National Institutes of Health
National Center for Research Resources

ONC – NIH Analysis Report

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Executive Summary

The Office of the National Coordinator for Health Care Information Technology (ONC) is a part of the Department of Health and Human Services. ONC was chartered on April 27, 2004, by President Bush and was given the mission to develop the Federal Health Architecture (as part of the Office of Management and Budget eGov Initiative). ONC also provides leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care and the ability of consumers to manage their care and safety.

As such, the ONC's work may have a significant effect on the National Institutes of Health's (NIH) ability to develop an effective informatics research infrastructure. This report provides an overview of ONC-sponsored activities as well as their relevance to NIH's National Center for Research Resources (NCRR).

NIH National Center for Research Resources (NCRR)

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Applying systems engineering and advanced technology to critical national problems.

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1. Introduction

The Office of the National Coordinator for Health Care Technology (ONC), initially lead by David Brailer, M.D., Ph.D., has been given the mission by President Bush to coordinate health care information exchanges that occur across the Federal government via the Federal Health Architecture (FHA), and across the private sector via the Nationwide Health Information Network (NHIN).

ONC-sponsored activities relate to the National Institutes of Health (NIH) in two ways:

- The ONC is sponsoring a public-private activity to develop a nationwide health information infrastructure (as defined below). There is great potential for using this infrastructure to support translational research, as long as the research informatics requirements are considered at the same time as the infrastructure is being defined. If the ONC is not aware of the research requirements, they will not be included. Currently, there is no institutional research representation on ONC's advisory body (the Community, described below).
- The ONC is responsible for defining the FHA, which is part of the federal eGov initiative. As such, the FHA will effect the standards and architectures available to the NIH.

As the NIH initiates new programs, such as the Clinical and Translational Science Awards (CTSAs), it will be increasingly important to track the activities of the ONC and participate in them so that the NIH can receive the most comprehensive possible benefit from them and also ensure that the infrastructure proposed via the ONC meets the NIH's needs.

Working with the ONC to gain access to the nationwide clinical data repositories seems likely to benefit NIH stakeholders. Limited available research indicates that integrating clinical data for research purposes yields better and faster research outcomes. For example, in a survey of researchers using its integrated electronic health record (EHR) infrastructure, the Massachusetts General Hospital reports that "85% of users found that it saved days in identifying patient cohorts, which is helpful in determining the feasibility of performing a clinical study, and in identifying prospective patients who meet study criteria."[1]

Since ONC is currently developing use cases to guide its work in developing a standards-based health information architecture, this document also contains several proposed new use cases for consideration for submission to the ONC. These proposed use cases propose ways in which the data available from the initial ONC implementations can support translational and clinical research.

[1] Henry Chueh, M.D., Massachusetts General Hospital,. Research Databases: The Research Patient Data Registry and Strategic Directions, presentation at the American Medical Informatics Association meeting, Boston, MA. March 29, 2005

2. Office of the National Coordinator

The purpose of this section is to describe the background and mission of the ONC, the executive order that established the office, enabling legislation, and funding, as well as ONC's strategy and goals, governance, and current contracts.

2.1 Background

The ONC was created as a specific organization within HHS by Executive Order.[2] ONC plays two key roles – (1) organizing and chartering the activities required to create the NHIN and, (2) the development and implementation of the FHA, which will create the guidance necessary to connect the federal health line of business to the NHIN. A completely interoperable network is envisioned that would allow transport of data from providers to each other throughout the entire nation, to federal agencies (such as for public health or caring for military dependents within to the private sector) and the reverse. They also envision an exchange of information with payers, researchers, and with patients themselves (via a personal health record).

This document does not go into detail concerning the FHA, which is being restructured to fit into the NHIN architecture.

2.2 ONC Strategy and Goals

2.2.1 Public-Private Partnership

ONC has strong public-private components to its mission and vision. The office is guided by The Community (see section below), which has both public and private members.

2.2.2 Goals

The case for shareable EHRs is well known.[3] A number of communities have come together to attempt to share EHR data over the past thirty years. One of the best known of these is the Indiana Health Information Exchange, Inc. (IHIE), a non-profit corporation for sharing clinical information among health care providers and other health care entities, which provides physicians with a single source for clinical results, including laboratory/pathology, radiology, electrocardiogram reports, transcriptions, and emergency department and hospital encounter information from all participating central Indiana hospitals.

The community-based health information networks are now commonly called Regional Health Information Networks, or RHIOs. RHIOs bring together groups of providers and other stakeholders in states or communities who exchange data to concerning patient care. Each RHIO defines its own participants. Some are organized around several major inpatient facilities and affiliated physicians and pharmacies. Some include reference laboratories and free-standing

[2] The details can be found at the following web site: http://www.hhs.gov/healthit/mission.html.

[3] National Center for Vital and Health Statistics, "NHI – Information for Health: A Strategy for Building the National Health Information Infrastructure," November 15, 2001

imaging centers. Others include payers as well. Some are connected to local public health authorities. Others are organized around specialties, such as pediatrics or rehabilitation.

Most RHIOs are temporarily funded through philanthropy or federal demonstration grants.

The ONC's goal is to create a market-driven infrastructure in which the various RHIOs can organize their communities' information and then share it with each other and the authorized users, under well-defined security and privacy guidelines and clinical term definitions in a nationwide network.

