

HITSP Manage Sharing of Documents Transaction Package

HITSP/TP13



Healthcare Information Technology Standards Panel

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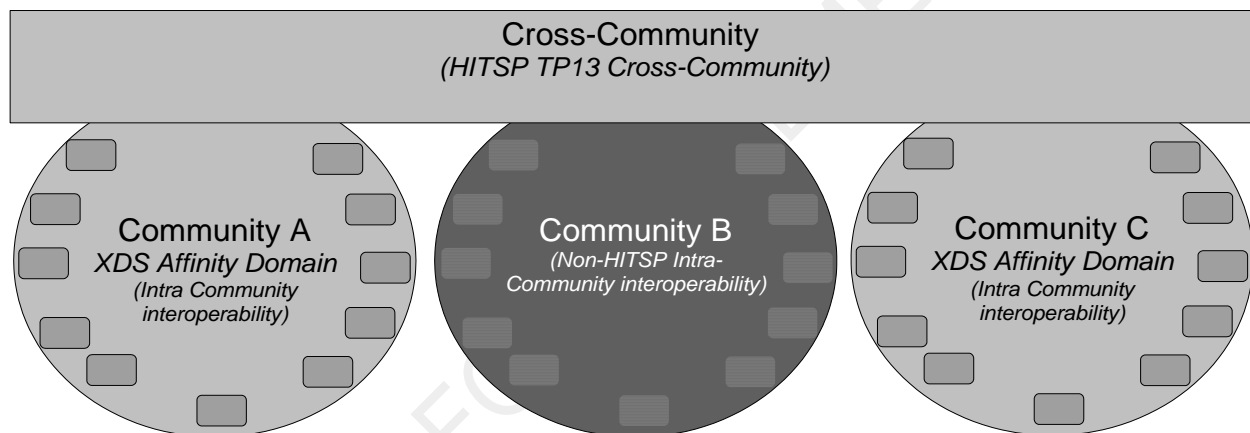
1.0 INTRODUCTION

1.1 OVERVIEW

This Healthcare Information Technology Standards Panel (HITSP) Transaction Package supports the sharing of patient records in the form of source attested objects called documents. A healthcare document is a composite of structured and coded health information, both narrative and tabular, that describes acts, observations and services for the purpose of exchange. No assumption is made by this construct in terms of the format and structure of the content of documents shared. Interoperability related to document content is addressed by HITSP in other constructs.

Documents may be shared within a community where a significant part of the document sharing for a consumer or patient may occur, as well as across communities. This construct addresses both the Intra-Community and the Cross-Community sharing of documents. In Cross-Community interoperability communities interconnecting their edge systems or enterprises in other ways than defined by this construct are also supported, as shown in Figure 1-1.

Figure 1-1 Intra and Cross-Community Document Sharing



NOTE: Implementation Options

This HITSP construct supports the choice of one or more of the following implementation options:

- XDS.a Option: Management of Document Sharing within a community according to IHE XDS.a
- [\(see Change History – Note 1\)](#) -- DEPRECATED
- XDS.b Option: Management of Document Sharing within a community according to IHE XDS.b
- This is an evolution of XDS which is functionally equivalent to XDS.a but which supports the most recent Web Services standards. This enables the support of Entity Identity Assertion on all transactions, simplifies implementation and is consistent with Cross-Community Access (XCA) [\(see Change History – Note 2\)](#)
- XCA Option: Management of Cross-Community Access according to IHE XCA
- This addresses the requirement for federating two or more communities using IHE XDS.b internally or other non-HITSP legacy means of communication [\(see Change History – Note 2\)](#)
- DSUB Option: Document Metadata Subscription
- This addresses the requirement for subscription and notification mechanism for use within an XDS Affinity Domain and across Communities. [\(see Change History – 4.13\)](#)

Each HITSP Interoperability Specification that requires the HITSP Manage Sharing of Documents Transaction Package specifies which option(s) are required. It is the intention of HITSP to select the



XDS.b option for Intra-Community interoperability in new Interoperability Specifications and in major updates to current Interoperability Specifications; support of XDS.a has been phased out. Migration strategies are discussed in the IHE IT Infrastructure Technical Framework XDS.b Supplement (Section 10.7).

1.2 COPYRIGHT PERMISSIONS

COPYRIGHT NOTICE

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

1.3 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. HITSP maintained reference documents can be retrieved from the www.hitsp.org Web Site.

Table 1-1 Reference Documents

Reference Document	Document Description
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
TN900 - Security and Privacy	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs

1.4 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface or code set has been implemented correctly.

1.4.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification or Capability, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also implement all of the required interfaces within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification or Capability with which this construct is associated.

1.4.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification or Capability must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for interface scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification or Capability to claim conformance.



1.4.2.1 INTRA-COMMUNITY SHARING OF DOCUMENTS (XDS.A OPTION) -- DEPRECATED

Please note that the XDS.a profile was deprecated by IHE in 2009. Please use XDS.b OPTION as specified in Section 1.4.2.2.

Within the XDS.a option, a number of options may be selected depending on the interface implemented as defined by Table 1-2.

Table 1-2 XDS.a – Options by Interfaces – DEPRECATED

Interface	Options	Vol & Section
Document Consumer	Verify Integrity of Document	Section 2.1.3.3
Document Registry	No options defined	
Document Repository	No options defined	
Document Source	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 Source Interface Integrated with a Document Repository Interface	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

1.4.2.2 INTRA-COMMUNITY SHARING OF DOCUMENTS (XDS.B OPTION)

Within the XDS.b option, a number of options may be selected depending on the interface implemented as defined by Table 1-3.

Table 1-3 XDS.b – Options by Interfaces

Interface	Options	Volume & Section
Document Consumer	Verify Integrity of Document	Section 2.1.3.3
Document Registry	No options defined	
Document Repository	No options defined	
Document Source	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 Source Interface Integrated with a Document Repository Interface	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

1.4.2.3 CROSS-COMMUNITY SHARING OF DOCUMENTS (XCA OPTION)

Within the XCA option, a number of options may be selected depending on the interface implemented as defined by Table 1-4.

Table 1-4 XCA – Options by Interfaces

Interface	Options	Vol & Section
Initiating Gateway	XDS Affinity Domain Option	ITI TF-1:18.2.1
Responding Gateway	No options defined	

1.4.2.4 DOCUMENT METADATA SUBSCRIPTION (DSUB OPTION)

Within the DSUB option, a number of options may be selected depending on the interface implemented as defined by Table 1-5.



Table 1-5 DSUB – Options by Interfaces

Interface	Options	Vol & Section
Document Metadata Notification Broker	Document Metadata Document Recipient Option	ITI TF-1:26.2
Document Metadata Subscriber	No options defined	
Document Metadata Publisher	No options defined	
Document Metadata Notification Recipient	No options defined	



2.0 TRANSACTION PACKAGE DEFINITION

2.1 CONTEXT OVERVIEW

To support this HITSP Manage Sharing of Documents Transaction Package, HITSP has selected the Integrating the Healthcare Enterprise (IHE) Cross-Enterprise Document Sharing (XDS), Document Metadata Subscription (DSUB) and the Cross Community Access (XCA) Integration Profiles, which facilitate the registration, distribution and access of patient electronic health records across healthcare enterprises and across communities of such enterprises. Cross-Enterprise Document Sharing is focused on providing a standards-based specification for managing the sharing of documents between healthcare enterprises, ranging from a private physician office, to a clinic, to an acute care inpatient facility and other healthcare IT systems. Cross Community Access is focused on creating a “network of networks” or communities by providing the means for a community to access consumer’s health records managed by other communities. Additional source material from the IHE IT Infrastructure (ITI) Technical Framework (TF) Cross-Enterprise Document Sharing (XDS) Integration Profile and associated supplements on Registry Stored Query, XDS.b, DSUB and XCA are quoted in this document to further clarify the actions and interactions.

