An Roinn Sláinte
DEPARTMENT OF HEALTH

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Interoperability Specification for Sharing Documents

Document Information	
Title:	Interoperability Specification for Sharing Documents
Purpose:	The purpose of this document is a Supporting Interoperability Specification for the sharing of documents in a nation-wide distributed environment organised around a document registry and one or more document repositories to which connect sources and consumers of documents.
Owners:	HSE Enterprise Architecture and Department of Health
Publication Date:	17th December 2018
Version:	1.1
Target Audience:	All relevant stakeholders in the implementation of the Irish National Contact Point for eHealth Services.
Review Date:	13th May 2020

EHEALTH DIGITIAL SERVICES INFRASTRUCTURE OPEN NATIONAL CONTACT POINT IMPLEMENTATION & TEST PLATFORM SERVICES

Interoperability Specification for Sharing Documents

Author: Hilary RAMANATSALAMA
Contract: Test Harness Support Service – HSE9100-LOT-2
Date: 17/12/2018
Version: 1.1
Status: Final
Reference: HSE9100-LOT2-IS-DOC_SHARING_1.1.docx

IHE-Europe – Bluepoint Building – 80, boulevard A. Ryers, 1030 Brussels Belgium

Document Lifecycle

Version	Date	Author	Update
0.1	27/07/2018	A-G BERGE	Creation
0.2	16/07/2018	Ch. PARISOT	Update following August 3rd T-con
0.3	27/08/2018	A-G BERGE	Review formatting
0.4	30/08/2018	H. RAMANANTSALAMA	Update following August 30th T-Con
0.5	11/10/2018	H.RAMANANTSALAMA	Add references
0.6	14/11/2018	A-G BERGE	Assign missing OIDs
1.0	17/12/2018	A-G BERGE	Clean up document
1.1	05/02/2019	H. RAMANANTSALAMA	Correction after Eamon review

Approval

Name	Responsibility	Signature
Eamon Coyne		

Distribution list

Name	Date	Contact	Purpose*
Eamon Coyne			V
Caitriona Wray			V
Peter Connolly			V

* A: for action / V: for Approval / C: for comments/ I: for information

Reference Documents

This section gathers the documents which are referenced in this document. In the body of this document, any reference to an external document is formatted using [KEYWORD] from the first column.

Keyword	Name and reference
[ITERM]	General Terminology Interoperability Specification HSE9100-LOT2-IS-TERMINOLOGY
[IPIM]	Patient Identification Management core Interoperability Specification HSE9100-LOT-2-IS-PAT_ID_MGMT
[ISEC]	Security and Privacy Interoperability Specification HSE9100-LOT-2-IS-SECURITY_PRIVACY
[UC_ANALYSIS]	ePrescription and Patient Summary use cases analysis HSE9100-LOT-2-2_DELIVERABLE-1A
[IHE_XDS]	IHE Cross-Enterprise Document Sharing IHE_ITI_TF_Vol1 (Section 10)
[IHE_XDS_HANDBOOK]	Document Sharing Metadata Handbook IHE_ITI_Handbook_Metadata
[IHE_TRANSACTIONS-A]	IHE IT Infrastructure Technical Framework Volume 2a (ITI TF-2a) Transactions Part A IHE_ITI_TF_Vol2a
[IHE_TRANSACTIONS-B]	IHE IT Infrastructure Technical Framework Volume 2b (ITI TF-2b) Transactions Part B IHE_ITI_TF_Vol2b
[IHE_XDS-MU]	IHE IT Infrastructure Technical Framework Supplement XDS Metadata Update
[IHE_RMD]	IHE IT Infrastructure Technical Framework Supplement Remove Metadata and Documents

Table of content

1. Preface

Ireland as a European country is becoming involved in the eHDSI (eHealth Digital Services Infrastructure) project led by the European Commission under the CEF (Connecting European Facilities) program and will participate to the deployment in the wave 3 (2020). To prepare the deployment of the NCPeH (National Contact Point for eHealth) in Ireland, the HSE (Health Service Executive) procured in 2017 the support services that will facilitate the implementation of the NCPeH and its connection to central Irish services. The first step of the project is to define the needed use cases to support and to design the architecture for connecting the Irish NCPeH. These tasks will be followed by the design of the architecture within Ireland, the corresponding Interoperability Specifications, the testing strategy including test plans and the implementation of Gazelle test platform that includes test cases, test tools and test data.