2.2.3 Strategy: Creating a Market Space for Interoperable Health Records

ONC's strategy for the evolution of the NHIN, the RHIOs, and the associated standards harmonization and certification activities is market-driven. By that we mean that the Federal government is providing an organizing infrastructure, particularly in regards to the Federal aspects of the activities (e.g., interactions with NIH or with Centers for Medicare and Medicaid Services (CMS) or Centers for Disease Control and Prevention (CDC)). ONC is funding some initial activities, such as the demonstration architectures described below and the standards harmonization and systems certification processes. But ONC does not anticipate establishing a Federally-run national health information system. Most of ONC's vendor contracts contain a requirement that a business model for future sustainability be developed, even for the standards harmonization activity. This sends a clear signal to the stakeholders that the Federal government is not going to fund activities forever—or even for an extended period of time. Stakeholders must find ways to add value in order to sustain their work.

The initial thrust of the ONC strategy was to convene opinion leaders from both the public and private sectors to provide the political will to break through barriers to connect the infrastructure. The interview quoted in the box below provides more of the rationale.

> "David Brailer: When I came into this role, I didn't spend a lot of time thinking about standards, because I, like many people, assumed that we had lots of good organizations that were developing standards and that the issue was the will to get something done and the demand for solutions on the part of the doctors and the hospitals. My intent was to spend most of my time focusing on demand-side solutions: how to get doctors to want to put these tools in place, how to get hospitals to put them in place, how to get consumers to start using health information.
>
> ***After a year of doing that, it became very clear that we had the theory but not the practice of standards.*** Many organizations are developing standards, but they reflect the health care industry itself: They're highly fragmented; there are many of them; they're semi-overlapping. And we don't have, for that reason, a set of standards that we can hand to a vendor, to a hospital, to a health plan, to a federal agency, and say, Here's the standard; go to work and implement this.
>
> If you develop things, you have to pick among different competing standards, you have to resolve ambiguities, you have to fill in the holes, you have to accept big chunks that are missing. And so what happens is that people make different choices—they fill in the holes differently. ***The old joke is, every vendor has an HL7 [Health Level Seven] implementation; they're just all different.*** It's true, because we have a world that just has not committed itself to having one unified, comprehensive set of standards."[4]

[4] Cunningham, Robert, "Interview; Action Through Collaboration: A Conversation With David Brailer; The national coordinator of HIT believes that facilitation, not mandates, are the way to move the agenda forward." *Health Affairs*, September, 2005, p. 2

2.3 Governance

ONC has a governance structure that the same as is required of any Federal agency. As such, the ONC is organized as a part of the Department of Health and Human Services (HHS), reporting directly to the Secretary. It also has an external governing board (The Community, described below) that is comprised of both Federal and external members. The Community plays a very active role in guiding the activities of the ONC.

2.3.1 American Health Information Community (AHIC or "The Community")

On September 13, 2005, HHS Secretary Mike Leavitt announced the membership for the American Health Information Community. The Community was formed to help advance efforts to implement President Bush's call for most Americans to have EHRs within ten years. The Community is a federally-chartered committee, under the Federal Advisory Committee Act (FACA).

The Community was chartered for two years, with the option to renew, and duration of no more than five years. The Department intends for the Community to be succeeded within five years by a private-sector health information community initiative that, among other things, would set additional needed standards, certify new health information technology (IT), and provide long-term governance for health care transformation.

The Community has identified "Breakthroughs" that it would like to see implemented in specific areas within a one-year time frame. For each Breakthrough, the Community has written a general and a specific charge (see below). Workgroups have been chartered to further define the requirements for each Breakthrough charge. The workgroups will cover the following areas: biosurveillance, consumer empowerment, chronic care, and EHRs. These workgroups are scheduled to meet approximately ten times per year, each. The meetings are covered under the FACA regulations, so they are open to the public.

The Breakthroughs are being used to guide the activities of the ONC contractors described below. For example, the standards needed for biosurveillance are being identified, gaps are being mapped out, use cases to implement the Breakthroughs are being defined, and the use cases are being used to develop prototype architectures for the NHIN.

The Community meets regularly in open sessions.[5]

2.3.1.1 The Community's Membership

The Community has a total of 17 members, including Secretary Leavitt, who serves as the Chair. The remaining 16 members were selected by Secretary Leavitt and come from both the public and private sectors. Note that few of the members are informatics experts. Instead, they represent broad stakeholder constituencies. Members selected to serve include:

- Secretary Michael O. Leavitt
- Scott P. Serota, President and CEO, Blue Cross Blue Shield Association
- Douglas E. Henley, M.D., Executive Vice President, American Academy of Family Physicians

[5] Its schedule is posted on the web at http://www.hhs.gov/healthit/ahic.html and all meetings are also available via WebCast.

- Lillee Smith Gelinas, R.N., Chief Nursing Officer, VHA Inc.
- Charles N. Kahn III, President, Federation of American Hospitals
- Nancy Davenport-Ennis, CEO, National Patient Advocate Foundation
- Steven S Reinemund, CEO and Chairman, PepsiCo
- Kevin D. Hutchinson, CEO, SureScripts
- Craig R. Barrett, Ph.D., Chairman, Intel Corporation
- E. Mitchell Roob, Secretary, Indiana Family and Social Services Administration
- Mark B. McClellan, M.D., Administrator, Centers for Medicare and Medicaid Services
- Julie Louise Gerberding, M.D., Director, Centers for Disease Control and Prevention
- Jonathan B. Perlin, M.D., Under Secretary for Health, Department of Veterans Affairs
- William Winkenwerder Jr., M.D., Assistant Secretary of Defense, Department of Defense
- Mark J. Warshawsky, Ph.D., Assistant Secretary for Economic Policy, Department of the Treasury
- Linda M. Springer, Director, Office of Personnel Management
- Michelle O'Neill, Acting Under Secretary for Technology, Department of Commerce

The Community has appointed certain of its members to co-chair the Community Workgroups described in section 2.3.1.2, below.

