. Other AHIC use cases include remote monitoring and remote consultation – reflecting growing interest in telehealth and rural health issues; personalized healthcare addressing integration of genomic test information into personal e-health records; referrals and transfer of care; public health case reporting, and response management.
In order to promote federally led efforts to implement more transparent and high-quality health care, Executive Order (EO) 13410 was issued by President Bush on August 22, 2006 (http://www.whitehouse.gov/news/releases/2006/08/20060822-2.html). It was the purpose of this order to ensure that health care programs administered or sponsored by the Federal Government promote quality and efficient delivery of health care through the use of health information technology, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers. It was the further purpose of this order to make relevant information available to these beneficiaries, enrollees, and providers in a readily useable manner and in collaboration with similar initiatives in the private sector and non-Federal public sector. Consistent with the purpose of improving the quality and efficiency of health care, the actions and steps taken by Federal Government agencies should not incur additional costs for the Federal Government. As such, the EO requires that as an Federal agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it must utilize, where available, HIT systems and products that meet recognized interoperability standards. Each agency shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades HIT systems, it shall utilize, where available, HIT systems and products that meet recognized interoperability standards.

For federal agencies to be required to conform with this EO, there must be “recognized” interoperability standards. In order to recognize such standards, however, they needed to be created or made ready for recognition; and this process was tasked to the Health Information Technology Standards Panel (HITSP). On January 23, 2008, the Secretary of HHS officially provided recognition of 30 HITSP “Interoperability Specifications” for use by federal agencies, including for EHR-lab results reporting, biosurveillance, and consumer empowerment (i.e., personal health records).
Methods to Achieve Interoperability

- Begin with consistent descriptions of network services (use cases) developed by AHIC
- Utilize standards selected by HITSP to enable the use cases to converge toward interoperability
- Constrain/limit the available options within the standards to achieve interoperability
- Local testing of interoperability of use cases
- Nationwide testing of interoperability of use cases
- Report areas where standards still need to be enhanced or gaps need to be addressed

HITSP has taken the lead to select standards that would enable the AHIC use cases to converge toward interoperability. This task is not without its challenges, including identifying gaps, overlaps, and testing. Further, HITSP Technical leadership draws attention to the need to draw a clear relationship between the HITSP work products and NHIN specifications.
HISPC Observations

• Relatively small number of states had a defined entity or program recognized as the “state HIE effort”
• No state “anchor” or multi-stakeholder body responsible for addressing health information privacy and security
• Underlying state infrastructure for health IT and HIE was lacking
• Few states had started statewide HIE planning efforts
• Organization and governance for a state HIE effort were evolving
• Key roles of state government as a participant, convener, and coordinator were emerging
• Ensuring consumer participation in the process was a major challenge.
• Financial models for initial development and sustainable operations developed

Research Triangle Institute International (RTI) was awarded a contract from HHS to work with ONC and the Agency for Healthcare Research and Quality (AHRQ) to implement a national collaborative effort to address privacy and security policy questions affecting interoperable health information exchange. A number of reports have been produced under this contract, but the Impact Analysis report delivered to ONC and AHRQ on December 20, 2007 provided an analysis of the many ways that the Privacy and Security Solutions project has impacted the landscape for HIE both within and across participating states.

To assess and analyze the impacts of this project and related activities, the states’ status at the start of the project was examined. The landscape before the project began was characterized as states being at all different stages of HIE development. Despite there being over 100 HIE projects in at least 35 states, relatively few of these projects were state-initiated or directed. That is, there was no body that had taken the formal role of facilitating, coordinating, convening, or operating HIE as a state initiative. Other important factors were also evident, including lack of a state infrastructure for HIT or HIE and little HIE planning efforts. At best, organization and governance and key roles for state government were only emerging and evolving. Consumer participation and financial models for sustainability were major challenges.
HISPC Results

