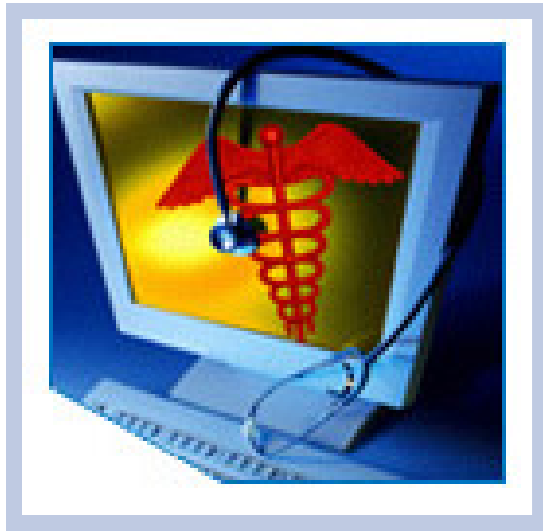


HITSP Interoperability Specification Overview



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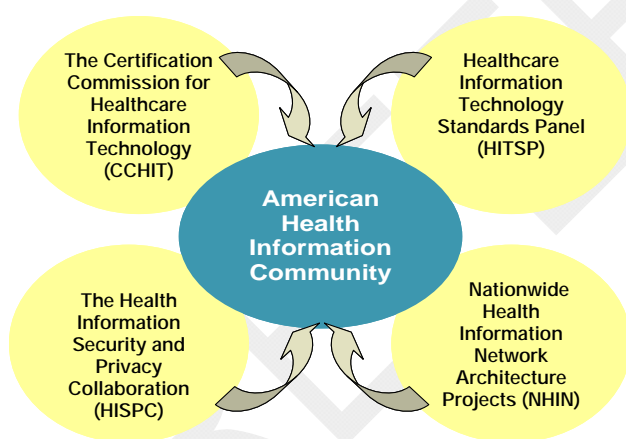
1.0 FOREWORD

This document provides an overview of the Healthcare Information Technology Standards Panel (HITSP) Interoperability Specifications, including a description of HITSP and its processes, and an introduction to the key HITSP principles that drive the consistent development and interpretation of the HITSP Interoperability Specifications.

The following paragraphs provide background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. They also describe the HITSP process for healthcare standards harmonization and explain how to use this document and other related documents to inform your health IT product development or product refinement.

1.1 U.S. NATIONWIDE HEALTH INFORMATION INTEROPERABILITY

Studies published by the Institute of Medicine and others have raised awareness of the extent to which the fragmented nature of clinical information adversely impacts the quality of care across the U.S. Health Information Technology (IT) can be used to enable better integration of clinical information. However, as of 2007, only a small number of U.S. healthcare providers have fully adopted health IT due, in part, to technical barriers associated with a lack of unambiguous and nationally recognized interoperability standards.



The American Health Information Community¹ (AHIC), a federal advisory body chartered in 2005, made up of leaders from public and private health sectors, was formed to make recommendations to the Secretary of the U.S. Department of Health and Human Services on how to accelerate the development and adoption of health information technology. At the same time, the Department of Health and Human Services, through the Office of the National Coordinator for Health IT (ONC) awarded contracts to 1) identify Interoperability Standards to facilitate the exchange of patient data

(HITSP), 2) define a process for certifying that health IT products comply with appropriate standards through the Certification Commission for Healthcare Information Technology (CCHIT), and 3) develop a series of prototypes to establish the requirements of a Nationwide Health Information Network (NHIN). Under a renewed second year contract, HITSP activities will include identifying and constraining the standards needed for a standards-based security framework that provides the mechanisms needed to protect patient privacy and maintain confidentiality of information about the patient, as well as further work

¹ <http://www.hhs.gov/healthit/ahic.html>



in additional Use Case priority areas recommended by AHIC. This year, CCHIT is expanding its certification efforts to inpatient, or hospital, electronic health record products. In January 2007, four NHIN prototypes were delivered based on the requirements for health information exchange. The next phase will be to connect the prototypes and state and regional health information exchange efforts in trial implementations. These activities share the goal of widespread adoption of interoperable electronic health records within 10 years through public-private collaboration.

