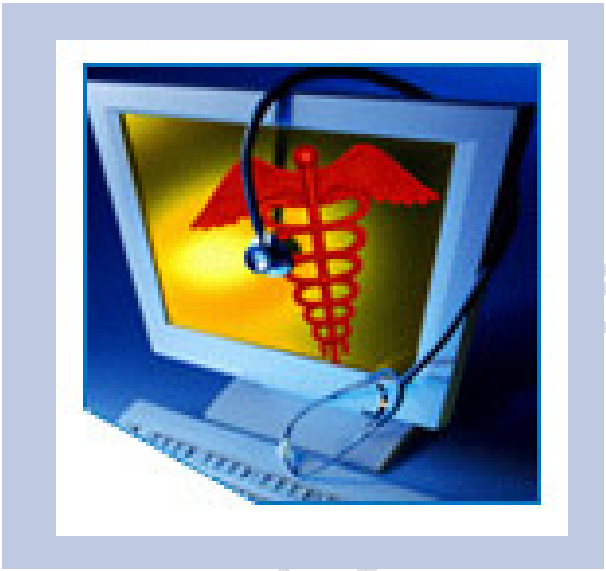
August 18, 2006
Version 1.0

HITSP Interoperability Specification: Electronic Health Records Laboratory Results Reporting

HITSP/IS-01



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Electronic Health Record Technical Committee

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DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final Draft	Electronic Health Record Technical Committee	18-August 2006

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1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) 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. 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 informatics to ensure that the resulting standards are globally relevant.
- Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case "breakthroughs areas" in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	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.
2.	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.
3.	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.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements imposed by the relevant use cases. It identifies and constrains standards where necessary, and creates groupings of specific actions and actors to further describe the relevant contexts. Where gaps and

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overlaps are identified, the interoperability specification provides recommendations and a roadmap for corrections to be made.

2.0 INTRODUCTION

The purpose of this Interoperability Specification is to describe the top-level specification for the vetted HITSP interpretation of the EHR use case. This use case comprises two scenarios that describe the entities and interactions that would be needed to implement an electronic EHR or other clinical data system with a laboratory interface. The goals supported by this Interoperability Specification are stated in the EHR Use Cases:

- Transmission of complete, preliminary, final and updated lab results to the EHR system (local or remote) of the ordering clinician;
- Transmission of complete, preliminary, final and updated (or notification) to the EHR system (local or remote) or other clinical data system of designated providers of care (with respect to a specific patient)

The EHR Use Case notes that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards.

This specification is the result of a considered assessment of the current practices in electronic laboratory results reporting and the requirements of the EHR Use Case. The EHR Technical Committee (EHR TC) chose this combination of standards because they meet the requirements of the Use Case and reflect both current practice and future directions for healthcare information sharing.

2.1 OVERVIEW

The Interoperability Specification focuses on a set of constrained standards for information interchange that address the core requirements of the Use Case described herein. It does 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.

This specification combines all of the transaction packages, stand-alone transactions, and components that comprise the solution set for the EHR Use Case. The core transaction packages are Send Lab Result Message with Optional Patient ID Cross-referencing (PIX) and Manage Sharing of Documents. Ancillary transaction packages address web services and Patent ID Cross-referencing. The Send Lab Result Transaction Package includes all the data definitions for the Health Level Seven (HL7) V2.5 Lab Result Message. The Manage Sharing of Documents Transaction Package is a generic document-sharing paradigm that can be used for any document. For this specification, the specific document of interest is the Lab Report Document, and an HL7 Clinical Document Architecture specification based the

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IHE Laboratory Technical Framework XDS-LAB. The Lab Report Document Structure Component Specification describes the Lab CDA document and the Lab Result Terminology Component describes the vocabulary for both the HL7 V2.5 message and the CDA document.

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The following sections of this specification describe how the EHR Use Case is satisfied by this collection of constructs and how the constructs are combined together to offer a coherent, flexible, and powerful framework.