• More than 300 state legislative initiatives related to health IT and health information exchange introduced
• A number of executive orders have identified, assigned, or created state bodies to guide development of state HIE efforts
• State initiatives covered 5 major areas:
  – increasing state funding to support the adoption of HIT (such as EHRs by state providers)
  – creating and supporting local and regional HIEs and providing core funding for implementation of a statewide HIE
  – establishing governance structures to guide and coordinate the planning and development of a statewide HIE
  – addressing privacy and security issues, such as consent approaches, and creating a state privacy and security board
  – supporting the participation of public health and Medicaid in state HIE pilot projects and initiatives
• State legislation
  – Attempt to update and align statutes with the electronic health information environment and address legal barriers to electronic exchange
  – HIEs have been able to reduce privacy and security variations in their application among organizations who engage in HIE

As the HISPC project was underway, however, there was considerable evolution of the state-HIE landscape. To date, the project has had the greatest impact on legislation, executive orders, leadership and governance, stakeholder education and knowledge, and development and sustainability of HIT/HIE efforts in the states.
The third of the three private sector initiatives supported by the federal government to advance HIT, EHR, and HIE is the Certification Commission for Health Information Technology (CCHIT). The graph depicted on this slide illustrates the current level of product certification for ambulatory EHRs, of which CCHIT estimates there are some 250 products, and inpatient EHRs, of which CCHIT estimates there are some 24 products. Approximately one-third of the ambulatory products were certified in 2006. Although product certification is good for three years, there are strong incentives for vendors to re-certify annually. First, the criteria are evolving, so that a product certified in 2006 only represents the criteria for 2006. In 2007, additional criteria, such as e-prescribing functionality, must be met to be certified. In addition, certification only within one year of an entity’s purchase of the product qualifies it for exception under the physician self-referral prohibition law (Stark) and safe harbor under the anti-kickback statutes. For the donation of interoperable EHR technology to physicians and other health care practitioners or entities to be exempted, HHS indicates that EHR software is “deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient].” CCHIT is an officially recognized certifying body. Because of the timing of the certification process, the number of products certified in a given CCHIT-year may vary with those identified as certified within the prior 12 months. For example, as of June 12, 2008, 34 products qualified, even though only 31 were 2007 certified. It should also be noted that 7 of these were pre-market, conditionally certified EHRs, which are new products that requires their operational use at a physician office site to be verified.
CCHIT Strategic Plans

- Evolution and broadening of stakeholder base
- Continued expansion to new domains
  - Child health
  - Behavioral healthcare
  - Emergency department
  - Long term care
  - Personal health records
  - Cardiovascular medicine
  - Other specialties
- Refinement within existing domains
- Increasing the efficiency of criteria development
- Greater sophistication in inspection and testing
  - Self-attestation (documentation review)
  - Jury observed
  - Technical testing
- Enhanced outreach and communication

Project Laika

- Pronounced “Like-ah,” means “little barker” in Russian, name of the dog launched into space November 1957
- Purpose is to create an EHR interoperability testing framework, under an open source licensing model, to be used for CCHIT certification testing, and be a testing resource for developers of EHR systems and health information networks
- CCHIT is collaborating with the MITRE Corporation, which operates Federally Funded Research and Development Centers and has an engineering team experienced in Open Source developments

As a result of the number of federal initiatives hinging on “interoperability” and CCHIT-certified products, CCHIT has greatly expanded its strategic plans. In addition to broadening its stakeholder base, it has expanded into new domains, refined existing domains, increased the efficiency of criteria development, and added greater sophistication in inspection and testing of products, especially in the area of interoperability testing through Project Laika – a collaborative activity with the MITRE Corporation that will create an EHR interoperability testing framework under an open source licensing model.
NHIN Prototype Projects

- Validated important basic principles that underlie current approach to NHIN
- Principles include:
  - The possibility of operating the NHIN as a network of networks without a central database or services
  - The criticality of common standards for developing the NHIN, particularly in the way that component exchanges interact with each other
  - Synergies and important capabilities can be achieved by supporting consumers and healthcare providers on the same infrastructure
  - Consumer controls can be implemented to manage how a consumer’s information is shared on the network
  - There can be benefits from an evolutionary approach that does not dictate wholesale replacement or modification of existing healthcare information systems

Of course, the two federal projects most focused on the NHIN are the architecture prototype project and trial implementations. As previously noted, a Summary of the NHIN Prototype Architecture Contracts was developed for ONC. This Summary observed that the four projects validated important basic principles that underlie the current approach to the NHIN. These relate to operating the NHIN as a network of networks, the criticality of common standards, the synergies and important capabilities that can be achieved by supporting consumer and providers on the same infrastructure, the ability to manage consumer controls, and that benefits can be achieved from an evolutionary approach that does not require a “rip and replace” strategy to update existing healthcare information systems.