1.2 HITSP'S ROLE WITHIN NATIONWIDE INTEROPERABILITY EFFORTS

The HITSP² is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. As used by HITSP, the term “standard” refers, but is not limited to Specifications, Implementation Guides, Code Sets, Terminologies, and Integration Profiles. A standard should be produced through a well defined approach that supports a business process and

1. has been agreed upon by a group of experts
2. has been publicly vetted
3. provides rules, guidelines, or characteristics
4. helps to ensure that materials, products, processes, and services are fit for their intended purpose
5. is available in an accessible format
6. is subject to an ongoing review and revision process

HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized Interoperability Specifications and information policies, including SDO work products (e.g., standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare information to ensure that the resulting standards are globally relevant
- Be Use Case driven, using information from stakeholders and basing decisions on industry needs

The work of the HITSP is conducted through formally chartered Technical Committees and Work Groups. The artifact of the Technical Committee and Work Group activities is an Interoperability Specification (IS) and related constructs referred to as Transaction Packages, Transactions, or Components. For additional information on these constructs, please refer to the [HITSP Harmonization Framework](#).

² www.hitsp.org

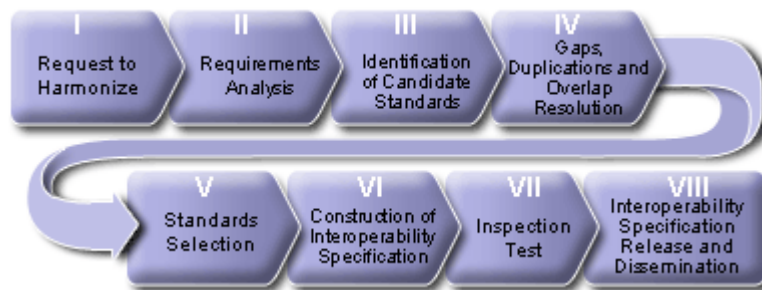


In its final state, each Interoperability Specification provides unambiguous instructions for how two or more systems should exchange information within the specific context of the Use Case.

1.3 HOW USE CASES AND HITSP INTEROPERABILITY SPECIFICATIONS ARE DEVELOPED

The American Health Information Community, as the representative of public and private health sector stakeholders, identifies Use Cases that drive the efforts of the HITSP. Nationwide public and private health sector priorities also continue to focus the efforts of the HITSP. The Use Case driven HITSP harmonization process is implemented by formally chartered Technical Committees. The volunteers that comprise a Technical Committee followed an 8 step process, depicted below.

Figure 1.3-1 HITSP Harmonization Process Steps



1.4 HOW TO READ THE INTEROPERABILITY SPECIFICATIONS

Each Interoperability Specification (IS) is actually a suite of documents that, taken as a whole, provide a detailed map to existing standards and specifications that will satisfy the requirements imposed by a given Use Case. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the Interoperability Specification provides recommendations and a roadmap for resolution.. Each Interoperability Specification includes the Transaction Packages, Transactions, and Components that are used to meet the Use Case requirements.



2.0 INTRODUCTION TO HITSP INTEROPERABILITY SPECIFICATIONS

Each Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of one or more Use Cases. It may not define all functions, constructs and standards necessary to implement a conforming system in a real world environment. In particular, an implementer must provide the technical infrastructure and security framework necessary to support operations in accordance with law, regulation, best practices and business agreements. The following paragraphs provide the HITSP principles with regard to several critical topics to ensure consistent interpretation of the Interoperability Specifications.