2.3.1.2 The Community's Workgroups

The Community decided at its November 29, 2005, meeting to form workgroups in the following areas: Biosurveillance, Consumer Empowerment, Chronic Care, and EHRs. These workgroups will make recommendations to the Community that will produce tangible and specific value to the health care consumer that can be realized within a one-year period.[6] The charges to the workgroups from the Community are shown in the box below.

[6] The notion of the timeframe is evolving as the Community continues its discussions. The proposals have ranged from 18 months to one year to five years, depending on the perspective of the speaker.

Biosurveillance Workgroup:

- **Broad Charge for the Workgroup:** To make recommendations to the Community to implement the informational tools and business operation to support real-time, nationwide public health event monitoring and rapid response management across public health and care delivery communities and other authorized government agencies.
- **Specific Charge for the Workgroup:** To make recommendations to the Community so that within one year, essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems can be transmitted in standardized and anonymized format to authorized public health agencies within 24 hours.

Chronic Care Workgroup:

- **Broad Charge for the Workgroup:** To make recommendations to the Community to deploy widely available, secure technologies solutions for remote monitoring and assessment of patients and for communication between clinicians about patients.
- **Specific Charge for the Workgroup:** To make recommendations to the Community so that within one year, widespread use of secure messaging, as appropriate, is fostered as a means of communication between clinicians and patients about care delivery.

Consumer Empowerment Workgroup:

- **Broad Charge for the Workgroup:** To make recommendations to the Community to gain wide spread adoption of a personal health record that is easy-to-use, portable, longitudinal, affordable, and consumer-centered.
- **Specific Charge for the Workgroup:** To make recommendations to the Community so that within one year, a pre-populated, consumer-directed and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available, pre-populated medication history linked to the registration summary is deployed.

Electronic Health Records Workgroup:

- **Broad Charge for the Workgroup:** To make recommendations to the Community on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.
- **Specific Charge for the Workgroup:** To make recommendations to the Community so that within one year, standardized, widely available and secure solutions for accessing current and historical laboratory results and interpretations is deployed for clinical care by authorized parties.

Note that the Chronic Care Workgroup is the least developed. The use cases for that area have not yet been created and, as of this writing, the group has not conducted any formal meetings.

2.3.1.3 Implications of Workgroup Activities for the NIH

No workgroup specifically addresses translational research. That does not mean that the informatics capabilities that they are considering could not be useful for the NIH. Having access to structured information concerning laboratory test results, prescriptions, and demographics across the country could facilitate the work of the NIH and its stakeholders. But, if the case is not made to the Community that translational research opportunities are important, then even basic things that could add value will be missed, such as a mechanism for principal investigators to identify their clinical trials participants and obtain their encounter records. The Community cannot consider requirements that are not presented to them. Based on the meetings to date, it is likely that the members of the Community would be very supportive of research priorities if they can be brought into the infrastructure without causing major schedule or resource problems.

One approach is to provide a specific use case that illustrates the value of the data being collected and standardized as a result of ONC initiatives to clinical research. This will help the Community prioritize actions that can support research, in particular, architectural infrastructure elements (as defined by the specific charges) and also the standards harmonization activities. If the standards being used do not support clinical research well, then there is the potential that the benefits of this large data set will not be realized by the translational research community. For

example, if the standards harmonization group decides to focus on ICD-9 for diagnostic coding purposes and not to support broad use of SNOMED, then specificity that would be useful for the NIH-related research programs would not be provided. Section 4, below, contains some examples of use cases that could be considered.

2.3.2 ONC Organization and Staffing

2.3.2.1 Organization Chart

The HHS organization chart shows ONC at the lower right.