Specifically, the prototype projects also demonstrated the advancement of:
- Capabilities to find and retrieve healthcare information inside of health information exchanges and between health information exchanges
- The delivery of new data to appropriate recipients
- Key consumer services such as control over who can access a personal health record, data searching, ability to choose not to use a network service
- User identity proofing, authentication and authorization
- Methods for match patients to their data without a national patient identifier
- Access control and other security protections
- Specialized network functions
- The feasibility of large-scale deployment
Additional First Year NHIN Accomplishments include Core Services and Capabilities

- **Data Services**
  - Secure data delivery
  - Data look-up, retrieval, and location registries
  - Notification of new or updated data
  - Subject-data matching
  - Summary patient record exchange
  - Data integrity and non-repudiation checking
  - Audit logging and error handling
  - Support for secondary use of clinical data
  - Data anonymization and re-identification, as well as HIPAA de-identification

- **Consumer Services**
  - Management of consumer-identified locations for PHRs
  - Location requests and data routing
  - Consumer-controlled providers of care and access permissions
  - Consumer choice not to participate
  - Consumer access to audit logging and disclosure information for PHR and HIE data
  - Routing of consumer requests for data corrections

- **User and Subject Identity Management Services**
  - User identity proofing and/or attestation of third-party identity proofing
  - User authentication and/or attestation of third-party authentication for those connected through that HIE
  - Subject and user identity arbitration with like identities from other HIEs
  - User credentialing
  - Support of an HIE-level, non-redundant methodology for managed identities

- **Management Services**
  - Management of available capabilities and services information for connected users and other HIEs
  - HIE system security including perimeter protection, system management and timely cross-HIE issue resolution
  - Temporary and permanent de-authorization of direct and third-party users when necessary
  - Emergency access capabilities to support appropriate individual and population emergency access needs

In addition to the prototype architectures, other significant accomplishments from the first year of the NHIN included:

- Public input from three NHIN public forums
- The initial set of initial NHIN functional requirements published by the National Committee on Vital and Health Statistics (NCVHS)
- Needed data and technical standards
- Security and business models
- Harmonized standards from the Health Information Technology Standards Panel (HITSP)
- Privacy and security recommendations from the NCVHS and the Confidentiality, Privacy, and Security working group of the American Health Information Community (AHIC)
- Core services and capabilities for Nationwide Health Information Network Health Information Exchanges (NHIE). These include data services, consumer services, user and subject identity management services, and management services in general – addressing connectivity, security, de-authorization of users when necessary, and emergency access.
Trial Implementation Activities

- Usual contract and project management
- Participation in NHIN “cooperative”
- Interface specifications for core services and use case capabilities
- Data use and reciprocal support agreements for trial implementations
- Service area-specific business plans
- Three NHIN public forums
- Testing material and scenarios
- Live “cooperative exchange testing”
- Demonstration of capabilities
- Evaluation of activities

Since the first deliverable for the NHIN trial implementations is not due until September 2008, we focus on the activities expected to be addressed in these projects. Usual contract and project management activities are expected, as is participation in a NHIN “cooperative.” In addition, interface specifications for core services and use case capabilities are a deliverable. Data use and support agreements are essential to HIE, and these will be developed also for the trial implementations in the NHIN. Each trial implementation also commits to a specific focal point, or service area – and will be expected to develop a business plan for such. A trial implementation must demonstrate its capabilities, so testing materials and scenarios, live “cooperative exchange testing,” and demonstration of capabilities are included. Finally, each project must evaluate its activities for lessons learned.
Elements of the HIE Challenge

• Open “governance”
• Trust relationships among participants
• Involve consumers
• Provide security
• Develop sustainable funding
• Provide capable business services and operations
• Develop technical capabilities and operations