The IHE XDS, DSUB and XCA Integration Profiles, which are reproduced in part in this specification, with specific written permission from IHE, provide sample scenarios depicting how specific interfaces should comply with the proposed standards for interoperability. Key concepts from the IHE XDS, DSUB and XCA Integration Profiles are introduced in this document to help the reader understand the context of the Profile.

Overview of IHE XDS Integration Profile

This section provides an overview of the IHE XDS Integration Profile. Its intent is to provide the reader with an introductory context to the XDS Profile. XDS provides the ability to register, store and query/retrieve documents containing consumer or patient-centric healthcare information.

The previous IHE XDS Integration Profile¹ is now referred to as XDS.a but remains technically without change. The current XDS Integration Profile referred to as XDS.b employs different versions of ebXML Registry (Versions 2.0 and 3.0) and specifications that have been superseded (like SOAP with Attachments or SwA). The IHE XDS.b Integration Profile accomplishes the following:

- Updates XDS Web Services implementation to allow for use of SOAP 1.2 and optionally SOAP 1.1
- Updates the XDS transactions to use ebXML Registry 3.0 metadata
- Updates Provide and Register Document Set “on-line” mode transaction to use MTOM instead of the legacy SOAP with Attachments (SwA) mechanism
- Defines a new transaction which provides a SOAP binding for the XDS Retrieve Document transaction that uses MTOM (new transaction now named “Retrieve Document Set”)
- Updates IHE XDS Registry Stored Query transaction to be consistent with other XDS.b transactions. The Registry Stored Query transaction is the same in XDS.a and XDS.b
- Provides informative Web Services Description Language (WSDL) contracts for all required IHE XDS.b Transactions and WSDL fragments for options

XDS.b introduces the new Patient Identity Feed HL7v3 transaction in addition to the existing Patient Identity Feed [ITI-8] transaction based on HL7v2. For more detailed explanations, examples and the complete specification see the IHE XDS Integration Profile at www.ihe.net.

¹ Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF), Volume 1, Revision 4.0, Section 10



Text from the IHE XDS Integration Profile begins here:

IHE Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of patient electronic health records or documents between any healthcare entity, ranging from a private physician office, to a clinic, to an acute care in-patient facility or other health information system.

The IHE XDS Integration Profile assumes that these enterprises belong to one or more XDS Affinity Domains. An XDS Affinity Domain is a group of healthcare enterprises that have agreed to share health information together using a common set of policies and share a common infrastructure.

Examples of XDS Affinity Domains include:

- Community of Care supported by a Health Information Exchange 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 an XDS 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 health 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 health 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 XDS 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 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, XDS is document content neutral. Any type of health information without regard to content and representation is supported. This makes the IHE XDS Integration Profile equally able to handle documents containing simple text, formatted text (e.g., HL7 CDA Release 1), images (e.g., DICOM) or structured and vocabulary coded clinical information (e.g., CDA Release 2, DICOM SR). In order to ensure the necessary interoperability between the Document Sources and the Document Consumers, the XDS Affinity Domain must adopt policies concerning document format, structure and content.

Text from the IHE XDS Integration Profile ends here.

Overview of the IHE XCA Integration Profile

This section provides an overview of the IHE XCA Integration Profile. Its intent is to provide the reader with an introductory context to the XCA Profile.



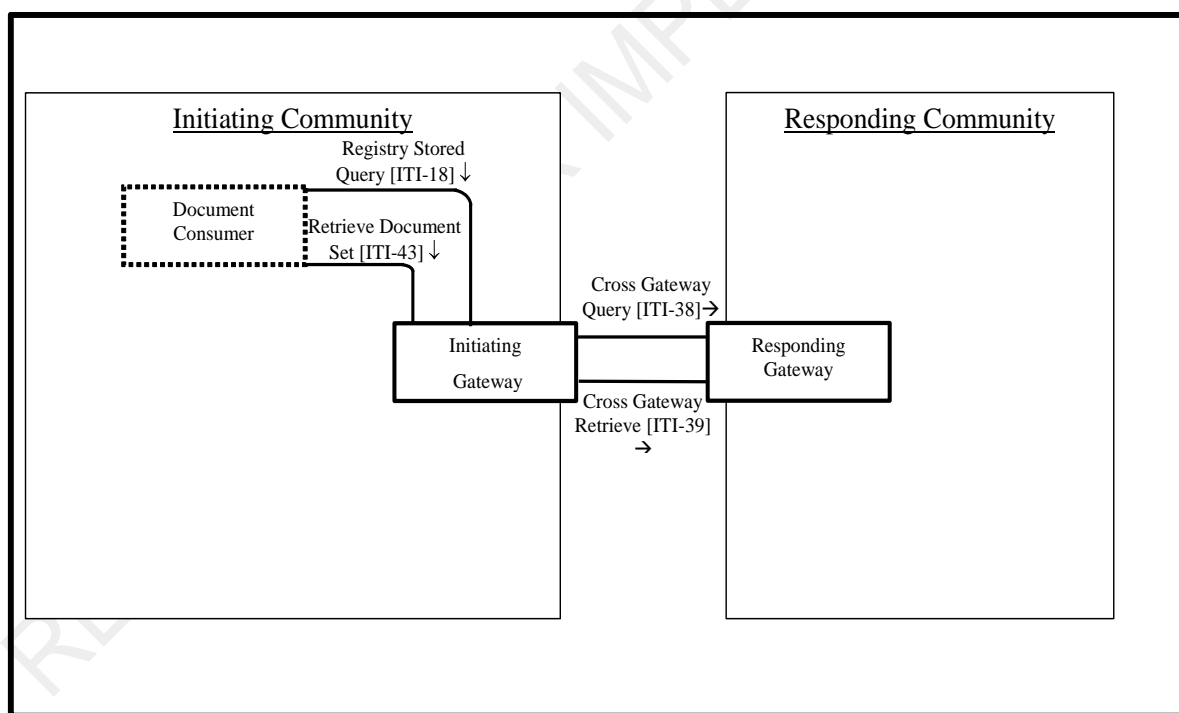
Text from the IHE XCA Integration Profile begins here:

The Cross Community Access (XCA) Profile supports the means to query and retrieve patient relevant medical data held by other communities. A community is defined as a coupling of facilities/enterprises that have agreed to work together using a common set of policies for the purpose of sharing clinical information via an established mechanism. Facilities/enterprises may host any type of healthcare application such as EHR, PHR, etc. A community is identifiable by a globally unique ID called the homeCommunityId. Membership of a facility/enterprise in one community does not preclude it from being a member in another community. Such communities may be XDS Affinity Domains which define document sharing using the XDS Profile or any other communities, no matter what their internal sharing structure.

