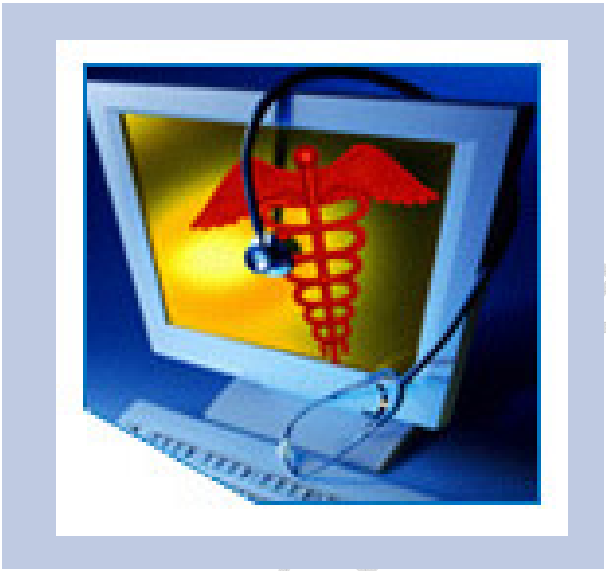
August 18, 2006
Version 1.0

HITSP Interoperability Specification: Manage Sharing of Documents Transaction Package

HITSP/ISTP-13



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Electronic Health Records Technical Committee

DOCUMENT CHANGE HISTORY

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

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.

Table 1.0-1 Use Case Areas

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

2.0 INTRODUCTION

To support "Manage Sharing of Documents", HITSP is using the ***Cross-Enterprise Document Sharing*** IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. Cross-Enterprise Document Sharing (**XDS**) is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprises, ranging from a private physician office to a clinic to an acute care in-patient facility.

2.1 OVERVIEW

This specification includes by reference the transactions and components that comprise the Manage Document Sharing Message package. It describes the processes supported by these structures and the work that is accomplished by implementing this transaction package. Source material was from the "Integrating the Healthcare Enterprise (IHE)" IT Infrastructure (ITI) Technical Framework (TF) Cross-Enterprise Document Sharing (XDS) profile. As a result of this work, five transaction specification documents were collapsed into the "Manage Document Sharing" transaction package IS including:

- HITSP Transaction: retrieve record/patient data
  - [ITI-16: Query Registry]
  - [ITI-17: Retrieve Document]
- HITSP Transaction: query for clinical document
  - [ITI-17: Retrieve Document]
- HITSP Transaction: register document in RLS (Report Location Service)
  - [XDS ITI-14: Register Document Set]
- HITSP Transaction: send document
  - [ITI-15: Provide & Register Document Set]
- HITSP Transaction: store query
  - [ITI-18: Registry Stored Query] (functionally identical to ITI-16)

Related Documents	Document Description	Document Name and Location
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	Volume 1 (ITI TF-1) Integration Profiles Revision 2 August 15, 2005	www.IHE.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	Volume 2 (ITI TF-2) Transactions Revision 2 August 15, 2005	www.IHE.net
Integrating the Healthcare	Supplement	www.IHE.net

Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	(ITI TF-Supplement) Registry Stored Query for XDS Integration Profile Jun 9, 2006	
HITSP Notification of Document Availability (NAV) Transaction	29 September 2006	HITSP/IST-29

Table 2.1-1 Related Documents

2.2 AUDIENCE

The 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 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>

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 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

IHE materials used in this document have been extracted from relevant copyrighted materials with permission of Integrating the Healthcare Enterprise (IHE). Copies of this standard may be retrieved from the IHE website at www.ihe.net.

2.7 LIST OF TRANSACTIONS

The following list of transactions and their definitions are used by the transaction package specification.

Transaction Name	Description	Document Name	Date Added
XDS ITI-16: Query Registry	HITSP Transaction: retrieve record/patient data	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	10 Aug 06
XDS ITI-17: Retrieve Document	HITSP Transaction: retrieve record/patient data	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	10 Aug 06
XDS ITI-18: Registry Stored Query	This message is initiated when the Document Consumer wants to query/retrieve document metadata.	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Supplement	15 Aug 06
XDS ITI-12: Retrieve Document for Display	HITSP Transaction: query for clinical document	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	10 Aug 06
XDS ITI-14: Register Document Set	HITSP Transaction: register document in RLS (Report Location Service)	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	10 Aug 06
XDS ITI-15: Provide & Register Document Set	HITSP Transaction: send document	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF)	10 Aug 06

Table 2.6-1 List of Transactions

2.7.1 DEPENDENCIES

The following table shows a list of transactions with their existing dependencies. Dependencies usually exist when there are some additional pre-requisites for a specific transaction specification.