1.1 Context

Directive 2011/24/EU provides rules for facilitating access to safe and high quality cross border healthcare and promotes cooperation on healthcare between member states. The aims of implementing the Irish NCPeH exchange of Patient Summaries and ePrescription are in line with the principles of cross-border care. The NCPeH and cross border exchange implementations are all key building blocks that will interact with the national data dictionary (single source of trust for clinical data definitions across the enterprise), the Patient Summary and ePrescribing documents and associated will be stored there as minimum data sets.

The main goals are to design the platform based on the needs that will be developed in the first steps of the project, these include:

- Use Cases for ePrescription and Patient Summary.
- Corresponding Interoperability specifications and architecture orchestration.
- Validated version of IHE Gazelle. The test harness will provide to the authority the ability to test prospective vendors and products against the above interoperability specifications.

1.2 Glossary

IHE profile: Provides a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. A Profile is a guideline for implementation of a specific process, by providing precise definitions of how standards can be implemented to meet specific clinical needs. [eHealth Interoperability Conformity Assessment Scheme for Europe (EURO-CAS).]

Interoperability use case: Description of a specific use of HIT (Health Information Technology) that includes depiction of both humans (business actors) and systems (technical actors), scope, workflows of tasks performed by healthcare professionals and associated data flows. It should be written in natural language and may include several scenarios. One or more use cases are derived from one business case. [IHE taskforce]

Realisation scenario: Description of human activities (business actors), systems (technical actors) roles (i.e., IHE actors) and transactions related to a set of technical use cases that support the interoperability infrastructure for use cases (implementable infrastructure). [IHE taskforce]

1.3 Document purpose

An Interoperability Specification provides a detailed set of requirements (including references to specific profiles and standards) that enable health information exchange in an e-health deployment (national, regional, cross-border and/or intra institution) for a specific topic.

When covering the requirements related to the realisation of an interoperability use case, the corresponding interoperability specification is called a Core Interoperability Specification. A (Core) Interoperability Specification (IS) is targeted to be the sole entry point for the technology developers, the compliance assessment testing, and the purchaser of IT systems in term of technical requirements that will ensure interoperability.

When covering a subset of the interoperability requirements for one or more use cases, the corresponding interoperability specification is called a Supporting Interoperability Specification. Indeed, it is intended to be referenced by one of more Core Interoperability Specifications.

The present document is a Supporting Interoperability Specification for the sharing of documents in a nation-wide distributed environment organised around a document registry and one or more document repositories to which connect sources and consumers of documents.

1.4 How to read this document

This document contains three normative sections (8, 9, and 10), as well as informative appendices for the reader convenience. The document is structured as follows:

- **Section 2:** Establishes the Conformance Requirements for the present Interoperability Specification.
- **Section 3:** Irish eHealth Constraints for the IHE Cross-enterprise Document Sharing Profile (XDS).
- **Section 4:** Lists referenced documents, as well as the international standards which underpin the Interoperability Specification.
- **Appendix A:** Provides sample XDS messages.
- **Appendix B:** Provides background information on IHE Document Sharing metadata and its usage.

1.5 References

From a (Core) Interoperability Specification Supporting Interoperability specifications may be referenced from one or more Core Interoperability Specification(s). The present Interoperability Specification is such a supporting interoperability specification in the area of document sharing.

This supporting Interoperability Specification also references other supporting or core interoperability specifications:

- Supporting General Terminology Interoperability Specification [ITERM].
- Core Interoperability Specification on Patient Identification [IPIM].

Interoperability Specifications include precise references to internationally adopted profiles and standards as well as Irish specific constraints.

Implementations are required to conform to the requirements within one or more (Core) Interoperability Specification(s); some of the requirements reference Supporting Interoperability Specifications (such as the present document), and the standards and profiles they specify.

1.6 Description

This Interoperability Specification describes the technical interface requirements to enable the publication of shared documents, their storage in one or more repositories and their access through queries applied to the metadata associated to each shared document. It is intended to be referenced by Core Interoperability Specifications (e.g. Patient Summary Sharing or ePrescription Sharing].