As an example, assume within a given domain, such as the State of California, that we have several healthcare communities (or XDS Affinity Domains or RHIOs/HIEs). One in Los Angeles is based on IHE-XDS. One in Sacramento is based on another form of healthcare sharing infrastructure. One in San Francisco is also based on IHE XDS. A patient X, who travels frequently, has received healthcare in each of these communities. Patient X is admitted to a hospital in Los Angeles. The attending physician uses his hospital information system to query across multiple domains for healthcare information about this patient. Once found, references to patient data outside the local domain are cached locally for easy future reference.

Figure 2-1 shows the interfaces directly involved in the XCA Integration Profile and the relevant transactions between them.

Figure 2-1 XCA Interface Diagram



The Document Consumer Interface is shown in Figure 2-1 to clarify the responsibility of the XDS Affinity Domain Option. Initiating Gateways, which support the XDS Affinity Domain Option, interact with Document Consumers within the XDS Affinity Domain served by the Initiating Gateway. Initiating Gateway interfaces, which support this option:

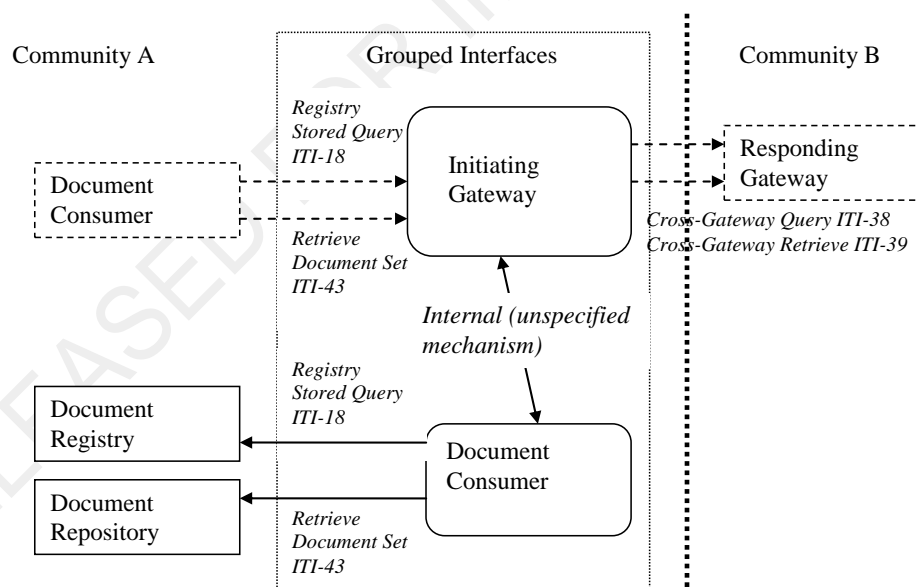


- Shall **receive** Registry Stored Query [ITI-18] transactions from a local Document Consumer interface and act on those requests on behalf of the Document Consumer. When receiving a Registry Stored Query from a local Document Consumer, shall require the homeCommunityId as an input parameter on relevant queries and shall specify the homeCommunityId attribute within its Registry Stored Query responses. See IHE XCA Section 18.3.2 for description of homeCommunityId
- Shall **receive** Retrieve Document Set [ITI-43] transactions from a local Document Consumer interface and act on those requests on behalf of the Document Consumer. When receiving a Retrieve Document Set from a local Document Consumer, shall require the homeCommunityId as an input parameter

When an Initiating Gateway does not support the XDS Affinity Domain option it is expected to be using non-IHE specified interactions to communicate remote community data to systems within its local community. These proprietary interactions are not further described within any IHE Profile. The use of XCA for the Integration of XDS and non-XDS communities is discussed further in the IHE ITI Technical Framework XCA Supplement, Appendix E Section E.6.

When an Initiating Gateway is supporting an XDS Affinity Domain, it can choose to query and retrieve from local interfaces in addition to remote communities. This is accomplished by grouping the Initiating Gateway Interface with a Document Consumer Interface. This grouping allows Document Consumers such as EHR/PHR/etc systems to query the Initiating Gateway to retrieve document information and content from both the local XDS Affinity Domain as well as remote communities. For details see IHE XCA Section 18.2.2.1. An Initiating Gateway Interface that is not grouped with a Document Consumer Interface is only able to return results from remote communities, so local EHR/PHR/etc. systems (Document Consumer Interfaces) must direct separate query and retrieve transactions internally and externally.

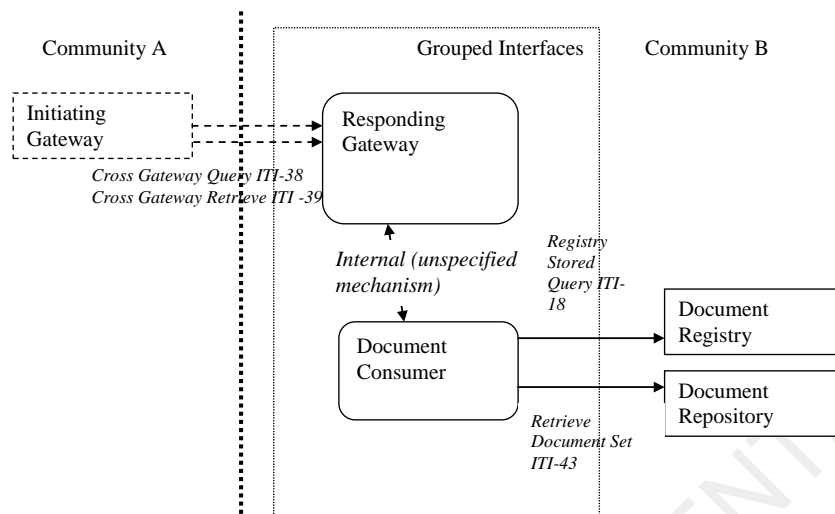
Figure 2-2 Initiating Gateway Grouped with Document Consumer



When a Responding Gateway is supporting an XDS Affinity Domain, it may resolve Cross Gateway Query and Cross Gateway Retrieve Transactions by grouping with a Document Consumer Interface and using the Registry Stored Query and Retrieve Document Set transactions. For details see IHE IT Infrastructure TF Section 18.2.2.2



Figure 2-3 Responding Gateway Grouped with Document Consumer



Text from the IHE XCA Integration Profile ends here.

Overview of the IHE DSUB Integration Profile

This section provides an overview of the IHE DSUB Integration Profile. Its intent is to provide the reader with an introductory context to the DSUB Profile.