Transaction Name	Depends On (Name of transaction that it depends on)	Dependency Type (Pre-condition, post-condition, general)	Purpose (Reason for this dependency)
all	Patient Identity feed	Pre-condition	Confirm patient exists

Table 2.6.1-1 Dependencies

2.7.2 CONSTRAINTS

Not Applicable

3.0 TRANSACTION PACKAGES

3.1 CONTEXT OVERVIEW

The IHE XDS specification was written and published in August 15, 2005 by Integrating the Healthcare Enterprise (IHE). The IHE XDS composite standard, which is reproduced in part in this specification with specific written permission from IHE, provides sample scenarios depicting how specific technical actors should comply with the proposed standards for interoperability. The entire IHE XDS composite standard is also available at http://www.ihe.net.

The document is included here to highlight the HITSP approaches to implementation, and to depict how the Manage Sharing of Docs Transaction Package should work between the relevant actors and actions. The descriptions for each scenario were taken in their entirety from the publication, and therefore the same terms are used throughout this specification. These terms have the same meaning for purposes of this discussion. Any comments on the IHE XDS specification may be submitted to IHE, through the http://ihe.net Web site. The text for the IHE XDS specification begins here:

The ***Cross-Enterprise Document Sharing (XDS)*** IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility. An **XDS Document** is the smallest unit of information that may be provided to a Document Repository Actor and be registered as an entry in the Document Registry Actor. An XDS Document is a composition of clinical information that contains observations and services for the purpose of exchange with the following characteristics: Persistence, Stewardship, Potential for Authentication, and Wholeness. These characteristics are defined in the HL7 Clinical Document Architecture Release 2 specification. An XDS Document may be human readable (with the appropriate application). In any case, it should comply with a published standard defining its structure, content and encoding. IHE intends to define content-oriented Integration Profiles relying on such content standards to be used in conjunction with XDS.

The XDS Integration Profile manages XDS Documents as a single unit of information; it does not provide mechanisms to access portions of an XDS Document. Only the Document Sources or Document Consumers have access to the internal information of the XDS Document. When submitted for sharing, an XDS Document is provided to the Document Repository Actor as an octet stream. When retrieved through the Retrieve Document transaction, it shall be unchanged from the octet stream that was submitted.

The Document Source Actor is responsible to produce the metadata that will be submitted to the Document Registry Actor to form the XDS Document Entry that will be used for query purposes by XDS Consumer Actors. The Document Source maintains responsibilities over the XDS Documents it has registered. It shall replace XDS Documents that may have been submitted in error. See ITI TF-1: Appendix K for a more detailed discussion of the concept of XDS Document.

XDS Documents are required to be globally uniquely identified. See ITI TF-2: Appendix B for a definition of globally unique identifiers.

An XDS Submission Request is a means to share XDS Documents. It may be conveyed:

- by a Document Source Actor in a *Provide and Register Document Set Transaction* to the Document Repository Actor, or
- by a Document Repository Actor in a *Register Document Set Transaction* to the Document Registry Actor

An XDS Submission Request contains elements of information that will ensure the proper registration of XDS Documents. These are:

1. Metadata to be placed in Document Entries for new XDS Documents being submitted,
2. A Submission Set that includes the list of all new XDS Documents and Folders being submitted and optionally a list of previously submitted XDS Documents,
3. If desired, Folders to be created with the list of included XDS Documents (new document being submitted as well as previously submitted),
4. If desired, addition to previously created Folders of lists of XDS Documents (new document being submitted as well as previously submitted), and
5. Zero or more XDS Document octet streams for the new XDS Documents being submitted.

Following a successful Submission Request, new XDS Documents, Submission Set, and Folders included in the Submission Request are available for sharing in an XDS Clinical Affinity Domain. In case of failure to process a Submission Request, the Submission Set and any XDS Documents and Folders shall not be registered.

An **XDS Submission Set** is related to care event(s) of a single patient provided by the care delivery organization EHR-CR performing the submission request. It creates a permanent record of new XDS Documents as well as pre-existing (i.e. already registered) XDS Documents that have a relationship with the same care event(s). It also includes the record of new XDS Folders creation.