Not unlike any given HIE, the trial implementations are challenged to use an open governance model, develop trust relationships among participants, involve consumers, provide security, develop sustainable funding, provide capable business services and operations, and develop technical capabilities and operations. With some 130 or more, depending on who counts what, how many HIEs will be able to sustain themselves is anyone’s guess. The trial implementations may be focused on the broader perspective of the NHIN, but will also help the nation study the challenges of sustaining HIEs in general. Some HIE experts suggest that the number of HIEs that do remain beyond initial government grants may be as low as in the single digits; and some within the HIE community have even suggested that it would have made more sense to fully fund only a very small number of models, find out what works, and then encourage a slower, but more sustainable roll out. Alternatively, some within HIEs that did not get very much early funding suggest that forcing them to make a solid business case for their existence made them stronger and more likely to succeed. Certainly the NHIN trial implementations will help determine what works in the face of many challenges for HIEs as well as the NHIN.
Functional Requirements
Needed for Initial Definition of NHIN (October 30, 2006)

1. **Certification:** Utilize a certification process that includes the requirements (standards and agreements) with which any entity’s health information users must conform for exchange of data within a nationwide health information network.

2. **Authentication:** Enable authentication of an entity’s users as well as independent users whenever location of information and/or data are exchanged within a nationwide health information network.

3. **Authorization:** Facilitate management of an individual’s permission/authorization to share information about location of health information or apply restrictions on access to specified health information.

4. **Person Identification:** Utilize a standard person identity/information correlation process to uniquely identify an individual.

5. **Location of Health Information:** Provide functionality that will locate where health information exists for identified individuals.

6. **Transport and Content Standards:** Transport requests for and responses regarding location of information, requests for data, data itself, and other types of messages (such as notifications of the availability of new data) to destinations using general industry-recognized transport types (e.g., Internet Protocol Version 6 [IPv6]) and authorized recipient’s specified mode (e.g., e-fax vs. transaction) to and from electronic addresses that are unambiguously identified in a standardized manner.

The National Committee on Vital and Health Statistics (NCVHS) was established by Congress to serve as an advisory body to the Department of Health and Human Services (HHS) on health data, statistics, and national health information policy. It fulfills important review and advisory functions relative to health data and statistical problems of national and international interest, stimulates or conducts studies of such problems, and makes proposals for improvement of the Nation’s health statistics and information systems. In 1996, the Committee was restructured to meet expanded responsibilities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It has also been tasked in the Medicare Modernization Act (MMA) to address standards for e-prescribing, and has taken an active role in promoting privacy, confidentiality, and security for use of health information technology in general, electronic health records (identified in HIPAA as “patient medical record information”), personal health records, and health information exchange/NHIN.

In 2001, it developed a report on what was termed the national health information infrastructure, with three overlapping domains of personal health, healthcare providers, and population health. Once the concept of NHIN was more formalized by ONC, NCVHS became the natural outreach to assist in providing advice on various aspects of the NHIN. Its first activity was to identify, at a high level, the functional requirements needed for initial definition of the NHIN. This report was released on October 30, 2006, and identified 11 functional categories, listed in order in which the functions might be applied by the NHIN. That is, any entity and their users and systems that want to participate in the NHIN must be certified. They then must be able to authenticate to the NHIN, have authorization to access services and exchange specific data. Person identification and record locator services are required to identify individuals and where there information may reside. Then transport and content standards enable the transmission of the data as requested.
7. **Data Transactions**: Provide functionality that will enable data transactions to occur among authorized entities and/or users upon specific trigger events, such as to automatically send final lab results for any previously sent preliminary results, send any changes in medications prescribed, report medication errors, notify public health about the occurrence of a bio-hazard event, inform individuals about the availability of a clinical trial, determine hospital census for disaster planning, etc.

8. **Auditing and Logging**: Log and audit all (intentional or unintentional) connections and disconnections to network services and all network configuration changes, generating alerts/notifications for system activity outside the normal range of monitoring levels/thresholds.

9. **Time-sensitive Data Access**: Enable time-sensitive data request/response interactions to specific target systems (e.g., query of immunization registry, request for current medication list).

10. **Communications**: Communicate health information using HITSP-identified standard content and message formats.

11. **Data Storage**: Enable the ability to aggregate data from disparate sources to facilitate communications. For example, temporarily hold information as it is being collected to communicate a concise summary of the information; or permanently store data from uncoordinated sources across time to support a data registry.

