Health Information Technology Standards Panel

HITSP Technical Committee Testimony to NCVHS

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Jamie Ferguson, Co-chair Electronic Health Record

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Contents

- HITSP – Context and process overview
- Consumer Empowerment -- Recommendations on requirements
- Electronic Health Record -- Recommendations on requirements
- Bio-surveillance -- Recommendations on requirements
The Community is the hub that drives opportunities for increasing nation wide health information interoperability

- CCHIT focuses on developing a mechanism for certification of health care IT products
- HITSP brings together all relevant stakeholders to identify appropriate IT standards
- HISPC addresses variations in business policy and state law that affect privacy and security
- NHIN is focused on interoperability pilots
HITSP was formed to prototype a process used to harmonize industry-wide HIT standards . . .

- HITSP formed under the sponsorship of the American National Standards Institute (ANSI), coordinator of the U.S. voluntary standardization system

- The Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI) and Booz Allen Hamilton serve as strategic partners with ANSI in this initiative

- Brings together a wide range of stakeholders into a formal “panel” to identify, select, and harmonize standards for communicating data throughout the healthcare spectrum

- Formation of the Panel was endorsed by a number of industry groups and has the oversight and backing ONCHIT

- John D. Halamka, MD, MS, CIO of the Harvard School of Medicine chairs the Panel

- A total of 155 organizations participate in HITSP representing consumer, SDO, non-SDOs, and government interests

- Non SDO make up 67% of the panel and include clinicians, providers, safety net providers, vendors, purchasers, payers, public health professionals, and researchers
The process is repeatable and fully integrated with CCHIT and AHIC

1. For each AHIC Use Case, HITSP Technical Committees identify candidate standards which are harmonized into a final list of standards
   - They also identify overlaps and highlight gaps. Gaps are forwarded to Standards Development Organizations for their guidance as to emerging candidate standards or new standards requirements.

2. The final standards chosen by the Technical Committees are discussed and ratified by the HITSP panel.

3. These standards are available for public comment and feedback.

4. Technical Committees work with SDOs and other groups to produce detailed specifications, an unambiguous “cookbook”, for the implementation of chosen standards. HITSP provides a convening and facilitation function for this activity.

5. HITSP work products are delivered to AHIC for their endorsement.

6. CCHIT will include functional criteria for interoperability based on HITSP specifications in its certification work.
The HITSP process results in creation of an Interoperability Specification used to promote nationwide interoperable health information exchange.

Harmonization Process Steps:

I. Harmonization Request
II. Requirements Analysis
III. Identification of Candidate Standards
IV. Gaps, Duplications and Overlaps Resolution
V. Standards Selection
VI. Construction of Interoperability Specification
VII. Inspection Test
VIII. Interoperability Specification Release and Dissemination
IX. Program Management

Evaluation of Standards Harmonization Process for HIT
The three HITSP Technical Committees are working toward a September deadline to publish Interoperability Specifications.

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<thead>
<tr>
<th>Committee</th>
<th>Description</th>
<th>Presenters</th>
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| Biosurveillance                    | Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time. | - **Floyd P. Eisenberg, MD MPH, SIEMENS Medical Solutions Health Services - Presenter**  
- Peter L. Elkin MD FACP, Mayo Clinic College of Medicine  
- Shaun Grannis, MD, The Regenstrief Institute, Indiana University School of Medicine |
| Consumer Empowerment               | Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals. | - **Charles Parisot, EHR Vendor Association**  
- Elaine A. Blechman PhD, Professor, Univ. of Colorado-Boulder |
| Electronic Health Record           | Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care. | - **Jamie Ferguson, Kaiser-Permanente - Presenter**  
- John Madden, MD, PhD, SNOMED Intl  
- Steve Wagner, Department of Veterans Affairs |
Progress to date has positioned each committee to provide NCVHS with relevant insights into NHIN requirements

- In June of 2006, HITSP reduced 570 candidate standards to 90 appropriate standards for secure exchange of medication, lab, allergy and demographic data.