2.1 INTEROPERABILITY SPECIFICATIONS NOT FUNCTIONAL SPECIFICATIONS

The HITSP Interoperability Specification defines how two or more systems exchange standard data content in a standardized manner. Interoperability Specifications define the necessary business and technical actors, the transactions between them including the message, content and terminology standards for the actual information exchange. Interoperability Specifications do not specify the functional requirements or behaviors of the systems or applications.

2.2 ARCHITECTURAL NEUTRALITY

HITSP Interoperability Specifications, unless otherwise noted, are not intended to define or prescribe any system architecture or implementation. At the most basic level, the Interoperability Specifications define specific information exchange standards that are to be used by any two systems. Information exchange must be placed within the context of a transaction between defined technical actors which fulfill higher level business requirements derived from the Use Case. In some cases the necessary technical actors may require some architectural structure or make some assumptions involving synchronous or asynchronous data exchanges, or require specific type of exchange, such as a message or document. These requirements may constrain to some degree the total range of choices regarding system architectures. When constraints are necessary to meet the Use Case requirements, the Interoperability Specification will note this and will retain as much architectural neutrality as possible. When appropriate, the Interoperability Specifications may provide architectural examples and discuss considerations of such examples.

2.3 THE USE OF MESSAGES AND DOCUMENTS AS APPROPRIATE

Within healthcare information there is an ongoing debate concerning the proper role of messages and documents as methods of exchanging data. Messages are typically non-persistent encapsulations of highly structured data that require external context. Documents are persistent encapsulations of both data and context which may be authenticated to insure nonrepudiation. Persistence as defined by Health Level Seven (HL7), means that a clinical document continues to exist in an unaltered state for a time period defined by local and regulatory requirements. Non-repudiation, as defined by the International



Organization for Standardization (ISO) adapted from ASTM E31, means a service that provides proof of the integrity and origin of data, which can be verified by any party. HITSP recognizes that requirements for both messages and documents exist and where consistent with harmonization will support both. For example, depending on specific phases of the workflow, a laboratory result might be exchanged as a message, as a document, or both. Business requirements may define which format is more effective.

2.4 TESTING

The Interoperability Specifications are evaluated by inspection testers (desktop review) and reviewed by HITSP members prior to HITSP approval. Although the Interoperability Specifications are based on approved standards, when published, they represent combinations and constraints that may not have been tested in actual implementations. HITSP enlists partners to develop test plans, data, and suites, to test the implementation, and then to support a program for progressive testing, feedback and deployment of implementations. Feedback from test implementers is used in the revisions to the published Interoperability Specification.

2.5 SECURITY AND PRIVACY

Currently, HITSP is charged by ONC to harmonize standards based on Use Cases derived from AHIC requirements and priorities. Implicitly and in some cases explicitly, each individual Use Case requires a secure infrastructure and certain security or privacy functions. Based upon prioritization by AHIC and ONC, HITSP, in its second year, is identifying and constraining the standards needed for standards-based security and privacy frameworks that provide the mechanisms needed to protect patient privacy and maintain confidentiality, integrity and availability (which are governed by policy). Standards-based security and privacy frameworks will support federal, state, local, and healthcare enterprise security and privacy policies and processes.

The Biosurveillance Use Case describes the process or interaction that each primary stakeholder will invoke in the capture, discovery, anonymization, and transmission of relevant data. The Use Case addresses the transmission of essential data from ambulatory care and emergency department visits, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in a standardized and appropriately anonymized format to authorized Public Health Agencies with less than one day lag time. The Biosurveillance Interoperability Specification is also required to support the ability for authorized public health personnel to go back to the data source to seek to re-link the biosurveillance data to the data source, and/or the subject of the data, as part of an appropriate public health investigation. Therefore, the management of data to ensure proper routing, security, privacy, and timely reporting is critical to enabling biosurveillance activities.