A variety of data transactions were envisioned, each logged in an audit trail and monitored. It was deemed critical to provide access to data in a time-sensitive manner – which would vary with the data and its use. HITSP-identified standards were recognized as key to communication capabilities. NCVHS also recognized that some or all HIEs and potentially some aspect of the NHIN may need to provide at least temporary storage of some data – perhaps to compile data needed for a complete transaction or to compile a data registry for specific, authorized purposes.
Summary of Recommendations for Privacy and Confidentiality in NHIN
(June 22, 2006)

1. Method by which personal health information is stored by health care providers should be left to the health care providers.

2. Individuals should have right to decide whether they want to have personally identifiable EHRs accessible via NHIN.

3. Providers should not be able to condition treatment on individual’s agreement to have EHR accessible via NHIN.

4. HHS should monitor development of opt-in/opt-out approaches; consider local, regional, and provider variations; collect evidence on health, economic, social, and other implications; and continue to evaluate in an open, transparent, and public process, whether a national policy on opt-in or opt-out is appropriate.

5. HHS should require that individuals be provided with understandable and culturally sensitive information and education to ensure that they realize implications of their decisions as to whether to participate in NHIN.

6. HHS should assess desirability and feasibility of allowing individuals to control access to the specific content of their health records via NHIN, and, if so, by what means.

7. If individuals are given right to control access to specific content of their health records via NHIN, the right should be limited, such as by being based on the age of information, nature of condition or treatment, or type of provider.

8. Role-based access should be employed as a means to limit personal health information accessible via NHIN and its components.

On June 22, 2006, NCVHS released a complementary report on recommendations for privacy and confidentiality within the NHIN. This recommendation is not intended to disturb traditional principles of public health reporting or other established legal requirements that might or might not be achieved via NHIN. Some 26, very specific recommendations were made to HHS concerning privacy, individual rights with respect to information exchanged within the NHIN, and specific access controls that should be employed.
The NCVHS privacy and confidentiality recommendations also addressed privacy in the broader context of the NHIN – expanding beyond HIPAA covered entities and their business associates, to what they identified as the need to protect “personal health information,” not just protected health information as designated by HIPAA. This would include information retained in personal health records not associated with a covered entity and other locations.

The NCVHS also observed that fair information practices should be adopted for the NHIN (refer to CPHIE VII on Data Stewardship), and that strong enforcement measures that produce high levels of compliance with rules applicable to the NHIN be required, but not impose an excessive level of complexity or cost.
Finally, NCVHS encouraged education, public input, and ongoing research to assess effectiveness and public confidence in the privacy, confidentiality, and security of the NHIN.
Enhanced Protections for Uses of Health Data:
A Stewardship Framework for “Secondary Uses” of Electronically Collected and Transmitted Health Data (December 19, 2007)

• In making its recommendations, NCVHS observes that currently,
  – the health industry relies upon the HIPAA construct of covered entities and business associates to protect health data.
  – Its recommendations call for a transformation, in which the focus is on appropriate data stewardship
    • for all uses of health data by all users,
    • independent of whether an organization is covered under HIPAA.
  – NCVHS considers the attributes of data stewardship as including, but are not limited to:
    • Accountability and chain of trust
    • Transparency
    • Individual participation
    • De-identification of health data
    • Security safeguards and controls
    • Data quality and integrity measures
    • Oversight of data uses
  – The recommendations also recognize the circumstances under which data stewardship may apply and where there may need to be further analysis and other actions

NCVHS was also asked by ONC to address enhanced protections for what ONC referred to as “secondary uses” of electronically collected and transmitted health data. NCVHS observed that such a moniker was inappropriate to apply to any health data – because the term “secondary” suggests lesser value or importance to data that may be critical, even to direct patient care as well as other uses. The result of its work led to the recognition of the importance of data stewardship, with attributes of accountability and chain of trust within the HIPAA construct, transparency, individual participation in HIE and the NHIN, strict definition and use de-identification processes when health data would be de-identified, security, data quality and integrity measures, and oversight of data uses. The report also reiterated, from its 2006 letter, its call for federal legislation or expanded regulations to extend HIPAA privacy protections more broadly.
Although there are many HIEs with success stories and interesting challenges, many have been highlighted throughout the CPHIE program and certainly many more in the literature. No HIE or NHIN grantee can be identified as “typical.” However, one case study is used to wrap up discussion of the NHIN that perhaps represents a less-frequently referenced project, but one that may be representative of many parts of the country.
Content Part 4.