An XDS Submission Set shall be created for each submission request. It is related to a single Document Source Actor and is conveyed by a single Provide & Register Document Set Transaction or a Register Document Set Transaction.

The Document Registry may be queried to find all documents registered in the same XDS Submission Set.

The same XDS Document, initially registered as part of a Submission Set, may also be referenced by later XDS Submission Set. This allows older documents relevant to the present care of a patient to be associated with more recent Submission Sets.

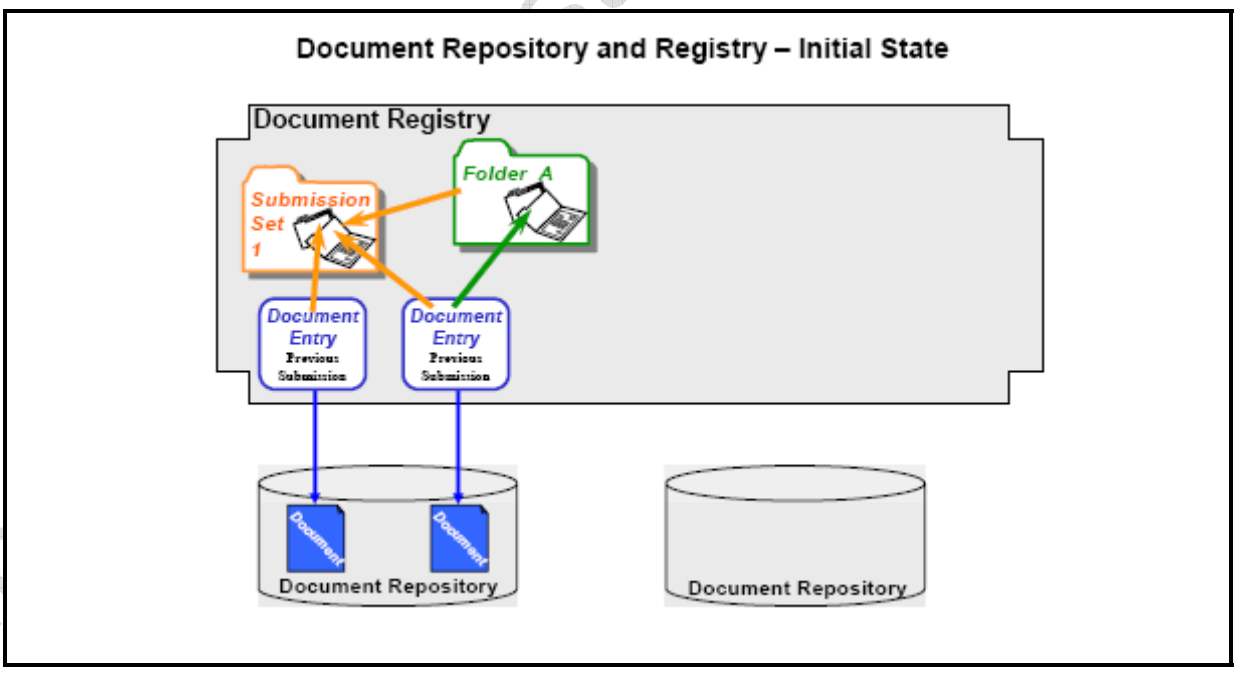
XDS provides complete flexibility to EHR-CRs to relate Documents and Submission Sets to an encounter, a visit, an episode of care, or various workflow processes within EHR-CRs.

The purpose of an **XDS Folder** is to provide a collaborative mechanism for several XDS Document Sources to group XDS Documents for a variety of reasons (e.g. a period of care, a problem,

immunizations, etc.) and to offer the Document Consumers a means to find all Document Entries placed in the same Folder. The following principles apply to an XDS Folder:

1. A Folder groups a set of XDS Documents related to the care of a single patient,
2. One or more Document Source Actors may submit documents in a given Folder,
3. A Folder may be created by a Document Source and/or predefined in an Affinity Domain,
4. The content of a Folder is qualified by a list of codes/meaning,
5. Document Source Actors may find existing Folders by querying the Document Registry or by means outside the scope of XDS (e.g. Cross-enterprise workflow, such ePrescription, eReferral, etc),
6. Once created a Folder is permanently known by the Document Registry,
7. Placing previously existing Documents in Folders is not recorded as part of the Submission Set,
8. Folders in XDS may not be nested,
9. The same documents can appear in more than one Folder, and
10. Folders have a globally unique identifier.