110 The HITSP documents and external documents included under this specification are listed in Table 2.1-1

Related Documents	Document Description	Document Name and Location
HITSP/ISC-35	HITSP Interoperability Specification: EHR Lab Terminology Component	ISC_HITSP_35_v1.0_2006
HITSP/ISC-36	HITSP Interoperability Specification: Lab Report Message Component	ISC_HITSP_36_v1.0_2006
HITSP/ISC-37	HITSP Interoperability Specification: Lab Report Document Structure Component	ISC_HITSP_37_v1.0_2006
HITSP/ISC-44	HITSP Interoperability Specification: Secure Web Connection Component	ISC_HITSP_44_v1.0_2006
HITSP/ISC-45	HITSP Interoperability Specification: Acknowledgements Component	ISC_HITSP_45_v1.0_2006
HITSP/IST-22	HITSP Interoperability Specification: Patient ID Cross Referencing Transaction	IST_HITSP_22_v1.0_2006
HITSP/IST-23	HITSP Interoperability Specification: Patient Demographics Query Transaction	IST_HITSP_23_v1.0_2006
HITSP/IST-29	HITSP Interoperability Specification: Notification of lab report availability Transaction	IST_HITSP_29_v1.0_2006
HITSP/ISTP-13	HITSP Interoperability Specification: Manage Sharing of Docs Transaction Package	ISTP_HITSP_13_v1.0_2006
HITSP/ISTP-14	HITSP Interoperability Specification: Send Lab Result Message to Ordering Clinician and Providers of Care Transaction Package	ISTP_HITSP_14_v1.0_2006
HITSP/ISTP-18	HITSP Interoperability Specification: View lab results from a web application Transaction Package	ISTP_HITSP_18_v1.0_2006

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2.2 AUDIENCE

The interoperability specification is designed to be used by analysts and architects 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 interoperability set of specifications is a key requirement for establishing interoperability compliance.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to glossary in the appendix.

2.4 CONVENTIONS

This specification uses the following to convey the full descriptions and usage of standards:

UML sequence and activity diagrams

In these diagrams, the actors and transactions are highlighted within the framework of the specific scenario or context. The actors involved in the specified use-scenario or context are mapped out, and the interactions between each action and actor for a particular context, and the flow of data are provided through the use of arrows. Diagrams are named according to the section in which they reside, and will use the following naming convention:

Figure <section number>-<consecutive number for the diagram, e.g. 1, 2, 3, etc.>. <Short name/description of diagram>. For example, a diagram residing in section 3.1.3 showing the Actor Interactions for the Send Lab Results transaction package is named:

Figure 3.1.3-1. Send Lab Results Transaction Package

Tables

Tables are used to indicate standards categorizations, as well as dependencies and constraints between constructs. Tables are named according to the section in which they reside, and will use the following naming convention:

Table <section number>-<consecutive number for the table, e.g. 1, 2, 3, etc.>. <Short name/description of table>. For example, a table residing in section 2.7.1 showing the Dependencies between the transactions for the Send Lab Results transaction package is named:

Table 2.7.1-1. Send Lab Results Transaction Package dependencies

References

When references are made to another section within an Interoperability Specification a section number is used by itself. When references are made to other constructs that are related to the Interoperability Specification, such as Transaction Packages, Components or Composite Standards, the HITSP document short name and section number are displayed as follows:

<HITSP Document short name or Composite Standard Short Name>-<Volume Number>: <section number>

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where:
<HITSP document short name> is a short designator for the construct (e.g. HITSP/ISTP-013)
<Composite Standard Short Name> is a short designator for the composite standard (e.g. IHE-ITI TF)
<Volume Number> is the applicable volume within the given composite standard (e.g. 1)
<section number> is the applicable section number (e.g. 3.1)

For example: HITSP/ISTP-013: 3.1 refers to Section 3.1 in the Interoperability Specification for a Transaction Package, IHE-ITI TF-2: 4.33 refers to Section 4.33 in volume 2 of the IHE IT Infrastructure Technical Framework.

Reproductions

Where large sections of composite standards or base standards are reproduced within a HITSP specification, the reproduced sections are cited with introductory text containing the reference information for the composite or base standard. In addition, the beginning and ending of the reproduced text are respectively shown using a beginning statement:

The text for the <composite or base standard name> specification begins here:

And an ending statement:

The text for the <composite or base standard name> ends here.

2.5 COPYRIGHT PERMISSIONS

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3.0 STANDARDS REFERENCES

The EHR Selected standards June v1.4 deliverable contains a list of all the considered standards and a designation as to which ones were selected and which ones were provisional. This selection was arrived at by a consensus of the members of the HITSP EHR and Biosurveillance Technical Committees and was ratified by the Panel after public comment. The criteria that were used for selection included the requirements of the use case, compatibility with other HITSP standards, and acceptance by the user community.

3.1 LIST OF BASE STANDARDS

It is HITSP's policy to incorporate only standards that have been approved according to the formal policy of the standards development organization that publishes the standard. HITSP interprets approval to include standards for trial use. The objective of this policy is to select standards that are managed within a formal life cycle process as defined by the SDO. In some cases, where we believe a not-yet-approved standard

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best meets the requirements of an Interoperability Specification, HITSP may provisionally select and conditionally use such standard subject to the following conditions:

- The standard is approved by the time that the Interoperability Specification is released by HITSP.
- The standard approved is substantially the same as it was when provisionally used.