• Lovelace Clinic Foundation and New Mexico Health Information Collaborative
  – New Mexico Priorities for HIE Services
  – Comparison to AHIC Priority Areas

Lovelace Clinic Foundation is the recipient of one of the NHIN trial implementation awards, and has also received other federal funding for its HIE development. Part 4 describes this organization’s activities relative to the NHIN.
Lovelace Clinic Foundation (LCF)

- LCF is an applied health research organization
  - Initiated the development of the New Mexico Health Information Collaborative (NMHIC) as a community-supported HIE network
  - Obtained funding from:
    - Federal (AHRQ grant 2004-2007)
    - State
    - Community (59 NMHIC stakeholders)
  - Developed prototype HIE network components
  - Conducted demonstration of components with Holy Cross Hospital in Taos

Founded in 1990, the Lovelace Clinic Foundation (LCF) is a not-for-profit, tax-exempt organization based in Albuquerque, New Mexico, that was formed to foster health services research among Lovelace Health System’s physicians and allied healthcare providers. Over the last decade, LCF has continued to focus on interventions to improve health and health care delivery while expanding to include continuing professional education, research related to environmental health and, more recently, information technology. Federal and state grants, private foundation awards and pharmaceutical and device companies support the LCF research. A Board of Directors that includes the President & Executive Director, the Lovelace Health System administrators and physicians, and members of the Albuquerque community govern the LCF.

In addition to receiving funding from AHRQ with matching funds from its community for HIE planning and implementation, it was awarded $1.5 million for 3 years to establish and implement a community-wide HIE, the New Mexico Health Information Collaborative (NMHIC). An additional $1.5 million in matching funds and in-kind contributions is being provided by community partners including local hospitals, HMOs, health insurance plans, progressive employers, medical associations, public school systems, philanthropic organizations, state government, and the University of New Mexico. Its goals are to improve health care coordination, improve chronic disease outcomes, and reduce unnecessary health care costs in New Mexico. NMHIC will address both urban and rural areas of New Mexico and in its initial 3-year phase, specifically, the Albuquerque Metropolitan area and the Taos community.
New Mexico Priorities for HIE Services (visa vie AHIC Priority Areas)

1. Receive laboratory and pathology results (A)
2. Access summary patient record (A)
3. Receive radiology and imaging reports (A)
4. Access medication lists (A)
5. e-Prescribing (F)
6. Receive hospital discharge summaries (A)

A. EHR-Laboratory Result Reporting
B. Consumer Empowerment—Registration and Medication History
C. Biosurveillance—Connecting Clinical Care to Public Health
D. Emergency Responder—EHR
E. Consumer Empowerment—Consumer Access to Clinical Information
F. Medication Management
G. Quality
H. Patient Authorization to Release Electronic Records to Social Security Administration

One of the most significant findings to date of LCF’s involvement in the NHIN trial implementations is from a survey of priorities for HIE services. The survey had 513 physician respondents, with priorities identified as first receiving lab and pathology results, second accessing patient summary information, third receiving radiology and imaging reports, fourth accessing medication lists, fifth e-prescribing, and sixth receiving hospital discharge summaries.

Since the NHIN trial implementations focus on 7 of the AHIC use cases plus the ability to process patient authorization to release electronic records to SSA for disability determination, a comparison of the physician priorities with these 8 areas of focus is very revealing, as all but one priority is largely focused on one use case – the EHR-Lab Result Reporting use case. Consumer empowerment, biosurveillance, emergency responder, and quality are notably absent from this list of priorities, although it must be noted that it was not the intent of the survey to prioritize the importance of the AHIC use cases to the community, but for the community to identify their most urgent needs.
This Course has summarized the concept of the NHIN and highlighted various initiatives of the federal government and HIEs to plan for and test various NHIN constructs. Perhaps the best conclusion that may be made is to encourage Course participants to “stay tuned” and to monitor the continuously evolving environment of the NHIN.

Use the quiz in the handout materials to test your understanding of the content just presented. Answers are provided following the quiz.