The sequence of figures below shows an example of a submission request that includes two new documents, a reference to a pre-existing document and the use of two folders. The first figure depicts the initial state of a Document Registry in which two Documents have been submitted where one is associated with a Folder A. The second figure depicts a submission request that adds two new documents, placing one of them into a pre-existing folder and the other one into a new Folder B.



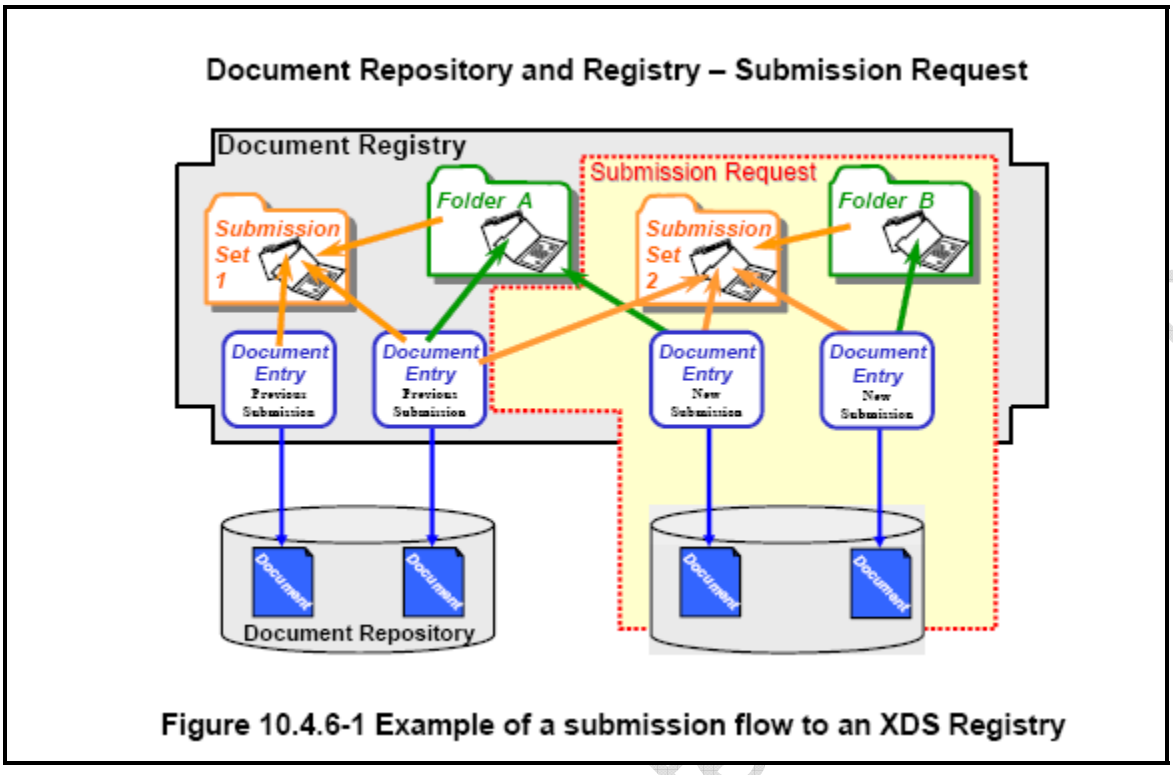


Figure 10.4.6-1 Example of a submission flow to an XDS Registry

NOTE: The above figure is from the IHE-ITI-TF-1 10.4.6

290 From the above example, the contents of a Submission Set are shown by the figure below. The Document Entries associated with the Submission Set are logical part of the Submission Set.