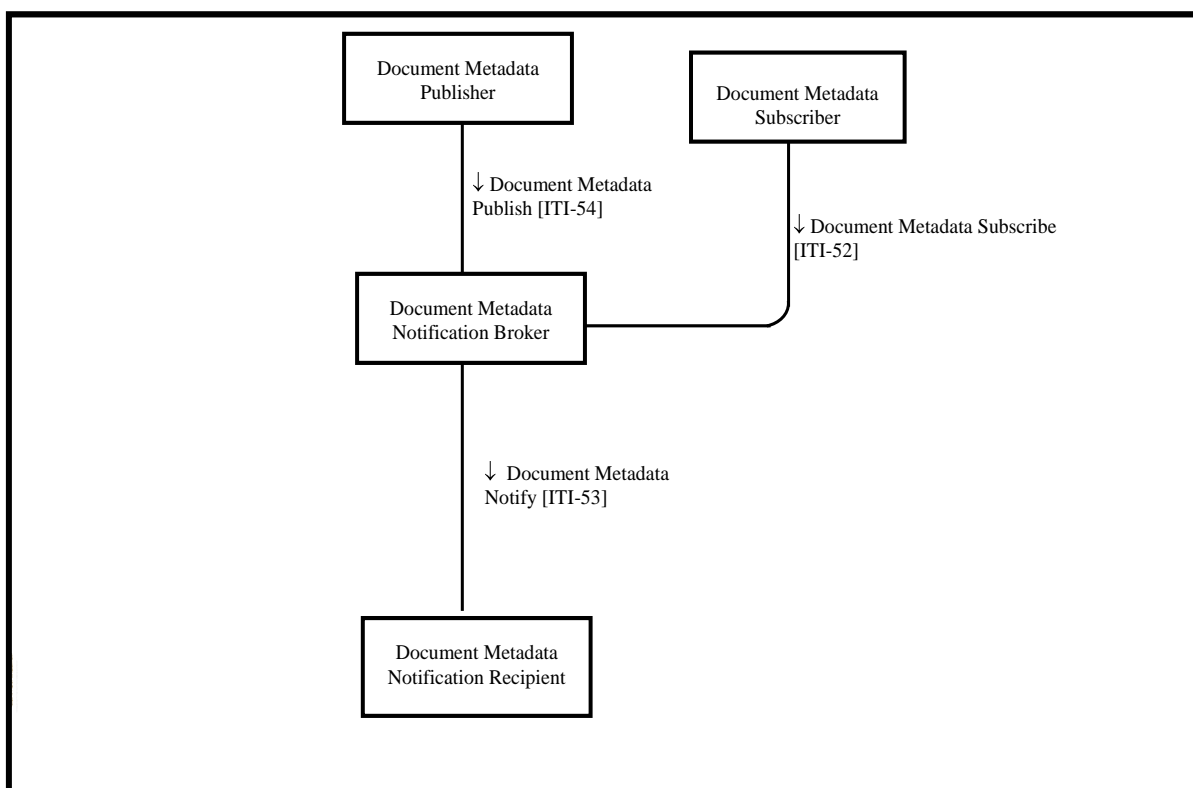
Text from the IHE DSUB Integration Profile begins here:

This profile describes the use of the subscription and notification mechanism for use within an XDS Affinity Domain and across communities. The subscription allows for the matching of metadata during the publication of a new document for a given patient, and results in the delivery of a notification.

The following figure shows the interfaces directly involved in the Document Metadata Subscription Integration Profile and the relevant transactions between them. Other interfaces that may be indirectly involved due to their participation in the XDS Integration Profile, etc. are not necessarily shown.



Figure 2-4 Interface Transactions within Document Metadata Subscription Integration Profile



Text from the IHE DSUB Integration Profile ends here.

2.1.1 INTERFACES

Options that may be selected for this construct are listed below:

- For the XDS.a Option, in IHE-ITI-TF-1, Section 10.2, Table 10.2-1 (in the IHE XDS Integration Profile) along with the Interfaces to which they apply -- DEPRECATED
- For the XDS.b Option, in IHE ITI-TF-1, Section 10.2, Table 10.2-1b XDS.b - Interfaces and Options
- For the XCA Option, In IHE-ITI-TF-1, Section 18.2, Table 18.2-1 (in the IHE XCA Integration Profile) along with the Interfaces to which they apply
- For the DSUB Option, In IHE ITI DSUB Supplement – Section 26.2, Table 26.2-1 Document Metadata Subscription Interfaces and Options



Table 2-1 Interfaces for XDS.a Option -- DEPRECATED

Interface	Description	Used in Component/Standard	Transaction/ Content ^{2, 3}	Optionality
Document Consumer	Queries a Document Registry Interface for documents meeting certain criteria and retrieves selected documents from one or more Document Repository interfaces	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Volume 2	ITI-17: Retrieve Document	R
			ITI-18: Registry Stored Query	R
Document Registry	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 interfaces about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Volume 2 Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), XDS Stored Query Supplement	ITI-14: Register Document Set	R
			ITI-18: Registry Stored Query	R
Document Repository	Responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier (URI) to documents for subsequent retrieval by a Document Consumer	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) Volume 2	ITI-15: Provide & Register Document Set	R
			ITI-17: Retrieve Document	R
			ITI-14: Register Document Set	R
Document Source	Producer and publisher of documents. It is responsible for sending documents to a Document Repository Interface. It also supplies metadata to the Document Repository Interface for subsequent registration of the documents with the Document Registry Interface	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Volume 2	ITI-15: Provide & Register Document Set	R

Optionality Legend: "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional

Table 2-2 List of Transactions for XDS.b Option

Interface Name	Description	Used in Component/Standard	Transaction/ Content ^{4, 5}	Optionality
Document Consumer	Queries a Document Registry Interface for documents meeting certain criteria and retrieves selected documents from one or more Document Repository interfaces	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Volume 2	ITI-43: Retrieve Document Set	R
			ITI-18: Registry Stored Query	R
Document Consumer	Queries a Document Registry Interface for documents meeting certain criteria and retrieves selected documents from one or more Document Repository interfaces	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) XDS Profile	ITI-43: Retrieve Document Set	R
		Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), XDS Profile	ITI-18: Registry Stored Query	R
Document Registry	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	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF) XDS.b Profile	ITI-42: Register Document Set-b	R

² IHE Transaction descriptions are provided in the Appendix

³ The IHE ITI Technical Framework 4.0 includes a Query Registry Transaction (ITI-16), which has been made optional and replaced by the ITI-18 Registry Stored Query introduced by the XDS Stored Query Supplement

⁴ IHE Transaction descriptions are provided in the Appendix

⁵ The IHE ITI Technical Framework 4.0 includes a Query Registry Transaction (ITI-16), which has been made optional and replaced by the ITI-18 Registry Stored Query introduced by the XDS Stored Query Supplement



Interface Name	Description	Used in Component/Standard	Transaction/ Content ^{4, 5}	Optionality
	queries from Document Consumer interfaces about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), XDS Stored Query Profile	ITI-18: Registry Stored Query	R
Document Repository	Responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a Uniform Resource Identifier (URI) to documents for subsequent retrieval by a Document Consumer	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), XDS.b Profile	ITI-41: Provide & Register Document Set-b	R
			ITI-42: Register Document Set-b	R
			ITI-43: Retrieve Document Set	R
Document Source	Producer and publisher of documents. It is responsible for sending documents to a Document Repository Interface. It also supplies metadata to the Document Repository Interface for subsequent registration of the documents with the Document Registry Interface	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), XDS.b Profile	ITI-41: Provide & Register Document Set-b	R

Optionality Legend: "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional

Table 2-3 Interfaces for XCA Option

Interface Name	Description	Used in Component/Standard	Transaction/ Content ^{6, 7}	Optionality
Initiating Gateway	Supports all outgoing inter-community communications	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Cross-Community Access (XCA) Profile	ITI-38: Cross Gateway Query	R
			ITI-39: Cross Gateway Retrieve	R
			ITI-18: Registry Stored Query	O
			ITI-43: Retrieve Document Set	O
Responding Gateway	Supports all incoming inter-community communications	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Cross-Community Access (XCA) Profile	ITI-38: Cross Gateway Query	R
			ITI-39: Cross Gateway Retrieve	R