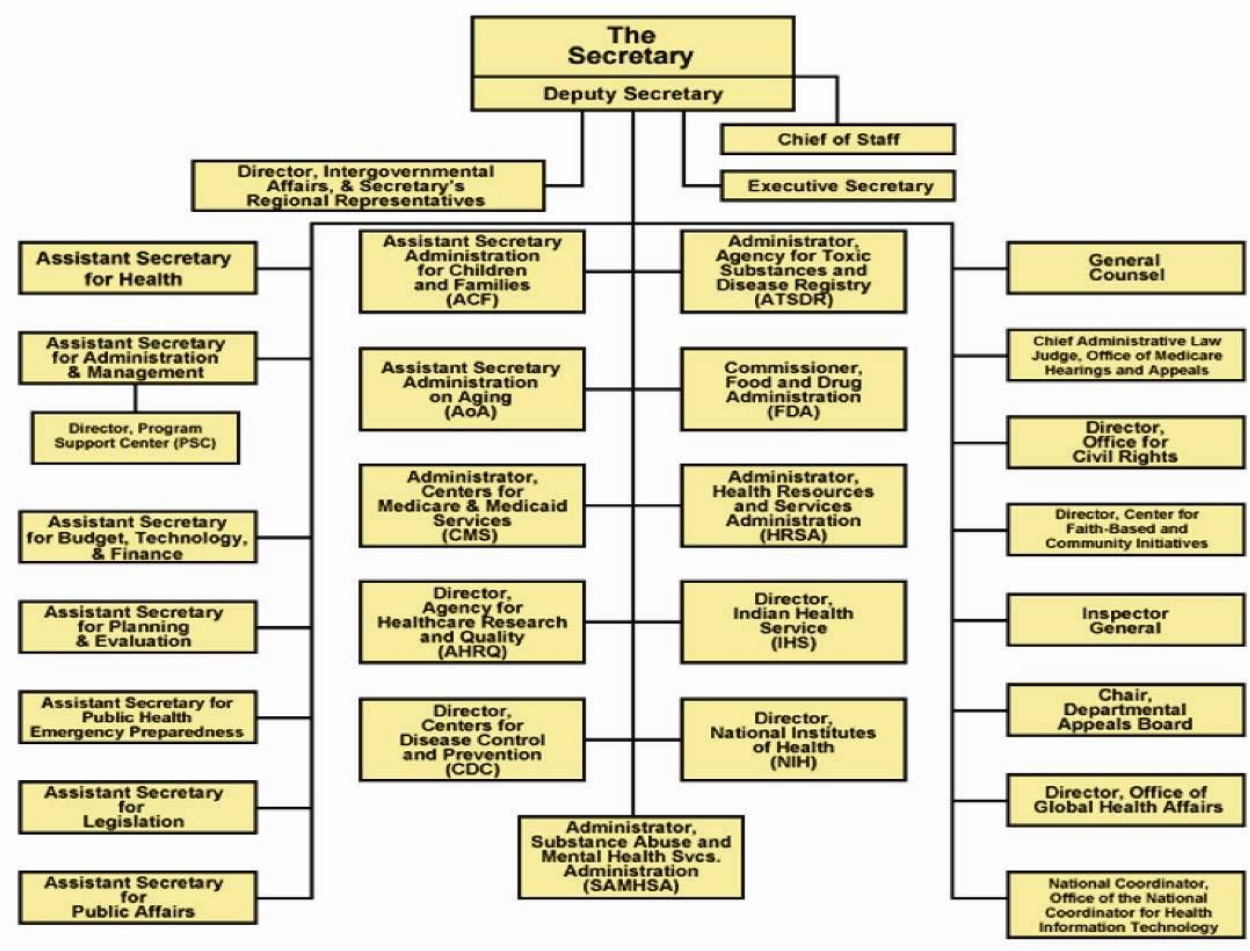

Figure 2-1. HHS Organization Chart

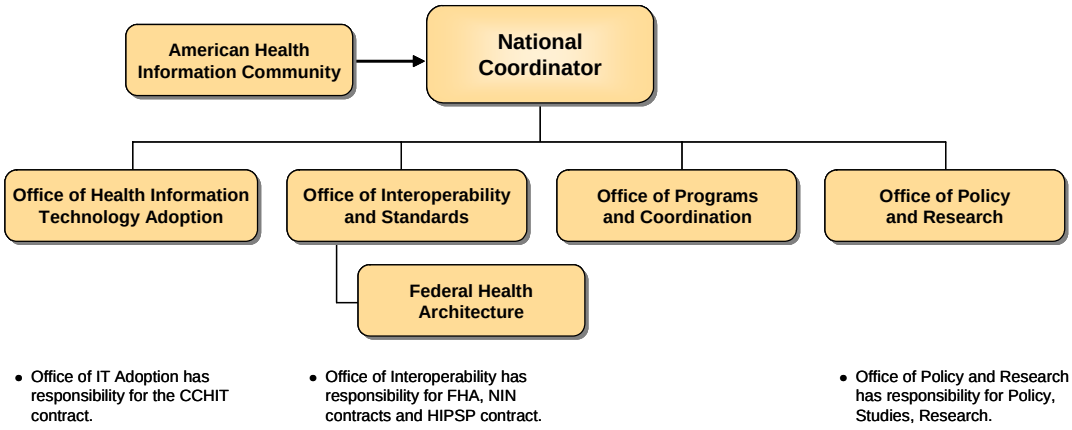

Figure 2-2. ONC Organization Chart

2.3.2.1.1 Other ONC Activities

On November 15, 2004, the ONC released a Request for Information (RFI) that sought public comment regarding how widespread interoperability of health information technologies and health information exchange can be achieved through the NHIN.

Five hundred and twelve organizations representing a cross-section of the industry as well as individuals submitted responses totaling nearly 5,000 pages of information. A report is available on the ONC web site at http://www.hhs.gov/healthit/rfisummaryreport.pdf. It provides some useful information on recommended architectures and standards, in particular.

2.3.2.2 ONC Budget

The following table was provided by the ONC. It covers all of the ONC activities except the FHA.

Table 2-1. ONC Budget

	FY 2004 Actual	FY 2005 Appropriation	FY 2005 Actual	FY 2006 Estimate	FY 2006 Request	FY 2006 Appropriation	FY 2007 Request
Budget Authority	$0	$0	$0	$75M	$75M	$42.8M	$88M
Evaluation Funds		$2.75M	$1.283M	$2.75M	$2.75M	$18.9M	
Other (TBD)							

2.4 Current ONC Contracts

There are currently five contracts being coordinated by ONC to support the National Health Information Network:

- Standards Harmonization Process – Health Information Technology Standards Panel (HITSP)
- Compliance Certification Process – Certification Commission for Health Information Technology (CCHIT)

- Privacy and Security Solutions – Health Information Security and Privacy Collaboration (HISPC)
- Nationwide Health Information Network (NHIN) architecture – Architecture Integrators
- Gulf Coast Recovery – digital health recovery for the Gulf Coast

The available Request for Proposals (RFP) that resulted in the five contracts can be found at Requests for Proposals and www.hhs.gov./healthit/contracts.html.

On February 14, 2006, HHS announced that it was planning to fund a study of RHIOs through the ONC. The RFP is expected to be released some time in March 2006. No further details are available at this time.[7]

The ONC also chartered studies, now completed, concerning the use of health care IT to prevent fraud and abuse in the health care industry.