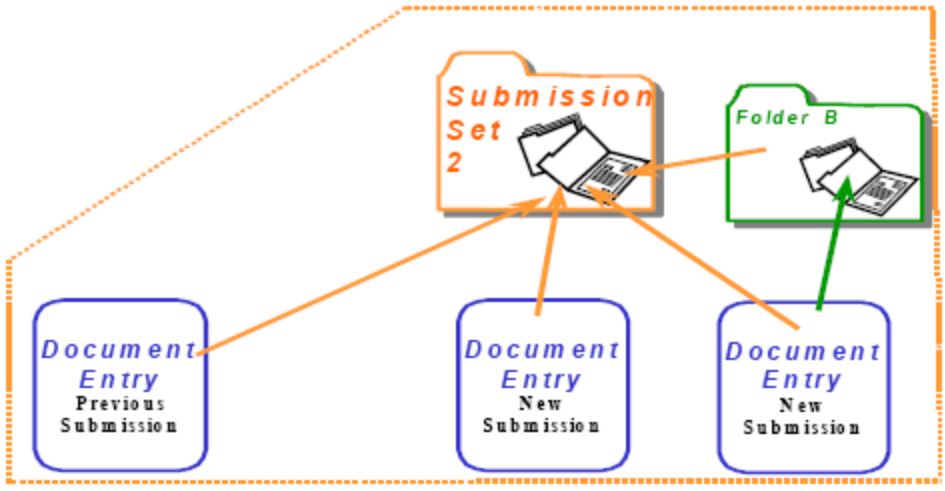


Figure 10.4.6-2 The logical content of a Submission Set

NOTE: The above figure is from the IHE-ITI-TF-1 10.4.6

3.1.1 CONTEXTUAL CONSTRAINTS

The XDS IHE Integration Profile assumes that these enterprises belong to one or more clinical affinity domains. A clinical affinity domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and share a common infrastructure.

Examples of affinity domains include:

- Community of Care supported by a regional health information organizations in order to serve all patients in a given region.
- Nationwide EHR
- Specialized or Disease-oriented Care
    - Cardiology Specialists and an Acute Cardiology Center
    - Oncology network
    - Diabetes network
- Federation of enterprises
    - A regional federation made up of several local hospitals and healthcare providers
- Government sponsored facilities (e.g., VA or Military)
- Insurance Provider Supported Communities

Within a clinical affinity domain, certain common policies and business rules must be defined. They include how patients are identified, consent is obtained, and access is controlled, as well as the format, content, structure, organization and representation of clinical information. This Integration Profile does not define specific policies and business rules, however it has been designed to accommodate a wide range of such policies to facilitate the deployment of standards-based infrastructures for sharing patient clinical documents. This is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain. These are distinct entities with separate responsibilities:

- A document repository is responsible for storing documents in a transparent, secure, reliable and persistent manner and responding to document retrieval requests.
- A document registry is responsible for storing information about those documents so that the documents of interest for the care of a patient may be easily found, selected and retrieved irrespective of the repository where they are actually stored.

The concept of a document in XDS is not limited to textual information. As XDS is document content neutral, any type of clinical information without regard to content and representation is supported. This makes the XDS IHE Integration Profile equally able to handle documents containing simple text, formatted text (*e.g.,* HL7 CDA Release 2), images (*e.g.*, DICOM) or structured and vocabulary coded clinical information (*e.g.*, CDA Release 2, CCR, CEN ENV 13606, DICOM SR). In order to ensure the necessary interoperability between the document sources and the document consumers, the Clinical Affinity Domain must adopt policies concerning document format, structure and content.

The XDS Integration Profile is not intended to address all cross-enterprise EHR communication needs. Some scenarios may require the use of other IHE Integration profiles, such as Patient Identifier Cross-Referencing, Audit Trail and Node Authentication, Cross-Enterprise User Authentication, and Retrieve Information for Display. Other scenarios may be only partially supported, while still others may require future IHE Integration profiles, which will be defined by IHE as soon as the necessary base standards are available. Specifically:

1. The management of dynamic information such as allergy lists, medication lists, problem lists, etc is not addressed by XDS. However, the Retrieve Information for Display Integration Profile does provide some transactions (e.g., LIST-ALLERGIES, LIST-MEDS) that may be used to provide an elementary support of such capabilities. A complementary approach to managing updates and structured application access to such dynamic clinical information may be expected as a separate Integration Profile in the future.

2. The placing and tracking of orders (e.g. drug prescriptions, radiology orders, etc.) is not supported by XDS. This does not preclude the use of XDS to store and register orders and corresponding results when such artifacts need to be recorded in the patient's health record. However, XDS provides no facilities for tracking progress of an order through its workflow, and therefore is not intended for order management. A complementary approach to cross-enterprise order workflow (ePrescription, eReferral) may be expected as separate Integration Profiles in the future.

3. The operation of any XDS Clinical Affinity Domain will require that a proper security model be put in place. It is expected that a range of security models should be possible. Although the XDS Integration Profile is not intended to include nor require any specific security model, it is expected that XDS implementers will group XDS Actors with actors from the IHE Audit Trail and Node Authentication and will need an Access Control capability that operates in such a cross-enterprise environment. Specific IHE Integration Profiles complementary to XDS are available (e.g. Cross-Enterprise User Authentication, Document Digital Signature, etc).