200 If either condition is not met at the date of the HITSP Interoperability Specification release, HITSP may continue to use the "standard" as it was in its provisional state until such time as HITSP can replace it with a more suitable artifact. In this circumstance, the SDO would have no responsibility to maintain or correct this artifact.

Information Interchange Standards	
Standard	Description
HL7 Version 2.5	The HL7 Version 2 Messaging Standard is an application protocol for electronic data exchange in healthcare that is maintained by HL7, an (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. In support of the HL7 messaging standard, HL7 also publishes value sets or code tables for use with specified fields in an HL7 message. Visit www.hl7.org for more information
HL7 Version 3.0	The HL7 Version 3 Messaging Standard is an application protocol for electronic data exchange in healthcare that is maintained by HL7, an (ANSI) -accredited Standards Developing Organizations (SDOs) operating in the healthcare arena. In support of the HL7 messaging standard, HL7 also publishes value sets or code tables for use with specified fields in an HL7 message. Visit www.hl7.org for more information
Terminology Standards	
Standard	Description
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)	A validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies, clinical trials, computerized physician order entry, disease surveillance, image indexing and consumer health information services. Maintained by the College of American Pathologists (CAP), information is available at www.snomed.org/snomedct/index.html.
Logical Observation Identifiers Names and Codes (LOINC®)	A database of Universal identifiers for laboratory and other clinical observations maintained by Regenstrief Institute. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology; etc. Contact the Regenstrief Institute at e-mail: loinc@regenstrief.org or visit www.regenstrief..org/loinc for more information.

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Legislative Standards	
Standard	Description
Clinical Laboratory Improvement Amendments (CLIA)	The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Visit www.cms.hhs.gov/clia for more information.
Health Insurance Portability and Accountability Act (HIPAA)	National standards for the protection of health information, as applied to the three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct certain health care transactions electronically. Visit www.hhs.gov/ocr/hipaa for more information.

3.2 LIST OF COMPOSITE STANDARDS

Composite Standard	Description
IHE IT Infrastructure Technical Framework , XDS Document Sharing	Integration Profile for managing the sharing of documents.
IHE Laboratory Technical Framework: IHE Content Integration Profile, Sharing Laboratory Reports (XDS-LAB) Vol. 3	Integration Profile for implementing a Lab Report as an electronic document.
IHE Patient Demographics Query and Patient ID Cross Referencing	Integration Profiles for matching patients based on demographics or by cross-referencing Patient Ids.
Unified Code for Units of Measure (UCUM)	The Unified Code for Units of Measure is a code system intended to include all units of measure used in science, engineering, and business with the goal of facilitating unambiguous electronic communication of quantities together with their units.

3.3 BASE STANDARDS GAPS AND OVERLAPS

The EHR TC has identified gaps in terminology standards for reporting lab results. These gaps are minimized by the selection of standards that give the widest coverage, but vocabulary domains with clinical content are very large and encompass many specialties. The innovation in healthcare informatics is fast-paced, resulting in gaps as the standards attempt to catch up. In particular, the following gaps have been identified:

Use Case Events and Associated Gaps:

Event Code	Event Description	Identified Gaps	Recommended Resolution
3.3.1.1	Create test results	SNOMED CT covers many precise areas of lab, but some specialty areas may not be fully covered in sufficient depth.	Observation value is a dynamic area and is continuously evolving. HITSP involvement may encourage more rapid evolution.
3.3.1.1	Create test results	LOINC is similar to SNOMED CT for Observation Identifier	Observation identifier is a dynamic area and is continuously evolving. HITSP involvement may encourage more rapid evolution

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3.3.1.1	Create test results	Universal Service Identifier does not have a standard vocabulary. One is needed.	There are a number of efforts underway to develop a terminology within some organizations, but these are often regional and vary by entity. There are also international efforts (Canada, Australia, and the UK, etc.) where this terminology is being developed nationally. HITSP could leverage some of these efforts after further analysis on current status.

STANDARDS OVERLAPS

In addition to gaps, there is a significant overlap. This overlap is well understood and monitored by the sponsoring SDO.

Event Description	Standard Duplication/ Overlap	Recommended Resolution
Multiple, including 3.2.1.0 and 3.4.1.1.	Results are reported through either the HL7 2.5 message or through the CDA document	It is recommended we leave this overlap in place because each solves different problems addressed by the use case. For example, documents are preferable for persistent storage, and messages are preferable for processing.