Optionality Legend: "R" for Required, "R2" for Required if known, "O" for Optional, or "C" for Conditional

Table 2-4 Interfaces for DSUB Option

Interface Name	Description	Used in Component/Standard	Transaction/ Content ^{8, 9}	Optionality
Document Metadata Notification Broker	Receiver of the Document Metadata Subscribe transaction containing a subscription request, or a subscription cancellation	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Document Metadata Subscription (DSUB) Profile	Document Metadata Subscribe	R
			Document Metadata Notify	R
			Document Metadata Publish	O

⁶ IHE Transaction descriptions are provided in the Appendix

⁷ The IHE ITI Technical Framework 4.0 includes a Query Registry Transaction (ITI-16), which has been made optional and replaced by the ITI-18 Registry Stored Query introduced by the XDS Stored Query Supplement

⁸ IHE Transaction descriptions are provided in the Appendix

⁹ The IHE ITI Technical Framework 4.0 includes a Query Registry Transaction (ITI-16), which has been made optional and replaced by the ITI-18 Registry Stored Query introduced by the XDS Stored Query Supplement



Interface Name	Description	Used in Component/Standard	Transaction/ Content ^{8, 9}	Optionality
Document Metadata Subscriber	Initiates and terminates subscriptions on behalf of a Document Metadata Notification Recipient	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Cross-Community Access (DSUB) Supplement	Document Metadata Subscribe	R
Document Metadata Publisher	Send a Document Metadata Publish transaction to the Document Metadata Notification Broker for any event for which a subscription may exist	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Cross-Community Access (DSUB) Supplement	Document Metadata Publish	R
Document Metadata Notification Recipient	Receives the notification about an event, when the subscription filters specified for this Document Metadata Notification Recipient are satisfied	Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (TF), Cross-Community Access (DSUB) Supplement	Document Metadata Notify	R

Optionality Legend: “R” for Required, “R2” for Required if known, “O” for Optional, or “C” for Conditional

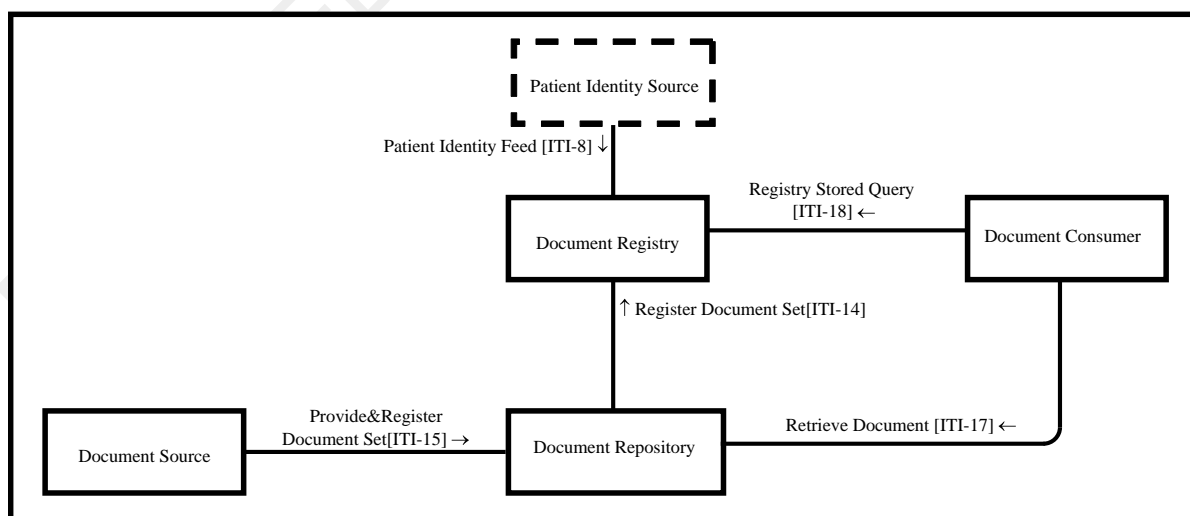
2.1.2 INTERFACE INTERACTIONS

Specifically, the following sections provide further detail about the interactions that are addressed by this Transaction Package.

2.1.2.1 CROSS-ENTERPRISE DOCUMENT SHARING – XDS.A OPTION -- DEPRECATED

The relationship between the interfaces and the transactions of this Transaction Package are shown in IHE-ITI-TF-1, Section 10.1 (in the IHE Technical Framework, XDS Integration Profile Chapter). The process flows supported by this Transaction Package are shown in IHE-ITI-TF-1 Section 10.4.1 (in the IHE XDS Integration Profile).

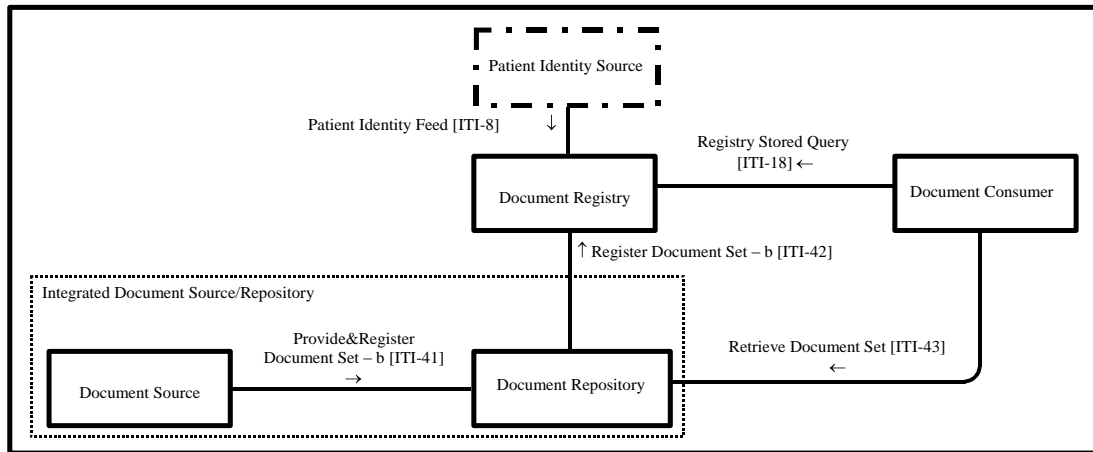
Figure 2-5 Cross-Enterprise Document Sharing – XDS.a Diagram – DEPRECATED



2.1.2.2 CROSS-ENTERPRISE DOCUMENT SHARING – XDS.B

The relationship between the interfaces and the transactions of this Transaction Package are shown in IHE-ITI-TF-1, Section 10.1 (in the IHE Technical Framework, XDS Integration Profile Chapter). The process flows supported by this Transaction Package are shown in IHE-ITI-TF-1 Section 10.4.1 (in the IHE XDS Integration Profile).