4. The establishment of independent but consistently XDS-based Affinity Domains will call for their federation, as patients expect their records to follow them as they move from region to region, or country to country. IHE foresees a need for transferring information from one Clinical Affinity Domain to another, or to allow access from one Affinity Domain to documents managed in other Affinity Domains. XDS has been designed with this extension in mind. An XDS Domains Federation Integration Profile that complements XDS may be anticipated in the future.

5. XDS does not address transactions for the management or configuration of a clinical affinity domain. For example, the configuration of network addresses or the definition of what type of clinical information is to be shared is specifically left up to the policies established by the clinical affinity domain.

The following table lists the document contents supported in other IHE Integration Profiles, which specify concrete content types for sharing of clinical documents in various domains. These profiles are built on

the XDS profile, and may define additional constraints and semantics for cross-enterprise document sharing in their specific use cases.

Table 10.1-1: List of IHE Integration Profiles and Document Types They Support

IHE Technical Framework Domain	Integration Profile Name	Document Content Supported
Patient Care Coordination	Cross-Enterprise Sharing of Medical Summaries	Medical Summary in the HL7 CDA format
Radiology	Cross-Enterprise Document Sharing for Imaging (XDS-I)	Radiology Diagnostic Report in the plain text or PDF formats
		Reference to a collection of DICOM SOP Instances in a manifest document in the DICOM Key Object Selection format

NOTE: The above table is from the IHE-ITI-TF-1 10.1

Options that may be selected for this Integration Profile are listed in the table 10.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in Notes.

Table 10.2-1 XDS - Actors and Options

Actor	Options	Vol & Section
Document Source	*Off-Line transaction mode*	ITI TF-1:10.4.7.1
	Multiple Document Submission	ITI TF-1:10.2.1
	Document Life Cycle Management	ITI TF-1:10.2.2
	Folder Management	ITI TF-1:10.2.3
Document Repository	*Off-Line transaction mode*	ITI TF-1:10.4.7.1
Document Registry	*No options defined*	- -
Document Consumer	*Query Registry Transaction (Note 1)*	ITI TF-2:3.16
	Retrieve Document Transaction (Note 1)	ITI TF-2:3.17
Patient Identity Source	*No options defined*	- -

Note1: For the XDS Document Consumer Actor, either one or both of the two options shall be selected.

NOTE: The above table is from the IHE-ITI-TF-1 10.2

3.1.2 TECHNICAL ACTORS

Table 10.1-1 XDS - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Document Consumer	Query Registry	~~R~~**O**	ITI TF-2:3.16
	Retrieve Document	R	ITI TF-2:3.17
	Registry Stored Query	**R**	
Document Source	Provide and Register Document Set	R (Note 1)	ITI TF-2:3.15
	Off-Line Transaction mode	O	ITI TF-1:10.4.7.1
	Multiple Documents Submission	O	ITI TF-2:3.15.5
	Document Life Cycle Management	O	ITI TF-2:3.15.5
	Folder Management	O	ITI TF-2:3.15.5
Document Repository	Provide and Register Document Set	R (Note 1)	ITI TF-2:3.15
	Register Document Set	R (Note 2)	ITI TF-2:3.14
	Retrieve Document	R	ITI TF-2:3.17
	Off-Line Transaction mode	O	ITI TF-1:10.4.7.1
Document Registry	Register Document Set	R (Note 2)	ITI TF-2:3.14
	Query Registry	~~R~~**O**	ITI TF-2:3.16
	Patient Identity Feed	R	ITI TF-2:3.8
	Registry Stored Query	**R**	
Patient Identity Source	Patient Identity Feed	R (Note 3)	ITI TF-2:3.8

NOTE: The above table is from the IHE-ITI-TF-1 10.1

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3.1.3 ACTOR INTERACTIONS

The relationship between the business actors and the technical actors is shown in the UML sequence diagram below.