RESOLUTION PLAN

The HITSP EHR TC makes the following recommendation to resolve the identified gaps in terminologies:

Date	Task to be Accomplished/Who is involved
2006	Consider leveraging HITSP influence to coordinate and drive activities to develop a universal service identifier.
2006	HITSP should ensure transparency in terminology development and other efforts in order to promote universal adoption of the selected terminologies for laboratory results reporting.

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4.0 INTEROPERABILITY REQUIREMENTS

4.1 USE CASE OVERVIEW

The EHR Use Case is relevant to clinical care providers who wish to have laboratory test results and laboratory interpretations electronically available for patients for whom they are providing care. Laboratory test results and interpretations are available for integration into an electronic health record (EHR, local or remote) or another clinical system. The use case includes two scenarios that cover typical interfaces involving an EHR system (or equivalent) and lab results.

4.1.1 SCENARIO OVERVIEW

Scenario #1

In the first scenario, lab test results are transmitted as a result of the order. The specifics of the ordering process are outside the scope of this use case. The test results are sent directly to the clinician's EHR system (local or remote) and/or another clinical data system, to provide lab results to ordering and non-ordering authorized recipients.

Scenario #2

A clinician accesses historical test results related to a specific patient by first discovering the data and then retrieving or receiving the data. Data may be sent automatically to the clinician's EHR or other clinical system (local or remote) upon selection, or the clinician may separately request the test results, possibly from a separate data repository.

4.1.1.1 SCENARIO CONSTRAINTS

The constraints or modifications placed on these scenarios are:

- Added interaction from Laboratory to clinician based on widespread usage of that interface today, and to meet needs implied in event code 3.4.1.1 and elsewhere. This has been shown in the Interaction diagram for Scenario #1 Messaging Alternative
- Although public health reporting is not explicitly cited within the EHR-Lab use case, the provision has been included to help satisfy Biosurveillance use case requirements.

4.1.1.2 SCENARIO PRE-CONDITIONS

In order to implement the information interchange conforming to this Interoperability Specification and its constructs in a real world environment, the implementer must ensure that the implementing systems operate within a secure infrastructure that insures the privacy, integrity and availability of all personally identifiable health information as prescribed by the Health Insurance Portability and Accountability Act, all other applicable laws and regulations and terms of any contracts and agreements. The information interchange standards may also assume that certain information technology infrastructure and functions are in place. These assumptions collectively are the general pre-conditions for conforming to this Interoperability Specification and its constructs.

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Specific preconditions for this scenario include:

- Assume that all pre-conditions from the lower level constructs (transaction packages etc) are incorporated
- Assume that an order for lab testing has been created and exists
- Relationships between organizations utilizing the HITSP IS are well defined and understood.
- When needed, the patient is uniquely registered with the patient ID cross referencing service
- The order contains an electronic address of all authorized electronic recipients
- Appropriate authorization, authentication and consent procedures are in place
- Secure electronic transport is assumed between sender(s) and receiver(s)

4.1.1.2.1 SCENARIO TRIGGERS

Triggers are conditions or real-world events that are necessary to start off any processing. The underlying processes need to recognize the following types of trigger events to initiate the transactions in this specification:

- Assume that all scenario triggers from the lower level constructs (transaction packages etc) are incorporated.
- The trigger for being able to transmit a result is that it is deemed is releasable (scenario #1)
- There is a clinical need, or other authorized use, for the patient lab result(s) (scenario #2)

4.1.1.3 SCENARIO POST-CONDITIONS

Assume that all scenario post-conditions from the lower level constructs (transaction packages etc) are incorporated.

4.1.1.3.1 SCENARIO OUTPUTS

The output from these two scenarios is that the result is received and is viewable or can be processed.

4.1.1.4 SCENARIO BUSINESS ACTORS

Actor	Description
Patient ID Cross-Referencing Service	An application that references a patient data base for the purpose of identifying a particular patient based on one of many IDs or by matching patient demographics.
Clinician	May be an individual, an organization or "system." When appropriate the clinician perspective is further specified as an 'ordering clinician' (responsible for ordering the lab test) or a 'provider of care' (providing care to the patient, but not the ordering clinician).
Patient	Receiver of care from a healthcare professional.
Laboratory	Produces the laboratory results. Organizations operating as the clinician perspective may also operate under the laboratory perspective if laboratory testing services are performed by the organization.

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Actor	Description
Repository	The system that provides the laboratory test results
Locator Service	Responds to queries for the test results by providing the list of available test results and their locations within data repositories.