- By September 29, 2006, HITSP will deliver unambiguous interoperability specifications which will enable vendors, hospitals and government to create software components for clinical data exchange.

- Beyond 2006, HITSP will develop harmonized standards and unambiguous implementation guides which provide precise instructions for data sharing for all future requests for harmonization.

- Also, it will standardize the interoperability specifications for technology products, while permitting differentiation and competitive advantage in the marketplace. HITSP hopes to empower patients and care providers with Electronic Health Records (EHR) that facilitate easy access to critical health data that is accurate, private and secure.

- HITSP is a key component of the Health and Human Services vision to create an interoperable healthcare system, and we look forward to our work products empowering patients, providers and government stakeholders in 2006 and beyond.
Today’s testimony is an encapsulation of current Technical Committee thinking and subject to full HITSP review in coming months

- The HITSP Technical Committees perform the detailed work in the process to harmonize standards and their work is subsequently packaged for review by the full Health IT Standards Panel membership

- The NCVHS invitation to have the Co-Chairs of the HITSP Technical Committees testify goes right to the source of the most active thinking about the current harmonization efforts, which we hope will be informative and helpful to you

- But the consequence, given the active stage of deliberations and the schedule of meetings for the HITSP Board and full Panel, is that our testimony has not undergone that critical review and consensus approval by the Panel

- Our testimony must be viewed as an encapsulation of the current thinking of each Technical Committee, not of HITSP more broadly, and is subject to our further deliberations and reviews over the coming months
Contents

- HITSP – *Context and process overview*

  - Consumer Empowerment -- *Recommendations on requirements*

- Bio-surveillance -- *Recommendations on requirements*

- Electronic Health Record -- *Recommendations on requirements*
# Proposed Nationwide Health Information Network Functional Categories

- Audit and logging
- Authentication
- Authorization
- Confidentiality
- Credentialing
- Data access and update
- Data content
- Data filtering
- Data mapping/translation
- Data quality/data integrity
- Data rendering
- Data retrieval (pull)
- Data routing
- Data source
- Data transmission (push)
- Data usage
- Identity/information correlation
- Persistent data storage
- Record location
- Transient data
The Current Consumer Empowerment Use Case

Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
The Personal Health Record (PHR) 
In Current & Future CE-TC Use Cases

• Operational definitions and technical standards for provider-controlled electronic health record systems (EHRs) have evolved since the early 1990s culminating in the HITSP process for harmonization of interoperability standards.

• Definitions and interoperability standards for consumer-controlled personal health record systems (PHRs) are just now emerging.
Consumer-Control & Interoperability

• The term PHR is now applied to systems that vary in consumer-controlled access privileges and interoperability.

• Consumer control. Via their PHRs, consumers establish and manage granular role- and relationship-based access privileges for exchange of their personal information with specific persons (including family caregivers and health and human service providers).

• Interoperability. Consumer-authorized PHR users may exercise their access privileges via diverse EHRs and edge systems.
1. Required for Consumer Empowerment: A Consumer-Controlled, Interoperable PHR

A Level 4, consumer-controlled, interoperable PHR is a prerequisite for current and future CE-TC use cases and for NHIN roll out and NHIN linkage.

<table>
<thead>
<tr>
<th>Interoperability</th>
<th>NO</th>
<th>YES</th>
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<tbody>
<tr>
<td>NO</td>
<td>Level 1 View into Provider EHR</td>
<td>Level 2 Freestanding Device</td>
</tr>
<tr>
<td>YES</td>
<td>Level 3 View into RHIO EHR</td>
<td>Level 4 Consumer-Controlled Interoperable</td>
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A Level 4, consumer-controlled, interoperable PHR exchanges information across the NHIN with multiple edge systems including, perhaps, a RHIO database.