2.4.1 Health Information Technology Standards Panel (HITSP)

Standards Harmonization Process: $3,300,000 (Total Awarded)

Standards development has primarily been done by Standards Development Organizations (SDOs), that rely on volunteers and industry specialists to develop standards and come to agreement on their content. It is then up to the vendors to implement the standards in the products that they deliver to the market. However, the health care market is so complex and the need for interoperability so important that there have been many recommendations for a national effort to harmonize standards.

> "Electronic Medical Record (EMR) diffusion is accelerating without aggressive government intervention, although somewhat unevenly. ***But essential data sharing and interoperability across communities and with Personal Health Records have generally been neglected***, severely limiting the social benefits to be gained from that investment, further fragmenting health care, and creating additional barriers to the development of a future standardized system because of the high costs of replacing or converting nonstandard EMRs. ***The development of standard-based networks of interoperable EMR systems cannot be left to providers alone***; they lack the capacity and the ability to appropriate the return on investment in such activities, despite the broader social usefulness of such activities."[8]

ONC has awarded a contract to the American National Standards Institute (ANSI), a non-profit organization that administers and coordinates voluntary standardization activities in the U.S., to convene the HITSP. The HITSP brings together SDOs and other stakeholders to develop, prototype, and evaluate a harmonization process for achieving a widely accepted and useful set of health IT standards that will support interoperability among health care software applications, particularly EHRs.

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[7] Mosquera, Mary, "RHIOs included in federal health IT efforts", *Government Computer News*, 02/14/06

[8] Roger Taylor, Anthony Bower, Federico Girosi, James Bigelow, Kateryna Fonkych, and Richard Hillestad, "Technology: Is There A Case For More-Aggressive Government Action? There are sufficient reasons for the federal government to invest now in policies to speed HIT adoption and accelerate its benefits," Health Affairs, September, 2005, p. 1

The HITSP is tasked to harmonize standards across the use cases identified by the Community so that the vendors can build to the standards in their commercial products and so that the CCHIT can certify that resulting products actually meet the standards and are interoperable.

HITSP has a membership profile that includes leading vendors, health care providers, academic medical centers, some medical associations, and SDOs. John Halamka, M.D., from the Harvard Medical School, is the chairman.

The governance of the HITSP is consensus-driven, which is typical for SDOs. This means that the governing board is actually more of an administrative body, rather than a decision-making body. The consensus-driven approach is a two-edged sword, of course. The standards may take a long time to evolve, but when they are approved, they should be acceptable to, and implementable by, major vendors in the health informatics market.

Further information on the HITSP can be found by following this link: http://www.ansi.org/hitsp.

2.4.1.1 HITSP Committees

The HITSP has organized several technical committees, which include:

- The Consumer Empowerment Technical Committee, consisting of 45 members. Co-chairs are Elaine Blechman, University of Colorado, Boulder; Charles Parisot, GE Healthcare; and Soloman Appavu, John Stroger Cook County Hospital.
- Biosurveillance Technical committee, consisting of 43 members. Co-chairs are Floyd Eisenberg MD, Siemens; Shaun Grannis, Indiana University School of Medicine; and Peter Elkin MD, Mayo Clinic College of Medicine.
- EHR Technical Committee, consisting of 41 members. Co-chairs are Steve Wagner, Department of Veteran Affairs; John Madden MD, Duke University Medical Center; and Jamie Ferguson, Kaiser Permanente.

2.4.2 Commission for Health Information Technology (CCHIT)

Compliance Certification Process: $2,700,000 (Total Awarded)

More than 200 EHR products are on the market, but there are no criteria for objectively evaluating product capabilities. This limits widespread investment in, and uptake of, these tools by physicians and hospitals and hinders informed purchasing decisions. There are also no criteria by which communication architectures can be standardized in a way that would allow two different EHRs to communicate with each other.

HHS has awarded a contract to the CCHIT to develop criteria and evaluation processes for certifying EHRs and the infrastructure or network components through which they interoperate. CCHIT is a private, non-profit organization established to develop an efficient, credible, and sustainable mechanism for certifying health care IT products. It was formed in July 2004 as a voluntary organization to provide a means to certify standards compliance by specific vendor products.

The CCHIT Commissioners include leaders from major SDOs, such as of Health Level 7 (a leading health messaging SDO), an executive from the Leapfrog Group (an employer-sponsored

association that strongly advocates use of computerized provider order entry systems) and representatives of consumer and provider organizations.

The CCHIT web site can be found at: http://www.cchit.org/

2.4.2.1 CCHIT Workgroups

CCHIT has formed several workgroups:

- Ambulatory Electronic Health Records—setting features and functions to meet an initial set of requirements.
- Interoperability—enabling standards-based data exchange with other sources of health care information.
- Security and Reliability—ensuring data privacy and robustness to prevent data loss.
- Certification Process—determining how vendors will apply for certification, how testing for compliance will be handled, and how the database of certified products will be maintained and publicized.
- Use Case/Test Plan Group—developing test procedures and scripts.

2.4.3 The Health Information Security and Privacy Collaboration (HISPC)

Privacy and Security Solutions: $11,500,000 (Total Awarded)

Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) established baseline health care privacy requirements for protected health information and established security requirements for electronic protected health information. 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.

The HISPC is a new partnership consisting of a multi-disciplinary team of experts and the National Governor's Association (NGA). The HISPC will work with approximately 40 states or territorial governments to assess and develop plans to address variations in organization-level business policies and state laws that affect privacy and security practices that may pose challenges to interoperable health information exchange. Overseeing the HISPC will be RTI International, a private, nonprofit corporation that has been selected as the HHS contract recipient.