Figure 2-6 Cross-Enterprise Document Sharing – XDS.b Diagram



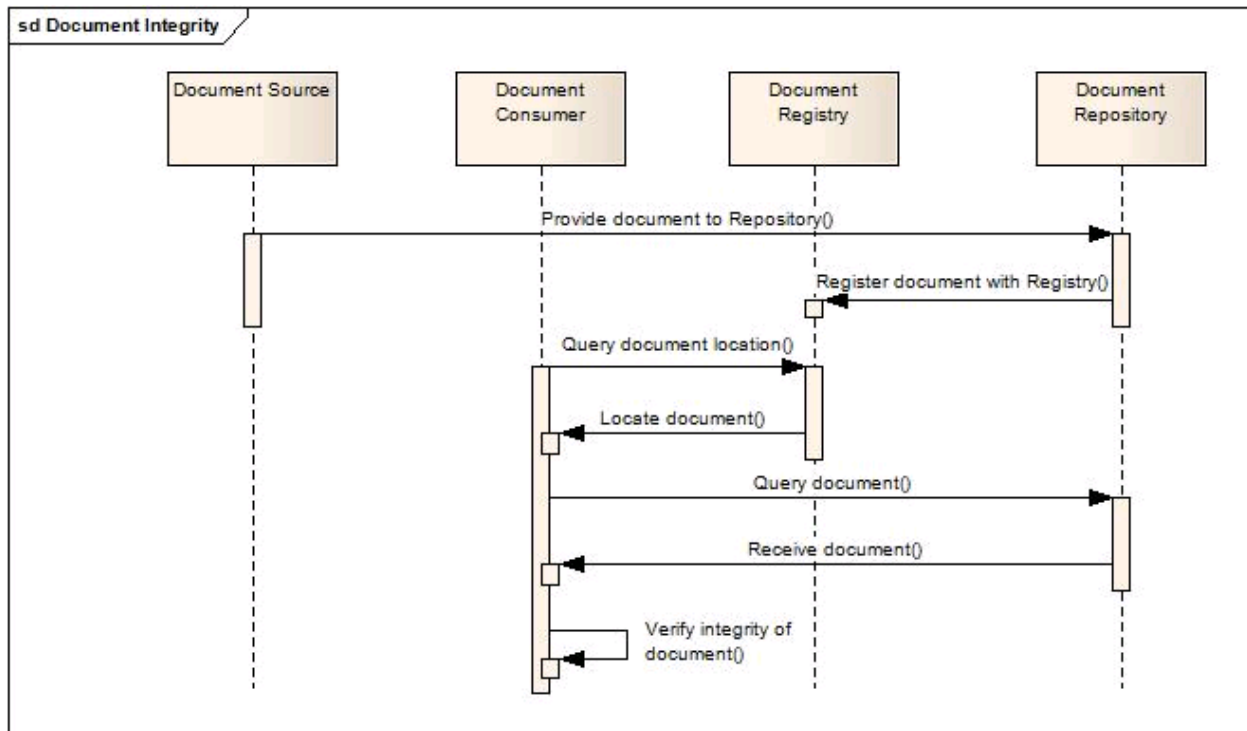
Note that each XDS option addresses the same set of interfaces and transactions, but reference different transactions from the IHE Technical Framework for Retrieve Document set, Provide and Register Document Set, Register Document Set.

2.1.2.3 DOCUMENT INTEGRITY OPTION

The following diagram further illustrates where the optional verification of Document Integrity is performed within an XDS Affinity Domain. This option applies both on the XDS.a and the XDS.b options.



Figure 2-7 Optional Document Integrity Sequence Diagram



The diagram above outlines several interactions that are integral to the establishment of Document Integrity. The storage and querying of documents, as occurs in the Provide Document to Repository transaction is the trigger by which the Document Integrity activity is invoked. Once a document is provided to the Document Repository by the Document Source, the document is also registered in a Registry, so that it can be located.

Once a document is stored into a Document Repository, it can be located through a registry query and then retrieved by the Document Consumer.

The “Verify Integrity of Document” interaction is an optional activity that occurs in order to ensure that Document Integrity is validated. This represents the validation of the SHA-1 hash attribute by the Document Consumer. This linked with the metadata and security audit log provides a moderate level of assurance of nonrepudiation of origin.

2.1.2.4 XCA – CROSS COMMUNITY ACCESS

The relationship between the interfaces and the transactions of this Transaction Package are shown in IHE-ITI-XCA Supplement. The process flows supported by this Transaction Package are shown in IHE-ITI-XCA Supplement Section 18.1 (in the IHE XCA Integration Profile). This is described in Section 2.1 Context Overview of this document.

2.1.2.5 GAPS

The following gaps have been identified for this Transaction Package.

2.1.2.5.1 Terminology

“Document Registration Terminology” is a gap. This Component will include the set of vocabularies used in the XDS Document Registry to populate the metadata 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 Document dimensions.

This Gap has been addressed by HITSP/C80 Clinical Document and Message Terminology Section 2.2.3.15 Document Metadata.

2.1.2.5.2 Cross-Affinity Domain Document Sharing

The HITSP Manage Sharing of Documents Transaction Package is based on the IHE-XDS and the IHE XCA Integration Profiles referenced by HITSP from the IHE IT Infrastructure Technical Framework. This section discusses the pre-conditions associated with document sharing environments across multiple independent domains.

The Integrating the Healthcare Enterprise has defined an Integration Profile called Cross-Enterprise Document Sharing (XDS), which defines document sharing among a number of entities or organizations forming an XDS Affinity Domain using the IHE XDS terminology. This construct also includes the means for Communities (XDS based or not) to access remote Communities (XDS based or not), leveraging the IHE Cross-Community Access (XCA) Integration Profile.

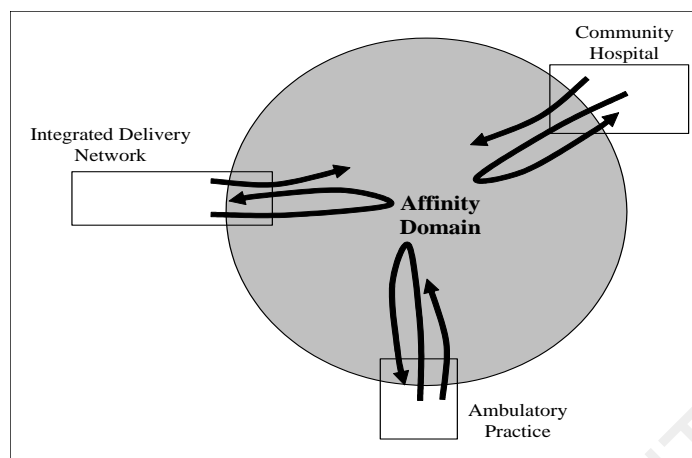
For Cross-Community Access, a number of additional interoperability requirements need to be addressed beyond XCA. Some of these are addressed by existing HITSP constructs, while others remain to be addressed:

- *Cross-Community Patient Identification Linkage.* In two common environments, this is addressed by the use of the existing HITSP/TP22 Patient Identity Cross-Referencing Transaction Package and HITSP/T23 Patient Demographics Query. This is discussed in detail in the IHE XCA supplement. Some specific issues may need further work for which HITSP should leverage lessons learned by the NHIN contractors, Connecting for Health, Federal Agencies, IHE and other implementation experiences
- *Community Discovery.* In this domain there are numerous strategies, some patient-centric such as use of a Patient Community Locator, consumer carried smart tokens conveying community addresses, etc. This may be handled by manual configurations which may be the most practical especially when the Cross-Community consent sharing remains a complex issue
- *Cross-Community Policy Matching.* This area requires much work and analysis. In the short to mid-term this may be handled by manual configuration among peer communities that have performed a matching of their document sharing policies

HITSP will contribute to and review the white paper being developed by IHE along with other input such as lessons learned by the NHIN contractors, Connecting for Health, Federal Agencies, IHE and other implementation experiences.