Thanks to Charles Parisot, CE-TC co-chair, for this figure.
2. Required for NHIN Roll Out: 

*NHIN, Trusted Steward of Consumer Information*

- The NHIN must be a trusted steward, efficiently and effectively storing and retrieving but not transforming, processing, or replicating consumer data.

- NHIN repositories must be faithful document-in, document-out information holders, but not processors.

- NHIN rollout requires consumer-trusted, tamper-proof, transparent, and end-to-end transport of document content with standards in place for:
  - Security infrastructure for all nodes end-to-end
  - Patient identification services
  - Document sharing including registry and repositories
3. Required for NHIN Roll Out: *NHIN, Fully Transparent Information Mediator*

The NCVHS functional categories should identify not only data push and data pull but also document/object sharing (both push and pull, where the NHIN is a fully transparent mediator).
4. Required for NHIN Roll Out: 
*Edge Systems Control Data*

• We believe that a trusted steward of consumer information must avoid certain functions that NCVHS has delineated for the NHIN.

• The following functions should reside with edge systems:
  • Data rendering
  • Data usage
  • Data filtering of document content
  • Data mapping and translation
  • Data content (unless setting standards for normalizing)
5. Required for NHIN Linkage: *PHRs Control Permissions*

• Successful NHIN linkage requires a robust infrastructure that guarantees that patient permissions are imposed and maintained.

• The PHR, as an edge system, must function to establish the source, manage, and maintain the individual’s role- and relationship-based permission controls.

• The PHR system must control the promulgation and perpetuation of consent to all edge systems attached to the NHIN.
6. Required for NHIN Linkage: 
*Edge Systems Communicate Over the NHIN*

• The NHIN, by definition, must act as a trusted, transparent, unobtrusive information steward.

• Individual Americans must perceive the NHIN as an effective means to better health care, but not as another intrusive government agency.

• The NCVHS discussion template positions the NHIN as an all-powerful force in which communication of edge systems goes through (and is controlled by) the NHIN.

• We recommend an alternative that positions the NHIN as an infrastructure in which communication of edge systems moves over (and is facilitated by) the NHIN.
Evaluation of Standards Harmonization Process for HIT

NCVHS Discussion Template of NHIN

Confidentiality and Security

Edge System

Examples:

Confidentiality & Security

Network Functional Requirements

Examples:

Patient Data/Record Location
Transport
Security
(e.g., Audit Trails, Authentication)

Policy

Public health systems

Other edge systems

E-prescribing systems

Electronic health records

Other edge systems

Personal health records

Immunization Registries

Draft – NCVHS - 071406
Evaluation of Standards Harmonization Process for HIT

HITSP-CE Modified Discussion Template of NHIN

Confidentiality and Security

Edge System
Examples:

Interoperability Requirements
Examples:
- Patient Data/Record
- Sharing/Location
- Transport
- Security
(e.g., Audit Trails, Authentication)

Public health systems

Other edge systems

Other edge systems

E-prescribing systems

Electronic health records

Immunization Registries

Personal health records
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Use Case Scenario #1: (Providing new lab results to ordering clinician, other authorized providers and data repositories)

Updated 7/18/06

1. Identify the lab result terminology
2a Call terminology service
2b. Patient ID Cross referencing
2bc Structure result as lab report document
3a. Send results message to ordering clinician
3b. Send results message to other authorized providers of care
3c. Send document to repository, store, and register in data locator service
4. Notification of lab report availability
5. Send report to authorized providers of care

**Logging, Authentication, Infrastructure are all out of scope for this diagram**
Use Case Scenario #2:
Query Repository for Retrieval of Historical Lab Results

Updated 7/18/06

3c. Send document to repository, store, and register in data locator service

4. Notification of lab report availability

6a. Query data locator service for lab results location and retrieve from repository

6b. Query repository and retrieve lab report directly from repository

7. Merge lab results into EHR

8. View lab results from a web application
Evaluation of Standards Harmonization Process for HIT

EHR Construct Framework
Draft Example

EHR - Interoperability Specification for Scenario 1

Define lab result terminology and Call terminology service (1 and 2a)