2.4.4 Nationwide Health Information Network (NHIN)

NHIN Architecture: $18,600,000 (Total Awarded)

ONC awarded contracts totaling $18.6 million to four groups of health care and health IT organizations to develop prototypes for the NHIN architecture. Further information on the NHIN contracts is available at: http://www.hhs.gov/news/press/2005pres/20051110.html.

2.4.4.1 NHIN Tasks

Each group will develop an architecture and a prototype network for secure information sharing among hospitals, laboratories, pharmacies, and physicians in the three participating markets. Additionally, all four consortia will work together to ensure that information can move seamlessly between each of the four networks to be developed, thus establishing a single infrastructure among all the consortia for the sharing of electronic health information. Essentially, they are each demonstrating how to connect three RHIOs in a prototype of a national architecture. Once created, the architecture design for each of the networks will be placed in the public domain to stimulate others to develop further innovative approaches to implementing health IT.

2.4.4.2 NHIN Teams

The four NHIN Consortia teams consist of the following organizations:

- The team led by Accenture, working with Apelon, Cisco, CGI-AMS, Creative Computing Solutions, eTech Security Pro, Intellithought, Lucent Glow, Oakland Consulting Group, Oracle, and Quovadx. This group will work with the following health market areas: Eastern Kentucky Regional Health Community (Kentucky), CareSpark (Tennessee), and West Virginia eHealth Initiative (West Virginia).
- The team led by CSC, working with Browsersoft, Business Networks International, Center for Information Technology Leadership, Connecting for Health, DB Consulting Group, eHealth Initiative, Electronic Health Record Vendors Association, Microsoft, Regenstrief Institute, SiloSmashers, and Sun Microsystems. This group will work with the following health market areas: IHIE (Indiana), MA-SHARE (Massachusetts), and Mendocino HRE (California).
- The team led by IBM, working with Argosy Omnimedia, Business Innovation, Cisco, HMS Technologies, IDL Solutions, Ingenium, and VICCS. This group will work with the following health market areas: Taconic Health Information Network and Community (New York), North Carolina Healthcare Information and Communications Alliance (Research Triangle, North Carolina), and North Carolina Healthcare Information and Communications Alliance (Rockingham County, North Carolina).
- The team led by Northrop Grumman, working with Air Commander, Axolotl, Client/Server Software Solutions, First Consulting Group, SphereCom Enterprises, and WebMD. This group will work with the following health market areas: Santa Cruz RHIO (Santa Cruz, California), HealthBridge (Cincinnati, Ohio), and University Hospitals Health System (Cleveland, Ohio).

2.4.5 ONC's Gulf Coast Recovery Program

The Gulf Coast Recovery project is an HHS-funded ONC activity designed to help the Hurricane Katrina-effected areas recover as much health information as possible and convert it to electronic form. They have established a task force of local and national experts to help area providers. This task force will help to implement, support, and disseminate state-of-the-art IT that will contribute to an infrastructure that supports interoperable health care data exchange.

3. Discussion of Findings Thus Far From NIH Perspective

3.1 Planned Implementation Capabilities as Related to NIH

The Community has defined, through its charges described above, the key features that it would like to see implemented in the near future. It will be a long time before a structured, standards-based, certified national health infrastructure is available. Still, it is important to begin somewhere. Because health care providers are now moving more rapidly toward installing EHRs, it is essential to work with the vendors to provide as much standards-based content as possible.

As the NHIN architecture rolls out, the NIH may be able to obtain value by having access to de-identified data that would allow better planning of research activities, as defined in the proposed use cases below. This can only happen, though, if the NIH can help shape the requirements of the NHIN so that research needs are considered and met within the resources available.

The NIH may also wish to consider establishing guidance for its grantee and contracted institutions that can help them identify systems that are NHIN-ready or CCHIT certified.

3.2 Barriers and Issues from the NIH Perspective

FasterCures[9] identified the key requirements for EHRs that will meet research needs. These are shown in the table below, each with a comment regarding the current state and planned ONC-related action (if any has yet been identified).

Table 3-1. EHR Requirements for Research Use

Requirement	Comment	ONC-Related Action
Reliable and complete data	Very few systems, if any, have enough data to be considered "complete," whatever that is defined to mean. Kaiser, the VA, DoD, Harvard, Mayo Clinic, and Cleveland Clinic are among the most sophisticated. Reliability is a function of both use of standards and ability to ensure that data errors are detected and corrected. The level of standardization available from a RHIO's data transmissions will be heavily dependent on the architectural strategy and implementation model chosen. If the architecture involves exchanging standardized messages, it is more likely to provide interoperable data than those that merely provide pointers to data stored in a participating repository.	The use of standards will improve reliability to the extent that standards are followed. The activities of the HITSP and CCHIT will help with that, though they do not address data quality. The ONC's approach cannot address completeness, because it is market driven. The market is deciding what data is valuable and in what context. To that extent, the records will not be complete for the foreseeable future. Every area is determining what is valuable according to its own priorities, resources and criteria.