4.1.1.5 SCENARIO TECHNICAL ACTORS

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A technical actor is a role assumed by an application for the purposes of performing some function. In this case, the function is to send or receive a transmission. The technical actors used by this specification are:

Actor	Description
Document Consumer	The Document Consumer Actor queries a Document Registry Actor for documents meeting certain criteria, and retrieves selected documents from one or more Document Repository actors.
Document Registry	The Document Registry Actor maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.
Document Repository	The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a URI to documents for subsequent retrieval by a Document Consumer.
Document Source	The Document Source Actor is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository Actor for subsequent registration of the documents with the Document Registry Actor.
Lab Result Receiver	This actor is the ordering clinician, other authorized provider of care or a document repository.
Lab Result Sender	This actor sends laboratory results as messages or as documents to the ordering clinician or other authorized providers of care, or to a document repository.
Notification Receiver	This actor receives notifications of availability for documents in an XDS registry, and may optionally send acknowledgments of them.
Notification Sender	This actor sends notifications of availability for documents in an XDS registry, and receives acknowledgements of these notifications.
Patient Identifier Cross Reference Consumer	Queries a Patient Identifier Cross Reference Manager for a set of identifiers for a patient.

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Actor	Description
Patient Identifier Cross Reference Manager	Responsible for creating, maintaining and providing lists of identifiers that are aliases of one another across different Patient Identifier Domains.
Patient Identity Source	Provider of unique identifiers for each patient.

4.1.1.6 SCENARIO ACTOR INTERACTIONS

This section describes the interactions between actors that comprise the two scenarios. The transactions shown in the UML diagrams are the transactions specified in the various sub-components of this interoperability specification. The event codes from the ONC harmonized use case are annotated on the diagrams to show how the transactions are implementing the use case.

Scenario #1

Two alternatives were selected to implement this scenario. Figure 4.1.1.6-1 shows the interactions for the messaging alternative and figure 4.1.1.6-2 shows the interactions for the document alternative.