Figure 2-8 XDS Affinity Domain



Within an XDS Affinity Domain, for the purpose of information exchange among the member organizations, certain common policies and business rules must be defined. Neither HITSP, nor IHE define these policies or what is the appropriate implementation of XDS Affinity Domains for the NHIN, RHIOs/HIEs, Sub-network Organizations or large enterprises such as Federal Agencies. HITSP does not rule on the number of organizations that partake. These choices are considered to be implementation, configuration or architecture decisions, not within the purview of HITSP.

Conclusion

The HITSP Manage Sharing of Documents Transaction Package addresses a number of environments while others are beyond its current scope:

- *Single Organization – Stand-alone XDS Affinity Domain.* An organization/enterprise implements IHE-XDS internally and chooses to be a single XDS Affinity Domain, where its internal systems are Document Sources and Document Consumers. There is a Document Registry and one or more Document Repositories in the XDS Affinity Domain
- *Multi-Organization – Stand-alone Affinity Domain.* A number of independent organizations choose to share documents by joining in an XDS Affinity Domain. Each organization chooses to be a Document Source and/or Document Consumer. Each organization may also choose to be its own Document Repository or to use one or more shared Document Repository. There is a Document Registry in the XDS Affinity Domain (possibly hosted by one of the member organizations)
- *Multi-Affinity Domains – Hierarchical Federation.* A number of XDS Affinity Domains, each independently managed, choose to establish a federation. With a federation-level PIX Manager (e.g., an RLS as defined by Connecting for Health) and the use of Cross-Community Access (XCA) as defined by this construct, Cross-Affinity Domain access is possible.
- *Multi-Affinity Domains – Lateral Cross-Community.* A number of XDS Affinity Domains, each independently managed, wish to establish peer-to-peer communication without establishing a federation. With the use of Cross-Community Access (XCA) as defined by this construct, Cross-Affinity Domain access is possible.

Approach 3 and 4 require further work in the area of community discovery, privacy and Cross-Community policy matching. HITSP will leverage lessons learned by the NHIN contractors, Connecting for Health, Federal Agencies, IHE and other implementation activities as they become available.

2.1.3 PRE-CONDITIONS



Table 2-5 Context for XDS.a and XDS.b Options

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
Organizations that share documents are part of the same XDS Affinity Domain. If they belong to different XDS Affinity Domains, these are hierarchically federated (e.g., sub-networks within one RHIO/HIE) or integrated by means not specified by HITSP (See Section 2.1.2.5.2 Cross-Affinity Domain Document Sharing)	Pre-condition
The HITSP 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 IHE XDS Integration Profile is to populate the registry with patient identifiers registered for the domain	Pre-condition
The security framework under which this Transaction Package operates is in accordance with the Interoperability Specification that references this construct. Therefore, all applicable HITSP Security and Privacy constructs are implemented as required	Pre-condition
The Document Consumer Interface queries a Document Registry Interface for documents meeting certain criteria and retrieves selected documents from one or more Document Repository interfaces	Trigger
The Document Registry Interface 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 Interfaces about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration	Trigger
The Document Repository is responsible for both the persistent storage of these documents and for their registration with the appropriate Document Registry. It specifies the location of documents for subsequent retrieval by a Document Consumer	Trigger
The Document Source Interface is producer and publisher of documents. It is responsible for sending the documents to a Document Repository Interface. It supplies metadata to the Document Repository Interface for subsequent registration of the documents with the Document Registry Interface	Trigger
The Patient Identity Source Interface is a provider of a unique identifier for each patient and maintains a collection of identity traits. The Patient Identity Source facilitates the validation of patient identifiers by the Registry Interface in its interactions with other interfaces	Trigger
Failed validation of the SHA-1 hash, the document shall be considered invalid by the supporting application	Post-condition
If the optional Document Integrity constraint is applied, then the following post-conditions are also required	Post-condition
Sources and consumers of document(s) were effectively identified	Post-condition
The authorized public health agencies have gained access to the document	Post-condition
The document was successfully retrieved by the requesting system (e.g., local or remote EHR system, authorized public health agencies)	Post-condition
The patient was successfully identified unambiguously	Post-condition
With successful validation of the SHA-1 hash, the document shall be considered valid by the supporting application	Post-condition

Table 2-6 Context for XCA Option

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
It is expected that the security framework under which this Transaction Package operates is in accordance with the Interoperability Specification that references this construct. Therefore all applicable HITSP Security and Privacy constructs are implemented as required	Pre-condition
The communities providing access to each other need to have agreed to a patient identification cross-referencing process. This may be supported dynamically by using other HITSP constructs such HITSP/TP22-Patient ID Cross-Referencing or HITSP/T23-Patient Demographics Query or other means agreed between pairs of communicating communities. Further development in this area may be expected in the future	Pre-condition
The communities providing access to each other need to have established a trust relationship, especially in terms of matching their respective security and privacy policies. This is likely to be achieved by peer-to-peer agreement without electronic transactions. Existing HITSP security constructs are likely to be relevant. For privacy and consent directive management, additional HITSP constructs may be developed in the future. IHE has developed a white paper (see www.ihe.net) and continues work in this area along with NHIN projects and several Health Information Exchange projects	Pre-condition



Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
The Initiating Gateway Interface supporting a Community queries one or more Responding Gateway Interface(s) each serving one or more communities for documents meeting certain criteria, and retrieves selected documents from the respective Responding Gateway Interfaces	Trigger
The Responding Gateway Interface supporting one or more communities receives queries and documents or retrieve requests from remote Initiating Gateways and responds to these requests	Trigger
Initiating and responding gateways were effectively identified	Post-condition
The documents were successfully retrieved by the requesting community (e.g., an XDS Affinity Domain, an integrated delivery network, a health information exchange which does not support the intra-community interoperability from this Transaction Package)	Post-condition
The patient was successfully identified unambiguously	Post-condition

Table 2-7 Context for DSUB Option

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
The Document Metadata Notification Broker is the receiver of the Document Metadata Subscribe transaction containing a subscription request, or a subscription cancellation. It keeps track of all subscriptions in the Metadata Notification domain, including the time limits of subscriptions. Based on the metadata associated with document registrations, this interface sends notifications to interested subscribers. This interface may optionally receive Document Metadata Publish Transactions representing the stream of events against which the existing subscriptions are matched	Trigger
The Document Metadata Subscriber initiates and terminates subscriptions on behalf of a Document Metadata Notification Recipient	Trigger
The Document Metadata Publisher shall send a Document Metadata Publish transaction to the Document Metadata Notification Broker for any event for which a subscription may exist	Trigger
The Document Metadata Notification Recipient receives the notification about an event, when the subscription filters specified for this Document Metadata Notification Recipient are satisfied	Trigger
Subscription is tracked	Post-condition
Notifications are delivered based on subscriptions	Post-condition

2.1.3.1 REQUIRED OUTPUTS

There were no identified outputs from the processes supported for the XDS.a and XDS.b options in this Transaction Package other than the integration of the documents into the clinician's EHR system and Biosurveillance database. If the optional Document Integrity constraint applied, then the following outputs are identified:

Table 2-8 Required Outputs

Required Output	Format/Usage
Require application to record an audit event to indicate a failed validation of the SHA-1 hash for Document Integrity	

2.1.4 DATA FLOWS

See IHE Infrastructure IT Technical Framework specifications for clinical examples.