[9] FasterCures, "Think Research: Using Electronic Medical Records to Bridge Patient Care and Research," Fall, 2005, p. 29

Requirement	Comment	ONC-Related Action
Ability to search across records	In an ONC context, this would mean the ability to search across the entire national network, when and if it ever develops. Since there is no national identifier, the record requestor will have to identify the requested patient at each RHIO (using the RHIO's patient identification scheme, which may be different from all other RHIOs' schemes), unless the NHIN comes up with a federated master person index. In order to conduct a successful search, it would also be desirable to be able to specify exactly what type of information is requested (e.g., all data regarding HBA1c for a given patient in a given time period). If the federated systems develop a unified querying system, that would be possible. Requestor authentication would also be required. This means that the NHIN would have to provide some means to authenticate the requestor as a valid user with a valid need to see the data and ensure that all participating systems in the network would honor that authentication. Furthermore, there would need to be a means to ensure that every patient whose records were requested had signed an appropriate consent to share data for the purpose. Management of permissions will be a significant technical challenge.	The prototype NHIN architectures will demonstrate approaches to federated patient identification. The NHIN architectures are intended to address authentication, though the final approach has not yet been identified. The discussions of patient consent issues have been focused on the patient-care domains, not research. This is an area where NIH could play an important role in defining requirements.
Secure accessibility	This is a major consideration that has numerous constraints, both technically and legally.	ONC has funded a study of state policies and regulations that will effect security and privacy infrastructures across the NHIN. The technical aspects of ensuring secure access are addressed in the NHIN architectures.
Common informatics standards and interoperable interfaces	Both goals are excellent, but they will take a long, long time to fully achieve across the entire spectrum of the health care domain. Standards do not exist for many significant areas and, when they do exist, they are not necessarily compatible nor implemented in an interoperable fashion. Health care informaticists have a lot of career opportunities going forward.	The HITSP contract is focused on harmonizing selected standards and identifying gaps. For the use cases that are defined as priorities, this is a real step forward. However, these will not necessarily be the standards that the NIH would prioritize. The NIH may wish to participate in this activity to ensure consideration of important research-related standards. The CCHIT activity will certify systems to ensure that they interoperate as envisioned by the HITSP and the Community work-groups. The NHIN vendors will demonstrate that the selected systems are, in fact, interoperable.
User-friendly informatics tools	This is a critical requirement. If the research community cannot readily access the data, it will not be used, no matter how well structured it is.	Not addressed by ONC activities.

Requirement	Comment	ONC-Related Action
Informatics tools that merge patient care data while maintaining data security and privacy		Not being addressed by ONC.
Standard definitions of diseases, conditions, and adverse events (ADE)	Actually, it would be advisable to think beyond standard definitions and begin to look at ontologies as well. The definitions need to be put into context and need to have standardized meta-data to be really useful in a research environment.	See discussion of common informatics standards, above.
The use of standard minimal (core) data elements across networks, diseases, and conditions.	The core data set for research purposes has not been defined for the ONC.	Not being considered from a research perspective. The ONC is putting together a core demographic data set via the Consumer Empowerment Work-group. The Biosurveillance Work-group and EHR Workgroup are developing core data sets as well, for their respective areas. NIH may wish to participate to ensure that research requirements are considered as these are developed.

4. Potential Use Cases

The purpose of these use cases is to present some detailed information to the ONC for consideration as the Community finalizes the direction to give to the NHIN participants. The NIH and the larger community of clinical research stakeholders should clarify and present their needs to the Community in order for the NHIN to also be a high-value research resource.The use case suggestions below are based on possible translational research uses for the use cases already under consideration by the Community. NCRR can develop translational research use cases to show how the data can be used for research purposes or could develop an entirely new translational research use case for ONC's consideration (but that would probably not be considered in the initial round of funding and implementation) or both.

It is important to participate in the development of use cases for the out year capabilities. These will drive the activities of vendors, RHIOs, and SDOs. If translational research requirements are not considered, then the infrastructure may be inflexible or difficult for researchers to use. Early participation can result in maximal understanding of the needs of the research community and communication of those needs to stakeholders who are not aware of them.

Initial use cases are still being developed by the Community, but it appears that they will provide the following data sets:

- Biosurveillance
  - Demographic data, chief complaint, and lab test results from emergency department and ambulatory care settings.
- EHR
  - Laboratory data, linked to demographic data
- Consumer empowerment
  - Patient demographics and registration data for the initial capability, but may expand to include medication history as well.

Some potential research-related use cases for consideration are shown in the tables below. These can be expanded through consultation with the NIH.

Table 4-1. Use Case 1: Case Report Filling

Actors	Transactions	Benefits
Clinical Trial PI NHIN messaging	1. Request demographics data for trial participants from NHIN 2. Update case report forms with chief complaints for all episodes of care, demographics at the time of each episode	Ability to identify all patient complaints during the course of the trial, ability to track patient name and location changes, ability to identify all episodes of care during the trial, less paperwork burden for participating physicians, more accurate records.

Table 4-2. Use Case 2: Clinical Trial Recruitment Support

Actors	Transactions	Benefits
Clinical Trial PI Patient's Physician NHIN Messaging	1. Request de-identified data of patients with clinical profiles that meet specific protocol criteria 2. Review results 3. Select patients who qualify for clinical trial 4. Request that the NHIN send notification message to physicians treating patients who qualify for the trial. This message would contain contact information for the clinical trial. Note that the PI would not receive identifying information, just a return message to state that the anonymous patient's physician has been notified of the trial. Should the physician wish to consider the trial, the physician could then contact the PI and make a decision concerning whether to discuss participation with the patient.	Ability to identify many more patients who qualify for a clinical trial. Ability to notify their physicians and seek their participation. Totally anonymous, so patient confidentiality is not breached.

Table 4-3. Use Case 3: Tracking Research Subject Changes in Demographics

Actors	Transactions	Benefits
Clinical Trial PI NHIN Messaging	1. PI identifies patients in the NHIN system who are participating in a clinical trial 2. NHIN validates patient agreement to share information with PI 3. PI subscribes to changes in patient demographic data 4. NHIN sends messages to the PI whenever the patient's demographic information changes (e.g., the patient moves, changes telephone number, gets married, etc.)	Ability to automatically update the patients' demographic records, without requiring any paperwork from anyone. Much more efficient and complete data collection.