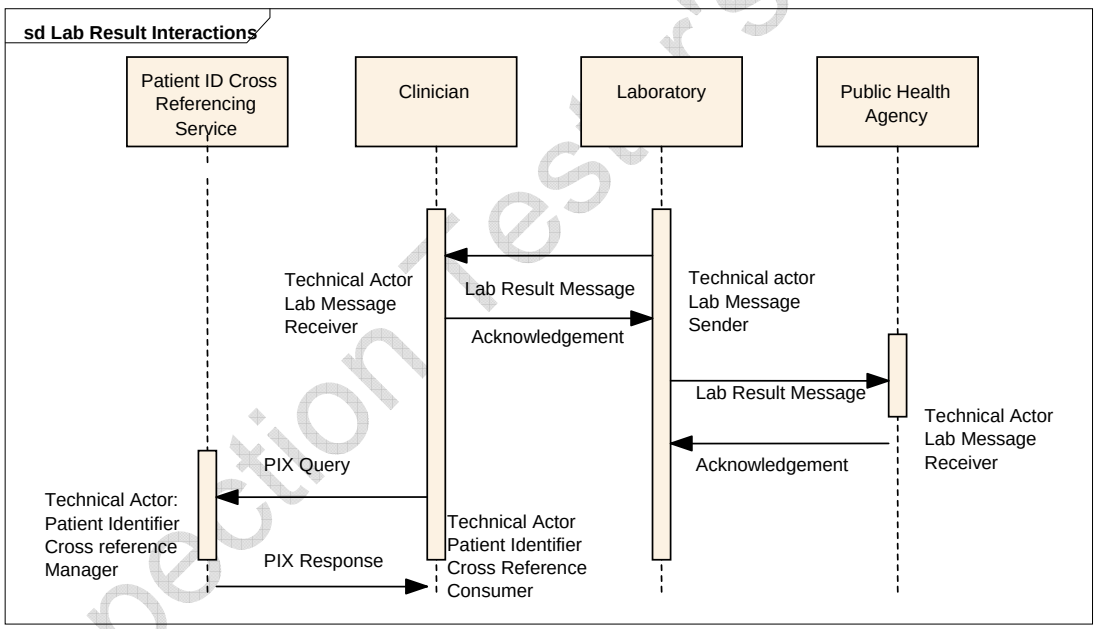

Figure 4.1.1.6-1 – Transactions for Messaging Alternative for Scenario #1

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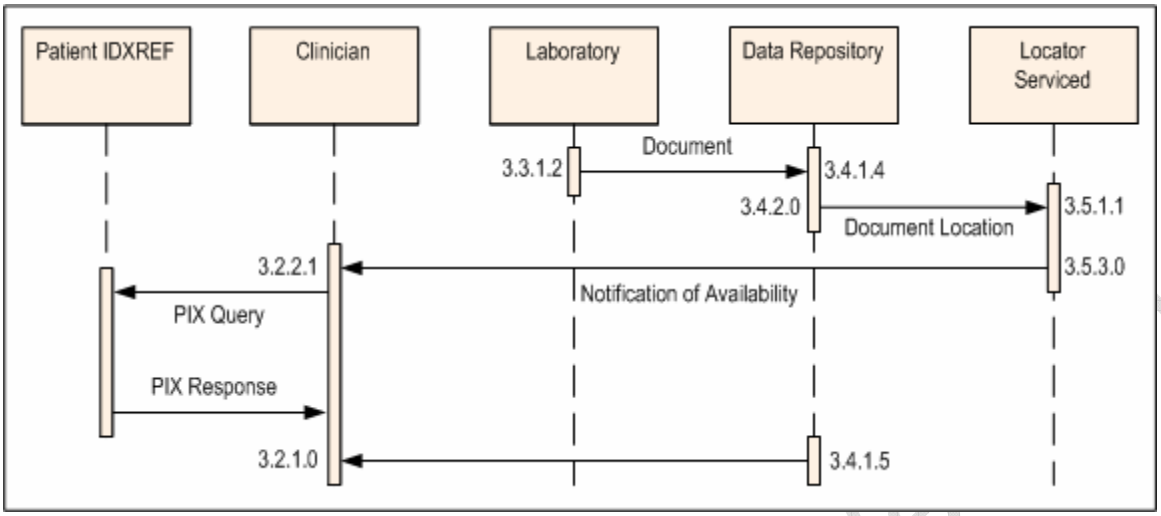

Figure 4.1.1.6-2 Transactions for the Document Alternative for Scenario #1

Scenario #2

This scenario is dependent on Scenario #1 in that the Laboratory must have sent the result to the Data Repository and the repository must have registered the location of the result in the Locator Service.

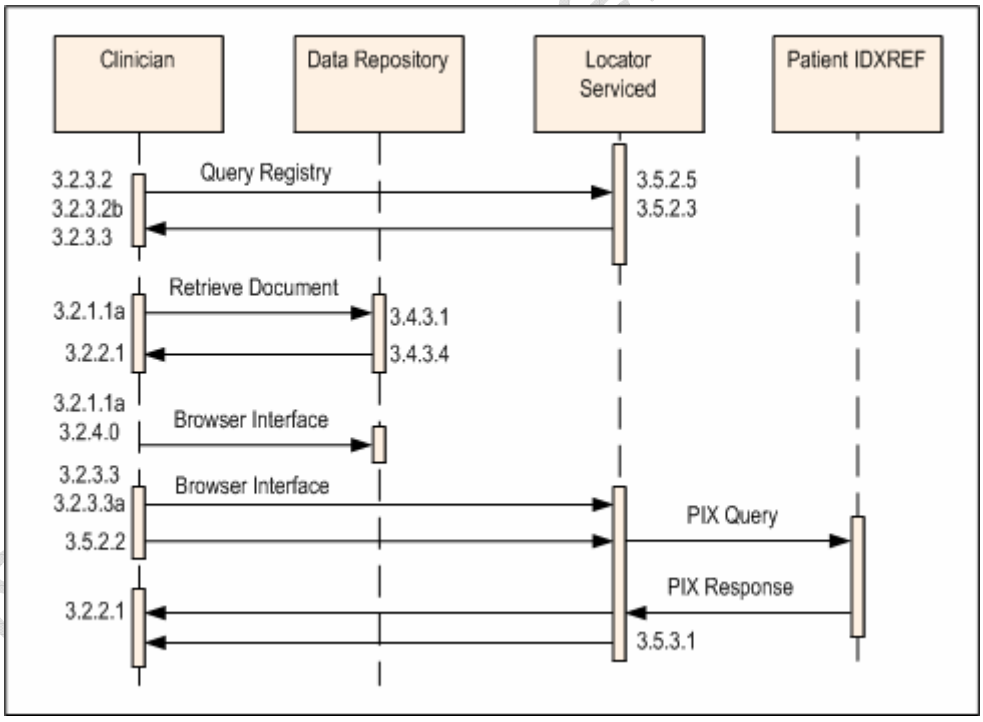

Figure 4.1.1.6-3 Transactions for Scenario #2

The following tables show the mappings between the business actors in the EHR Use Case and the technical actors described for the transactions. It is important to note that a business actor can assume the role of more than one technical actor depending on how many transactions are involved.