2.2 LIST OF HITSP CONSTRUCTS

Table 2-9 List of Constructs

Construct Name	Description
No applicable constructs	



2.2.1 CONSTRUCT DEPENDENCIES

Table 2-10 Construct Dependencies

Construct	Depends On (Name of Transaction that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
Register Document Set on Document Registry Interface (XDS.a Option) – DEPRECATED	HITSP/TP22 – Patient Identity Cross-Referencing	Pre-condition	Confirm patient exists before registering one or more documents in a submission set
Register Document Set-b on Document Registry Interface (XDS.b Option)	HITSP/TP22 – Patient Identity Cross-Referencing	Pre-condition	Confirm patient exists before registering one or more documents in a submission set

2.2.2 ADDITIONAL CONSTRAINTS ON REQUIRED CONSTRUCTS

Table 2-11 Additional Constraints on Required Constructs

Constraint ID	Data Element	Construct	Constraint	Constraint Type (Pre-condition, Post-condition, general)	Purpose (Reason for this constraint)
No applicable additional constraints					

2.3 STANDARDS

2.3.1 REGULATORY GUIDANCE

Table 2-12 Regulatory Guidance

Regulation	Description
No applicable regulatory guidance	

2.3.2 SELECTED STANDARDS

Table 2-13 Selected Standards¹⁰

Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 6.0 or later, Section 10 Cross-Enterprise Document Sharing (XDS)	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 6.0 for Final Text, specifies the IHE transactions defined and implemented as of August 10, 2009. For more information visit www.ihe.net
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) - Document Metadata Subscription (DSUB) Profile Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Document Metadata Subscription (DSUB) Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. For more information visit www.ihe.net

¹⁰ The specific references to the underlying Web Services standards (e.g., SOAP, WSDL, MTOM, etc.) upon which the listed profiles and standards rely upon, may be found in the IHE Technical Framework Volume X: Appendix V



2.3.3 INFORMATIVE REFERENCE STANDARDS

Table 2-14 Informative Reference Standards

Standard	Reason for Use
No applicable informative reference standards	



3.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

3.1 IHE TRANSACTIONS

The following table lists the IHE XDS transactions and their descriptions:

Table 3-1 IHE Transaction Descriptions

Transaction Name	Description
ITI-14: Register Document Set – DEPRECATED	Register Document Set Transaction passes a Submission Request for documents from a repository to a registry
ITI-15: Provide & Register Document Set – DEPRECATED	Provide and Register Document Set is used to provide a set of documents to a repository and to request that the repository store these documents and then register them with a registry
ITI-17: Retrieve Document – DEPRECATED	Retrieve Document is used by a Document Consumer to retrieve a document from a repository
ITI-18: Registry Stored Query	Registry Stored Query is used by a Document Consumer to query a registry for information about documents indexed in the registry
ITI-38: Cross Gateway Query	Cross-Community Query is used by a community to query another community in order to identify what healthcare information satisfying specific criteria may be available in the target community
ITI-39: Cross Gateway Retrieve	Cross Gateway Retrieve requests the retrieval of a specific set of healthcare information (a document or documents) from a remote location
ITI-41: Provide & Register Document Set-b	Provide and Register Document Set is used to provide a set of documents to a repository and to request that the repository store these documents and then register them with a registry
ITI-42: Register Document Set-b	Register Document Set Transaction passes a Submission Request for documents from a repository to a registry
ITI-43: Retrieve Document Set	Retrieve Document Set is used by a Document Consumer to retrieve one or more documents from a repository
Document Metadata Subscribe	This Transaction is sent by the Document Metadata Subscriber to the Document Metadata Notification Broker in order to start a subscription for a particular set of topics, indicating possible start and end time for the subscription. Subscriptions cannot be modified. Any subscriber interface can cancel a subscription, as long as they have the subscription ID. The subscription request shall specify whether a full notification or a minimal notification will be sent when there is a match to the subscription's filter
Document Metadata Notify:	This is a Transaction from the Document Metadata Notification Broker to the Document Metadata Notification Recipients, sending a notification about the availability of a document or documents of interest, based on the subscribers' filters on selected topics
Document Metadata Publish:	This Transaction is sent from the Document Metadata Publisher to the Document Metadata Notification Broker when an event occurs for which there may be a subscription



4.0 DOCUMENT UPDATES

The following sections provide the history of changes made to this document.

4.1 NOVEMBER 6, 2007

The changes in this cycle introduce the optional use of XDS.b and the optional use of XCA. These changes reflect the response of IHE to address identified gaps in the previous versions. Minor updates to text throughout this document have been made where appropriate to indicate where optionality can be exercised and what additional constraints apply when optionality is invoked.

4.1.1 VERSION COMPATIBILITY:

NOTE 1: This is identical to the interoperability supported by HITSP/TP13 Version 2.0

NOTE 2: Gap identified in XDS as defined by HITSP/TP13 Version 2.0, June 2006

4.2 DECEMBER 5, 2007

The changes in this cycle address the following comments:

- 2557

4.3 DECEMBER 13, 2007

Upon approval by the HITSP Panel on December 13, 2007, this document is now Released for Implementation.

4.4 MARCH 19, 2008

This document has been updated with the HITSP Security and Privacy requirements and has been updated to reflect the new template.

The following changes have been made to the construct:

- Updated references to IHE Technical Framework supplements for XDS.b and ITI-18
- Removed constraints as these are now inherent in the referenced IHE Framework transactions

4.5 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation.

The following changes have been made to the construct:

- Modified the following standard names/descriptions in **Table 2-13 Selected Standards** to provide more clarity and specificity for the optionality described in HITSP/TP13:
 - Removed high level reference to IHE ITI-TF Revision 4
 - Added specific reference to Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0, Section 10 Cross-Enterprise Document Sharing (XDS.a)
 - Modified Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b) description by moving extraneous content into the narrative of HITSP/TP13



- Modified Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement standard name by adding [ITI-18] for additional clarity

4.6 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

Corrections were made to interface descriptions and transactions.

4.7 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.

4.8 DECEMBER 10, 2008

The changes in this construct address the following comments received during the Public Comment and Inspection Testing period (September 29 – October 24, 2008).

- 5418
- Updated reference to IHE XCA Standard to: Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Supplement 2008-2009, Cross-Community Access (XCA), Trial Implementation, October 10, 2008

Minor editorial changes were made to this document.

4.9 DECEMBER 18, 2008

Upon approval by the HITSP Panel on December 18, 2008, this document is now Released for Implementation.

4.10 JUNE 30, 2009

Minor editorial changes were made to this document. Removed boilerplate text for simplification. The term “actor” was replaced with “interface.”

4.11 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.

4.12 NOVEMBER 9, 2009

The following changes have been made to the construct:

- Deprecated XDS.a to be consistent with IHE Deprecation
- Updated Section 2.1.2.3 to explain how nonrepudiation of origin is achieved at moderate level assurance with the Document Integrity Option
- Updated 2.3.2 to remove trial-implementation supplements as they are now formally incorporated into IHE ITI TF Version 6.0
- Updated to include DSUB Option
- Closed Gap 2.1.2.5.1 through a reference to HITSP/C80

4.13 JANUARY 18, 2010

The document has been updated to reflect the HITSP Transaction Package Template Version 2.7.



4.14 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

RELEASED FOR IMPLEMENTATION