Send lab results message to authorized recipients with Patient ID X-Ref (3a/b, 2b)

Patient ID Cross Referencing (2b)

Send document to data repository, store, and register in RLS (3c)

Call terminology service (2a)

Send results message to authorized recipients (3a, 3b)

Structure lab result as lab report document: (2bc)

Send report to ordering clinician and other authorized providers of care (5)

Notification of lab report availability to ordering clinician and other authorized providers of care (4)

Define Lab Result Terminology (1)
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Biosurveillance Use Case Data Submission

Clinical Care
Ambulatory  Hospital  Lab  Care

Authorized Public Health Agencies
Local  Regional  State  CDC

Patient Encounter  (Lab, EMR)
Resource System

Document
Message

BIS

Anonymized, Pseudonymized, De-identified Data

Secure Point-to-Point Communication

Shared Document Resource
Biosurveillance - Scenarios

- 3 Functional Scenarios
  - Message-Based Data Submission
  - Document-Based Data Submission
  - Resource Utilization

- 3 Clinical Exemplar Scenarios
  - Pandemic Influenza
  - Bioterrorism – Anthrax
  - Sexually-Transmitted Disease – Chlamydia

  ➢ Identification
  ➢ Situational Awareness
Evaluation of Standards Harmonization Process for HIT

Surveillance Message-Based Data Submission Functional Flow

Patient Encounter (Lab, EMR)

- Verify Authorizations, (IP15)

Retrieve Form for Data Capture (IP39) (Optional)

- Collect and Communicate Audit Trail (IP2)
- Verify authenticity of transmission contents (IP46)

Communicate Message-based Encounter Summaries (IP42)

- Identify Communication Recipients (IP43)

Communicate Message-based Laboratory/Radiology Orders (IP58)

- Anonymize and Pseudonymize Data (IP19)
- Manage Provider Credentials Machine only (IP26)
- Maintain Consistent Time across enterprises (IP22)

- Digitally Sign (Machine Signature Only) (IP4)

Communicate Message-based Laboratory/Radiology Results (IP44)

- Secure point-to-point messaging (IP51)
- Public Health System: Secure point-to-point communication (IP51)

Existing Work
Current Effort
Derivative of Current
New Work
Biosurveillance: Requirements from Core System

- Universal Authorization
  - Manage machine credentials
  - Establish policy for issuing machine credentials for edge systems
  - Secure communication channel and node authentication

- Method for requestor (edge) to specify high-level crude filtering requirements

- Integrate related network function functional requirements and relationships
  - EMS Infrastructure for Resource Management and Biosurveillance Use Case Resource Utilization

- Support restricted communication environment for authorized secondary users of data and data sources
  - Public Health users
  - Research – Public Health and others will require additional security and privacy risk assessment
Biosurveillance: Requirements from Edge Systems

- **Interoperability**
  - Methodology for data communication
    - Secure point-to-point communication
    - Shared document resource
  - High-level crude filtering – Essential Data at Sending and Receiving End
  - Associated Services
    - Secure
    - Terminology services
    - Pseudonymization services

- **Anonymization**

- **Timely data flow management** (near real time)

- **Management of large volumes of data transmission facilitated by NHIN**
  - Legal and policy implications are significant for edge systems
  - Workflow must be addressed at each edge
General Comments – Core and Edge Systems

› For Syndromic Surveillance and Situational Awareness
  – Aggregate monitoring is actively managed today
    • Monitoring bed utilization
    • Types of conditions for which patients are seen in Emergency Depts
  – HITSP can enhance the process

› Public Health is more similar to clinical healthcare delivery than it is different
  – Aggregate monitoring is required to manage trends
  – Individual case and contact management requires as much data as possible

› Requirements for core and edge systems inform and are informed by architecture

› SDO efforts at harmonization and standard enhancement are a moving target. HITSP efforts must be evolutionary to accommodate and drive those targets.