Business Actor	Technical Actor
Patient ID Cross-Referencing Service	Patient Identifier Cross Reference Manager
Clinician	Patient Identifier Cross Reference Consumer

Table 4.1.1.6-1 Mapping for Consumer/Patient ID Cross-Referencing Transaction Package

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Business Actor	Technical Actor
Patient	Not Applicable (MPI Service is a stand-in for Patient)
Laboratory	Document Source
Clinician	Document Consumer
Repository	Document Repository
Locator Service	Document Registry
Locator Service	Patient Identity Source

Table 4.1.1.6-2 Mapping for Manage Sharing of Doc Transaction Package

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Business Actor	Technical Actor
Patient	Not Applicable (MPI Service is a stand-in for Patient)
Laboratory	Lab Result Sender
Clinician	Lab Result Receiver

Table 4.1.1.6-3 Mapping for Send Lab Result Transaction Package

Business Actor	Technical Actor
Patient	Not Applicable (MPI Service is a stand-in for Patient)
Laboratory	Lab Result Sender
Clinician	Lab Result Receiver

Table 4.1.1.6-4 Mapping for Notification of Lab Report Availability

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Business Actor	Technical Actor
Locator Service	Notice of Availability Sender
Clinician	Notice of Availability Receiver

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4.2 LIST OF TRANSACTION PACKAGES AND INDEPENDENT TRANSACTIONS

The following list of transaction packages and their definitions are used by the interoperability specification.

Transaction Package/Independent Transaction	Description	Document References	Date Added
Send Lab Result	Specification for sending a lab result as a message or as a document	HITSP/ISTP-14	8-2006
Manage Sharing of Docs	Specification for a data locator and repository for shared storage of documents	HITSP/ISTP-13	8-2006
Patient Demographics Query and Patient ID Cross Referencing	Uniquely identify a patient through query and/or matching of key elements. Query and retrieve any patient demographic	HITSP/ISTP-22	8-2006
Acknowledgements	Automated assertion that the information was received and correct	HITSP/ISC-25	8-2006
Notification of document availability	Defines a mechanism for point-to-point notifications between systems or users within an XDS Affinity Domain. These notifications can be used to trigger various activities within applications that implement both XDS and NAV.	HITSP/IST-29	8-2006

4.2.1 DEPENDENCIES

The following table shows a list of transaction packages with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific transaction package or independent transaction specification. To support a dependent transaction or transaction package, a technical actor must implement all the required constructs in the prerequisite transaction package, or be grouped together with another transaction package as specified in the table below:

Transaction Package/Independent Transaction	Depends On (Name of transaction or transaction package that it depends on)	Dependency Type (Pre-requisite, grouping)	Purpose (Reason for this dependency)
Send Results Message Transaction Package	Patient ID Cross-Referencing	Pre-requisite	Send Results Message Transaction Package contains Patient ID Cross-Referencing
Patient ID Cross-Referencing			
Manage Shared Documents	Structured Lab Document Component	Pre- requisite	Payload

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Transaction Package/Independent Transaction	Depends On (Name of transaction or transaction package that it depends on)	Dependency Type (Pre-requisite, grouping)	Purpose (Reason for this dependency)
Manage Shared Documents	Lab Result Terminologies Component	Pre- requisite	Vocabulary
View Web Results from a Web Application	Secure Web Connection	Pre- requisite	Connection
Secure Web Connection	None		

4.2.2 CONSTRAINTS

Transaction Package/Transaction	Constraint	Constraint Type (Pre-condition, post-condition, general)	Purpose (Reason for this constraint)
Noted above.			

5.0 TECHNICAL IMPLEMENTATION

5.1 CONFORMANCE

A system conforming to this specification must implement this complete specification.. Conformance also includes supporting the pre and post conditions and implementing the constraints to the standards specified in the component, transaction and transaction package specifications associated with this Interoperability Specification as well as those in the Interoperability Specification.

6.0 APPENDIX

6.1 HITSP HARMONIZATION FRAMEWORK

There are several constructs that are being used to define the interoperability specification, with each level providing more granularity to the standards applicable for fulfillment of the Use Case. The table below describes the current framework within which the interoperability specification is being built, the relationships between each construct, and further illustrative examples.