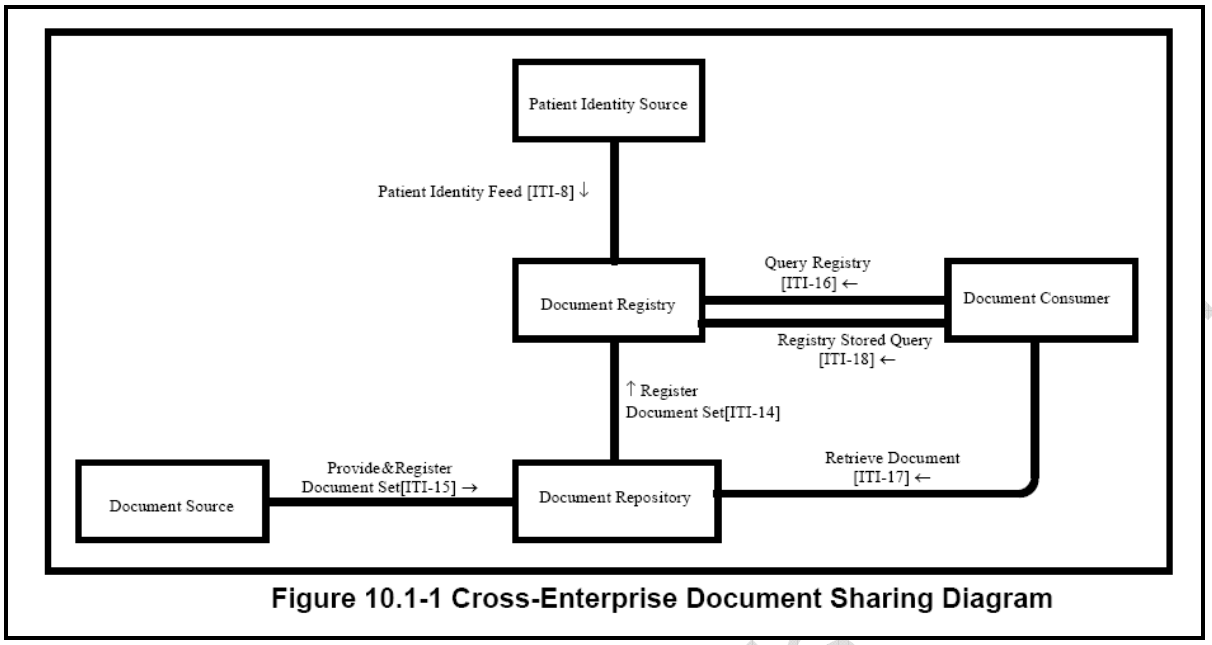

Figure 10.1-1 Cross-Enterprise Document Sharing Diagram

NOTE: The above figure is from the IHE-ITI-TF-1 10.1

3.2 PROCESS FLOWS

The process flows supported by this transaction package are shown in the diagram below.

An EHR-CR or Care-delivery Record abstracts the information system or systems of a care delivery organization, which may support a broad variety of healthcare facilities: private practice, nursing home, ambulatory clinic, acute care in-patient facility, etc.

Typically a patient goes through a sequence of encounters in different care settings as depicted in the figure below.

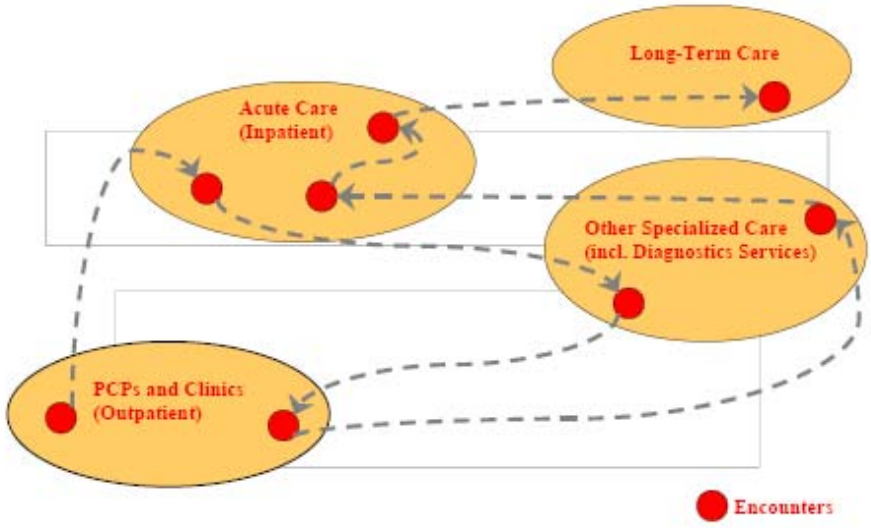

Figure 10.4.1-1 Sequence of encounters across care delivery organizations

NOTE: The above figure is from the IHE-ITI-TF-1 10.4.1

It is out of the scope of this IHE Integration Profile to define or restrict the type of care provided, nor the internal workflow of a care delivery organization. The EHR-CR system participates only to the cross-enterprise clinical document sharing as Document Source and Document Consumer Actors according to the following principles:

1. EHR-CR as Document Source contributes documents in any one of the document formats that are supported by the XDS Affinity Domain (e.g. CDA Release 2 with specific templates, DICOM Composite SOP Classes, ASTM-CCR, CEN ENV 13606 etc).
2. This Profile does not require that the EHR-CR as Document Sources and Consumers store and manage their internal information in the form of documents as they are shared throughout the XDS Affinity Domain.
3. By grouping a Document Source with a Document Repository, an EHR-CR may leverage existing storage to provide a unified access mechanism without needing to duplicate storage. 4. EHR-CRs as Document Sources and Consumers are responsible to map their local codes into the affinity domain codes if necessary. The XDS Documents shared by the EHR-CR and tracked by the XDS Registry form a Longitudinal Record for the patients that received care among the EHR-CRs of the XDS Affinity domain.

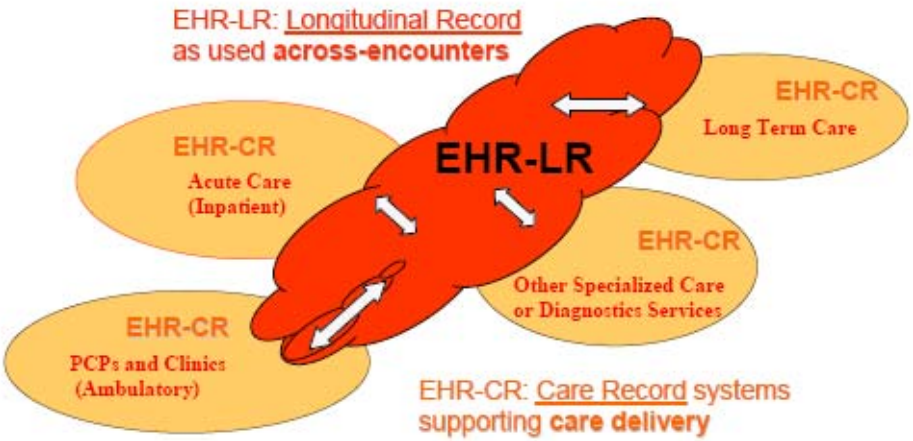

Figure 10.4.1-2 Contributing and sharing to a patients' longitudinal health record

NOTE: The above figure is from the IHE-ITI-TF-1 10.4.1

This shared clinical record is called an EHR-LR in this Integration Profile.

3.2.1 PROCESS PRE-CONDITIONS

The following pre-conditions are assumed to be in place for the successful execution of this transaction package:

The **Patient Identity Feed Transaction** conveys the patient identifier. It conveys the patient identifier and corroborating demographic data, captured when a patient's identity is established, modified or merged or in cases where the key corroborating demographic data has been modified. Its purpose in the XDS Integration Profile is to populate the registry with patient identifiers that have been registered for the affinity domain.

3.2.1.1 PROCESS TRIGGERS

- 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.
- 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.
- 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.

- 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.
- The **Patient Identity Source Actor** is a provider of unique identifier for each patient and maintains a collection of identity traits. The Patient Identify Source facilitates the validation of patient identifiers by the Registry Actor in its interactions with other actors.

The text for the IHE XDS specification ends here.

3.2.2 PROCESS POST-CONDITIONS

The desired post conditions for these transaction package are:

- The patient was successfully identified unambiguously
- Sources and consumers of document(s) were effectively identified ← XDS dependency of node identification
- The document was successfully retrieved by the requesting system (e.g., local or remote EHR system, authorized public health agencies)
- The authorized public health agencies have gained access to the document.

3.2.2.1 PROCESS OUTPUTS

There were no identified outputs from the processes supported by this transaction package other than the integration of the documents into the clinician's EHR system and biosurveillance database.

3.3 DATA FLOWS

See IHE TF specifications for clinical exemplars.

4.0 TECHNICAL IMPLEMENTATION

4.1 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.

4.2 SUPPORTING DOCUMENTS

See Volume 1 and 2 of the IHE TF specification.

5.0 APPENDIX

5.1 GAPS

"Document Registration Terminology" is a gap. This Component will include the set of vocabularies used in the XDS Doc Registry to populate the meta-data associated with each document. There is no "ready terminology" to reference, but we will leverage subsets of existing terminology structures such as those used by LOINC Doc dimensions.

5.2 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 in the following folder on the HITSP site:

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