1.7 Document Convention

Interoperability Specifications contain numbered requirements that follow this format:

[ABCD-###] - Where ABCD is a three or four letter acronym unique to that Interoperability Specification for convenient referencing purposes, and ### is the unique number for that requirement within the Interoperability Specification.

These numbered requirements are the elements of the Interoperability Specification that the system conforms to. In other words, in order to implement a system that fully supports the Core Interoperability Specification associated to a Use Case, the system shall be able to demonstrate that it conforms to every numbered requirement (including the Core IS) as well as in the referenced supporting ISs for the Use Case actors to which it is claiming conformance.

Please note that all numbered requirements are numbered uniquely, however numbered requirements are not always sequential.

1.7.1 Requirements language

Throughout this document the following conventions[1] are used to specify requirement levels:

- **SHALL:** The definition is an absolute requirement of the specification.
- **SHALL NOT:** The definition is an absolute prohibition of the specification.
- **SHOULD:** There may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
- **SHOULD NOT:** There may exist valid reasons, in particular circumstances, when the particular behaviour is acceptable or even useful. But the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.
- **MAY or OPTIONAL:** Means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

1.8 Methodology

This Interoperability Specification has been developed with input from various Irish stakeholders collected during several months through workshops and teleconferences. Stakeholders included Physicians from many different disciplines and Irish IT specialists.

The development of a Core Interoperability Specification relies on the high-level requirements set by the associated Use Case. These high-level requirements are not restated in this specification and readers may consider reviewing the related Use Case document.

1.8.1 Introduction of the use case driven approach

This methodology[2] has the objective to

- Define Use cases and their prioritization to answer the eHealth strategy objectives of nation/region;
- From use cases to design the interoperability specifications and infrastructure based on IHE profiles;
- To define the testing strategy and identify test plan and test methods (test cases, test tools and test data);
- To support Project teams to procure products or solutions for their eHealth Project (Telemedicine, national/regional EHR, replacement of product in hospitals etc.).

The methodology is based on experiences and good practices in other countries or regions. It is further described in section 4 of [UC_ANALYSIS].

[1] Definitions based upon IETF RFC 2119
[2] Bourquard, Karima and Berler, Alexander. Use case driven approach for a pragmatic implementation of interoperability in eHealth. IGI Global Journal

2 Conformance to the Irish constraints for the document sharing interoperability specification

Systems shall NOT claim conformance to this Interoperability Specification. Systems shall claim conformance to the requirements defined in the Core Interoperability Specifications that reference this document. The Core Interoperability Specifications deliver a user-relevant set of requirements corresponding to an Interoperability Use Case and places in context the requirements of this supporting Interoperability Specification.

3 Irish eHealth Constraints for the IHE Document Sharing Profile

This Section specifies Irish eHealth extensions and constraints to the IHE Cross-enterprise Document Sharing (XDS) profile. All details of the IHE XDS Profile and transactions are specified in IHE ITI Technical Framework, beginning with Volume 1 chapter 10 (IHE ITI TF-1: 10). For more information on IHE Document Sharing Profiles, see Section 4 Referenced documents and standards.

3.1 Requirements for IHE Patient Identity Source Actor

The Document Registry uses the Irish IHI number as its patient ID against which documents may be published and queried.

> **[IXDS-001]** The XDS Profile Patient Identity Source Actor shall be grouped with the Patient Demographic Supplier Actor (IHI Register) of the Patient Identity Management Interoperability Specification (IPIM).

Grouping of Actors is an IHE concept which implies that the services supported by both actors are implemented together to meet the Interoperability Specification in a way that ensures that appropriate health information is shared – (Patient IDs in this case). The Document Sharing Patient ID metadata attribute will always contain an existing and valid IHI number.

Note: The means by which the Identity Source Actor and the XDS Document Registry are synchronized with IHI numbers is out of scope for this Interoperability Specification and is left up to the Irish eHealth Infrastructure Internal Architecture design.

3.2 Requirements for IHE Document Source Actor

The Document Source actor of the IHE XDS.b Profile provides the capability to publish documents to an XDS.b Document Repository actor (and to register the documents metadata to the Document Registry).Those requirements also apply to the Integrated Document Source/Repository actor.