The security and privacy considerations for the Consumer Empowerment Use Case surround the identification of the principle stakeholders and flow of events for the authorized and secure exchange of consumers' registration summaries and medication histories. These include enabling consumers to establish permissions and access rights for viewing their individually identifiable health information;



authenticating consumers, designated caregivers, and health professionals; querying other organizations for data and matching to the consumer; accepting “batch” data from other organizations and matching to the appropriate consumers; and finally accessing, viewing, and sharing registration summaries and medication histories.

For the EHR-Lab Use Case, the goal is to allow a clinician to order and electronically obtain laboratory test results, and to electronically obtain historical and other relevant test results for the purpose of the clinical care of a patient. There is a requirement for interoperability between clinical care providers’ systems (which may include electronic health records), laboratory systems and the necessary supporting network, information and security services. Further security considerations include making use of services that manage patient identity, result delivery and notification, and that guarantee confidentiality, integrity and patient privacy.

In summary, the requirements for security and privacy are interwoven and directly derivable from the Harmonized Use Cases.

2.6 AUDIENCE

Each Interoperability Specification is designed to be used by analysts who need to understand the interoperability requirements for the described Use Case, and by implementers working to develop interoperable applications. Understanding and using the relevant set of Interoperability Specifications is a key requirement for establishing interoperability compliance.

2.7 COPYRIGHT PERMISSIONS

Each Interoperability Specification contains a copyright notice indicating the conditions under which the material may be used.

COPYRIGHT NOTICE

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2.8 INTEROPERABILITY SPECIFICATION MAINTENANCE PROCESS

The HITSP documentation process is a controlled publication process that is described in the HITSP Interoperability Specification Maintenance Process document and includes the following:

- Guiding principles for assessing the major, minor or editorial impact to releases
- Document status indicators and appropriate business use for each
- Document versioning scheme
- Description of the editing process
- Approval process for advancing changes through the Panel



- An illustration of how these guidelines and procedures interact for each level of publication

2.9 REFERENCED STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of standards organization, as defined by HITSP, which publishes the standard. HITSP interprets approval to include Draft Standards for Trial Use. The objective is to incorporate only standards that are managed within a formal life cycle process as defined by the standards organization. In some cases, where it is believed that a standard that is not yet approved may best meet the requirements of an Interoperability Specification, HITSP may provide a roadmap of its future intent conditional on future actions by either or both the standards organizations and the HITSP Technical Committee. Thus there are four classes of HITSP-committed standards.

- Approved for Use – standards included for unconditional use within a HITSP construct
- Interim – standards included for use now within a HITSP construct but for a defined time period or conditional on future actions, e.g., “Intended for Use” standard is available
- Provisional - standards that are not yet but are expected to be approved by the Standards Organization by the time the Interoperability Specification is released by HITSP. A "Provisional" standard becomes an "Approved for Use" standard only if:
 - It is approved by the Standards Organization by the time that the Interoperability Specification is released by HITSP and
 - It is substantially the same as it was when it was provisionally used and
 - It requires no further action by the Technical Committee
- Intended for Use – proposed standards that are roadmapped for future use pending actions by the Technical Committee and/or the standards organization. Therefore a standard is defined as “Intended for Use” because it will not likely be approved by the time that the HITSP construct is released but is sufficiently defined to enable detailed evaluation of how well it will meet technical and business requirements

HITSP may continue to use “Provisional” or “Interim” standards as they existed when incorporated into the HITSP construct if the expected conditions are not satisfied until such time as HITSP can replace them with a more suitable standard. In this circumstance, the Standards Organization would have no responsibility to maintain or correct this artifact. If a standard “Intended for Use” is not developed and approved in terms of time frame or content as expected by the Technical Committee at the time of its initial selection, it may be replaced. All standards used by HITSP must meet the HITSP selection criteria. The use of “Interim” and “Intended for Use” standards will be weighed against the alternative of simply declaring a gap for HITSP and the Standards Organizations to resolve.