Table 4-4. Use Case 4: Adverse Event Detection

Actors	Transactions	Benefits
Clinical Trial PI NHIN Messaging	1. PI identifies to the NHIN the list of patients being monitored for a clinical trial 2. NHIN confirms that the patient has consented to share clinical data with the PI 3. PI subscribes to messages concerning any clinical encounters that the patient has (e.g., emergency room visits, outpatient visits, inpatient admissions) 4. NHIN sends messages to the PI whenever the patient has a clinical encounter.	Ability to identify all clinical encounters for the clinical trial patient. Will give a much better picture of the patient's overall progress. Will allow the PI to identify incidents that may indicate a potential ADE. Will be much more efficient. Will reveal much more data than is usually available to the PI, because the patient's caregivers may not recognize an ADE or may not realize that the patient is participating in a trial or may not know how to reach the PI to report a potential ADE.

Table 4-5. Use Case 5: Disease Burden Analysis

Actors	Transactions	Benefits
Clinical Trial PI or Biomedical Researcher NHIN Network	1. Request access to de-identified data repository 2. Perform queries to determine the disease burden by disease type, demographics, geographic area, laboratory findings, etc.	Would allow investigators to determine prevalence, severity, and nature of the disease burdens in large populations. Would allow better refinement of target populations, better identification of sites for trials, better determination of types of diseases or organisms requiring investigation (e.g., incidences of pseudomonas infection in a geriatric population). Would also allow rapid determination of whether there was a large enough potential population for a specific type of study (e.g., if there were enough patients who have an orphan disease within a given age group).

5. Conclusion

5.1 Potential Role in ONC-sponsored Activities for Biomedical Research Community Going Forward

The needs of the biomedical research community will not be recognized unless the Community and the ONC are aware of them. There currently is no participation (that the authors of this document are aware of) by NIH, the primary sponsor of the biomedical research community in the United States, on the Community's panels. Some of the important NIH-supported institutions are represented as leading members of CCHIT and HITSP. However, this will not guarantee that the full scope of the biomedical research community's requirements will be presented for consideration. Furthermore, the meetings of the HITSP and CCHIT are excellent learning opportunities, providing greater insight as to the quality of the data available, sources of improved standards, etc.

The NIH may wish to consider sending representatives to the Community, HITSP, and CCHIT meetings, and perhaps seeking official representation in the governance bodies. NIH may also wish to participate in the committees of each of these bodies for two reasons:

- Gaining a comprehensive view of the activities of all of the stakeholders, particularly SDOs, and improving their understanding of clinical research informatics
- Influencing the nature and direction of the committees' recommendations.

The NIH may also wish to develop some use cases to add to the set currently under consideration by the ONC for standards harmonization and implementation. Section 4, above, contains some suggested use cases that use the data already prioritized by the Community for research-related purposes. More comprehensive use cases can be developed as additional data becomes available through the NHIN.

5.1.1 Possible Collaboration with the Agency for Health Care Quality and Research (AHRQ)

The AHRQ actively partners with the ONC and provides funding for some of the ONC activities. As such, it is a major stakeholder. AHRQ is a part of HHS. Its mission is to "improve the quality, safety, efficiency, and effectiveness of health care for all Americans." According to Dr. Carolyn Clancy, AHRQ Director, it "focuses on how to improve the efficiency of the systems through which we receive personal health care and the effectiveness and comparative effectiveness of services."[10]

AHRQ is very concerned about speeding research results through the process so that important improvements in the quality of care are available more quickly. Dr. Clancy noted in her speech that "it takes 17 years to turn 14 percent of original research to the benefit of patient care." Thus, AHRQ is funding work in health IT to help clinicians apply the knowledge at the point of care. AHRQ is more focused on taking the best practices that are already understood (such as using aspirin after a heart attack) and ensuring that these practices are reinforced throughout the care delivery system.

[10] Speech at Clinical Research Forum, March 29, 2005.

AHRQ and NIH may wish to collaborate on activities to bring the benefits of the ONC-related projects to their specific stakeholders.

5.2 Critical Success Factors for NIH's Use of NHIN Data

There are some additional requirements that should be considered if the NHIN data is to be used to support the NIH's research needs. These include:

- Uniform anonymization services that can be used across the entire NHIN to preserve subject data integrity across all master patient indexes. That is, if John Doe is a patient who has records in two separate RHIOs and 15 total provider institutions, the anonymization system would be able to determine that all of these records are related to the same John Doe and would be able to anonymize them under a standardized record locator number so that the researchers would have a complete picture of the John Doe's episodes of care and related clinical information
- Uniform secure access and authentication across all NHIN components for translational researchers
- Uniform patient consent management
- Uniform methods for approval to use data for research protocols
- Standardized vocabulary normalization services across the entire network
- Standardized laboratory value normalization rules and metadata across the entire network
- Ability to request and store data sets in research-only data marts
- Patient recruitment tools for clinical trials (identification of potentially eligible patients and their physicians, etc.)
- Ability to track ADEs across all participants in a clinical trial over all episodes of care and all care venues.

5.3 Clinical Data Standardization Is Moving Forward: Research Benefits May Be Achieved

There is tremendous potential for benefit to the research community by collaborating with the ONC, the NHIN vendors, and the SDOs as the clinical data interoperability models are finalized. By becoming involved as the standards are finalized and harmonized and as the vendor products are certified, the translational research community can ensure that research needs are fully considered and the maximum benefit is achieved.

Appendix A.

Authors

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