	Construct	Definition	Example	Rules
1	Use Case Harmonization Request	Defines business/functional requirements and specifies the relevant context	ONC Harmonized ONC Harmonized EHR Use Case	
2	Interoperability Specification	Models the business/functional requirements, identifies technical/system requirements to meet the specified use-case, and then identifies how to use one or more standards to meet the use-case	HITSP HER Interoperability Specification	Based on UML diagram to identify actors and actions Sets context Testable functional requirements Identifies transaction(s) or packages

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	Construct	Definition	Example	Rules
				of transactions
3	Transaction Package	Defines how two or more transactions are used to support a stand-alone information exchange within a defined context between two or more systems	Record Locator Service, Entity Identification Service	Thin context and functional requirements Testable Based on analysis of like actors, context and content harmonized across the transactions May be fulfilled by one or more complex standards Expresses constraints on how the transactions are used together
4	Transaction	Logical grouping of actions, including necessary content and context, that must all succeed or fail as a group.	Query lab result, Send lab result	Fulfills all actions between two systems that meet one or more functional requirements Testable Expresses constraints on how the components and/or standards are used together
5	Component	An atomic construct used to support an information interchange or to meet an infrastructure requirement (e.g., security, logging/audit)	Lab result message, Lab result context	Typically will use one "primary" standard and may have other "secondary" standards May express constraints on how the standards are used
6	Base Standard	A standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization.	Messaging standard, Security standard, Code set.	Per HITSP definition the term "standard" refers to (and is not limited to): –Specifications –Implementation Guides –Code Sets –Terminologies –Integration Profiles
7	Composite Standard	Grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. In HITSP, it can serve as a component, transaction or transaction package functional requirements.	Integration profiles Implementation guides Health transaction services	Per HITSP Definition

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6.2 USE CASE ACTIONS AND EVENTS

Event/Action Code	Description
3.1.1.0 Event: Provide patient identity information, update as needed	
3.1.1.1	Action: Provide identification data
3.1.2.0 Event: Identify providers of care, update as needed	
3.1.2.1	Action: Provide list of providers of care
3.1.2.1a	Alternate Action: Indicate that test results should not be made available to other providers of care
3.2.1.0 Event: Integrate results and view in EHR	
3.2.1.1a	Alternate Action: Send request for historical lab test result content to data repository(ies)
3.2.1.6	Action: Acknowledge receipt of lab results
3.2.2.0 Event: Receive notification of lab test results	
3.2.2.1	Action: Receive notification that test results are available
3.2.3.0 Event: Query for laboratory (historical) test results	
3.2.3.2	Action: Clinician and locator system agree on patient identity through patient trait matching
3.2.3.2b	Alternate Action: Clinician and locator system agree on patient identity based on patient identifier matching
3.2.3.3	Action: Transmit request for specific lab test results based on order number or other unique test result identification
3.2.3.3a	Alternate Action: Browse, select and confirm the relevant test results for the correct patient and transmit request
3.2.3.4	Action: Receive the data repository location where the test results are stored
3.2.4.0 Event: View results using another clinical data system (non–EHR system)	
3.2.4.1	Action: Send request for lab test result content to data repository(ies)
3.2.4.3	Action: Receive and view laboratory test results
3.2.4.5	Action: Acknowledge receipt of lab results
3.3.1.0 Event: Process Laboratory Order	
3.3.1.1	Action: Create test results
3.3.1.2	Action: Send results to data repository
3.4.1.0 Event: Store laboratory results	
3.4.1.3	Action: Acknowledge receipt of test lab results
3.4.1.4	Action: Store test lab results
3.4.1.5	Action: Transmit lab test results to ordering clinician and other providers of care if appropriate
3.4.2.0 Event: Notify locator service of laboratory results	
3.4.2.2	Action: Send result location and related information to locator service
3.4.3.0 Event: Process Request for Laboratory Test Results	
3.4.3.1	Action: Receive and validate the query request

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Event/Action Code	Description
3.4.3.4	Action: Transmit lab results of an identified patient to an ordering clinician or provider of care
3.5.1.0 Event: Publish availability of laboratory test results	
3.5.1.1	Action: Receive test result (file) location information and related information
3.5.2.0 Event: Process query to provide laboratory test result location(s)	
3.5.2.2	Action: Clinician and locator system agree on patient identity
3.5.2.3	Action: Receive request for lab test results based on lab order number or other unique lab test identifier
3.5.2.3a	Alternate Action: Provide lab result availability information based on clinician query/browse
3.5.2.5	Action: Send lab result location (links) pointers to authorized clinician.
3.5.3.0 Event: Notify provider(s) of care of new laboratory test results	
3.5.3.1	Action: Send notification to provider(s) of care

6.3 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found at: http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel

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