3.2.1 Handling of Document Sharing Metadata

The Document Source is responsible for accurately creating the metadata as per the specification of the IHE XDS.b Profile in the IHE ITI Technical Framework Volume 3 (ITI TF3: 4.2.3).

Note: An overview of the Document Sharing metadata is provided in Appendix B of this document. The IHE Document Sharing Profile defines specific metadata requirements. These requirements are not restated by this Interoperability Specification. This Interoperability Specification focuses only on the Irish eHealth specific constraints. The reader is advised to study the IHE XDS Metadata Handbook ([IHE_XDS_HANDBOOK])).

> **[IXDS-002]** The Document Source Actor shall create metadata attributes ensuring consistency across all healthcare document submissions.

These metadata attributes accurately reflect the specific content of the published documents.

> **[IXDS-003]** Each value selected from a value set for a metadata attribute shall not conflict with the values selected for other metadata attributes.

Such a conflict would create an ambiguous situation and render the metadata unsafe.

Note: Document Sources should apply the same rigor in control and quality assurance for the metadata attributes as they apply for the clinical data they manage.

3.2.1.1 Class Code

This code specifies the particular kind of document at a coarse-grained level.

> **[IXDS-005]** The class Code metadata shall have a single value.

> **[IXDS-006]** The value of the class Code metadata shall be one of the values from the Document Class Code Value Set (OID= 1.3.6.1.4.1.19376.1.2.6.1.1).

Note: The document class Code value set is specific to the content of various documents being shared by using the IHE Document Sharing Profiles. The value to be used is specified by the specific Core Interoperability Specifications that constraints sharing of the documents.

3.2.1.2 Confidentiality Code

This code specifies the level of confidentiality of the document.

> **[IXDS-007]** The confidentiality Code metadata shall have one or more values.

> **[IXDS-008]** The value of confidentiality Code metadata shall be one of the values from the Confidentiality Code value set (OID= 1.3.6.1.4.1.12559.11.10.1.3.1.42.31).

Note: This value set is restricted in its use to the values: Normal (N) and Restricted (R), until the Irish Health Information Exchange policies are further refined. This value set is compatible with the one selected by the EU Cross-Border eHDSI project (OID= 2.16.840.1.113883.1.11.16926). However, the third value defined by eHDSI, Very Restricted (VR), is not used at this time in Ireland.

3.2.1.3 Healthcare Facility Type Code

This code represents the type of organization (and type of care) where the clinical encounter during which the documented act occurred.

[IXDS-009] The healthcare Facility Type Code metadata shall have a single value.

[IXDS-010] The value of healthcare Facility Type Code shall be one of the values from the Organization Provider Type Values Set (OID= 1.2.372.980010.3.2) as specified in the Irish Provider Service Directory and documented in the General Terminology Interoperability Specification [ITERM].

3.2.1.4 Practice Setting Code

This code specifies the clinical specialty where the act that resulted in the document was performed (e.g., Intensive Care, General Medicine, Laboratory and Radiology).

[IXDS-011] The practice Setting Code metadata shall have a single value.

[IXDS-012] The value of the practice Setting Code shall be from one of the values of the Organization Specialty Values Set (OID= 1.2.372.980010.3.3) as specified in the General Terminology Interoperability Specification.

3.2.1.5 Type Code

This code specifies the precise kind of document at a fine-grained level (e.g., Encounter Summary, Discharge Summary, Ultrasound Report and Prescription).

[IXDS-013] The Type Code metadata shall have a single value.

Note: The document Type Code value set is specific to the content of various documents being shared by using the IHE Document Sharing Profiles. The value to be used is specified by the specific Core Interoperability Specifications that constraints sharing of the documents.

3.2.1.6 Format Code

This code specifies the syntactic encoding of the document as defined by the Interoperability Specification on the document content.

[IXDS-014] The Format Code metadata shall have a single value.

Note: The document Format Code value set is specific to the content of various documents being shared by using the IHE Document Sharing Profiles. The value to be used is specified by the specific Core Interoperability Specifications that constraints sharing of the documents.

3.2.1.7 MIME Type

This code specifies the MIME type as defined by the Interoperability Specification on the document content.

[IXDS-016] The MIME Type metadata shall have a single value.

Note: The document MIME Type value set is specific to the content of various documents being shared by using the IHE Document Sharing Profiles. The value to be used is specified by the specific Core Interoperability Specifications that constraints sharing of the documents.

3.2.1.8 Patient Id

This metadata represents a valid IHI number verified with the Patient Demographics Supplier Actor. It is used in the Document Entry, Submission Set and Folder Metadata. The Actor grouping requirements for the flow of consistent patient IDs applies between the Document Source and the Patient Demographics Consumer when documents are submitted to the Document Repository Use Case Actor (supporting both the XDS Document Repository and the XDS Document Registry).

[IXDS-018] The Patient Id metadata shall contain a patient ID with a universal ID value of "1.2.372.980010.1.2", which stands for the Registration Authority OID.

Note: It is outside the scope of this specification to define the technical means by which this flow of consistent Patient IDs is achieved. (See the Core Interoperability Specification that referenced this Document Sharing IS).

3.2.1.9 Event Code List

This list of codes represents the main clinical "key words" that may be added for certain types of documents and used for associated queries.

[IXDS-019] Event Code List shall have zero or more values.

[IXDS-020] The Coding Scheme for each event Code shall use the OID of the value set related to the specific event Code.

Note: The semantics associated with each keyword are not defined by IHE XDS.b nor are they defined by this Interoperability Specification, as they are specific to the types of document content being shared (e.g. acquisition modality is a keyword for radiology imaging content).The event Code elements (Coding Scheme, Code value and Code meaning) are specific to the various documents shared using the IHE Document Sharing Profiles. Therefore, the event Code value sets are defined in the relevant Core Interoperability Specifications.

Note: A case of usage of an event Code is to list the identifiers of Acknowledged Privacy Policies with the metadata associated with the Privacy Acknowledgement Document specified by the IHE BPPC Profiles and customized for Ireland in the supporting Security and Privacy Interoperability Specification.

3.2.1.10 Source Patient Id, source Patient Info, legal Authenticator

[IXDS-021] The source Patient Id, the source Patient Info, and the legal Authenticator metadata Attributes shall be empty.

3.2.1.11 Intended Recipient (Optional)

The intended Recipient attribute conveys configured values defined by the eHealth Infrastructure platform.

[IXDS-022] The intended Recipient attribute shall be empty unless a notification is to be issued to a Document Consumer for a specific document.(See the Core Interoperability Specification that references this IS.)

3.2.2 Document Replacement Option

This option ensures that all published documents maybe updated if a correction is needed. Further details about such situations are specified in the Core Interoperability Specification that refers to this IS.

[IXDS-023] A system which implements the Document Source actor shall also support the Document Replacement option as defined in IHE ITI TF-1 10.2.1.

3.2.3 Document Transformation Option

This option (see [IHE_XDS]: 10.2.2) shall be supported by Document Source Actors, in scenarios when required by the Core Interoperability Specification that refers to this IS.

3.2.4 Metadata Update

[IXDS-024] Systems which implement the Document Source Actor shall also support the Document Administrator Actor as defined by the IHE Metadata Update Supplement (see [IHE_XDS-MU]) to the Document Sharing Profiles.

[IXDS-025] Systems which implement the Document Administrator Actor shall support the Delete Option (see [IHE_RMD]).

The Delete option allows the removal of documents filed in error for the wrong patient.

Note: a new profile Supplement RMU (Restricted Metadata Update) is being defined to further enhance the metadata update service and may be considered in the future.

3.2.5 Optional Services

3.2.5.1 Document Addendum (Document Source only-Optional)

[IXDS-026] The Document Addendum option (see [IHE_XDS] 10.2.2) may be supported by Document Source Actors.

Note: This XDS.b Option allows associating a distinct document to include additional content to an earlier published document without deprecating the earlier published document. It has been

decided rather to create a new document that combines the earlier published content and the additional content into a new document that replaces the earlier document (See above).

3.2.5.2 Folder Management (Optional)

This option (see [IHE_XDS] 10.2.2) may be supported by Document Source Actors, in scenarios when required by the referring Core Interoperability Specification.

3.2.5.3 Asynchronous Web Services Exchange (Optional)

[IXDS-027] This option may be supported by Document Source Actors (See [IHSE_XDS] 10.2.5).

3.3 Requirements for IHE Document Consumer Actor

3.3.1.1 Handling of Document Sharing Metadata

[XDS-030] Document Consumers Actors, when including in their queries metadata elements defined in Section3.2.1shall use metadata value codes from the value sets defined by the requirements of Section 2.2.1.

3.3.1.2 Handling of Document Sharing Registry Queries

[IXDS-031] Document Consumer Actors shall implement one or more patterns for querying and retrieving healthcare documents.

Note: This flexibility is required to obtain the most appropriate set of documents based upon the point of service specific needs (i.e. admission, nursing, discharge, primary care encounter, etc.).In each one of these situations different type of queries may be offered to the health professional, or automatically triggered from within the clinical application using the most appropriate combination of metadata elements proposed in Appendix B. Document Consumer Actors may also “pre-define” specific queries based upon the various code value sets specified. These “pre-defined” queries facilitate automated queries for common point of service needs, such as automated document retrieval and document content aggregation and processing (See Appendix B for different levels of query strategies).

3.3.1.3 Asynchronous Web Services Exchange Option

[IXDS-032] The Asynchronous Web Services Exchange option may be supported by Document Source Actors (See [IHE_XDS]: 10.2.5).

3.3.1.4 On-Demand Documents Option

The On-Demand Documents Option maybe supported by Document Consumer Actors.

Note: Further constraint on usage of this option is given by the Core Interoperability Specifications.

3.3.1.5 Delayed Document Assembly Option

The Delayed Document Assembly Option may be supported by Document Consumer Actors.

Note: Further constraint on usage of this option is given by the Core Interoperability Specifications.

Note: With this option, Document Consumers are able to understand that some documents included in the response to a Registry Stored Query will have a zero size and hash value but once retrieved those attributes will be updated to the correct values. This allows interactions with XDS Document Repositories built as "façade" to existing clinical data repositories such as a prescription repository, where a small proportion of the prescriptions registered may be retrieved.

3.4 Requirements for Document Registry and Repository

3.4.1.1 Handling of Document Sharing Metadata

[IXDS-040] The XDS Document Registry Actor shall verify at document registration time that only codes from the value sets defined in Section3.2.1 are used.

[IXDS-041] Use of unknown code values shall result in rejection of the [ITI-42] Register Document Set – b (and related [ITI-41] Provide and Register Document Set-b Transaction).

[IXDS-042] The Document Registry Actor shall support the Delete Option ([ITI-62] Delete Document Set transaction) specified in the IHE Remove Metadata and Document [IHE_RMD] Supplement.

3.4.1.2 Patient Identity Feed (HL7V2.5 based)

This option (See ITI TF-2a: 3.8) is not defined in this Interoperability Specification. The means by which the Identity Source Actor, the Patient Demographics Supplier Actor of the National Patient Registry and the XDS Document Registry are synchronized about patients are beyond the scope of this Interoperability Specification and are part of the internal Irish eHealth Infrastructure architecture design decisions.

3.4.1.3 Patient Identity Feed HL7v3

This option (see ITI TF-2b: 3.44) is not defined in this Interoperability Specification.

3.4.1.4 Asynchronous Web Services Exchange- Optional

[IXDS-043] This option may be supported by Document Source Actors (See [IHE_XDS] 10.2.5).

3.4.1.5 Document Replacement

[IXDS-044] The XDS Document Registry shall enforce that only the Document Source Actor that has published a document is authorised to replace it (based on source Id in metadata).

Note: Exceptions to this default rule may be specified in the referring Core Interoperability Specification.

3.4.1.6 On-Demand Documents

[IXDS-045] The XDS Document Registry SHALL support the On-Demand Documents option.

[IXDS-046] The XDS Document Registry SHALL support the ability to be configured to notify the appropriate On-Demand Document Source when a patient is queried for Use Case specific content for which no On-Demand document registry entry exists prior to completion of query processing, allowing the On-Demand Document Source to create a new registry entry if needed. See section 3.5 Requirements for On-Demand Document Source Actor for more details on this requirement.

3.4.1.7 Delayed Document Assembly

[IXDS-047] The Delayed Document Assembly Option MAY be supported by Integrated Document Source/Repository Actors.

Note: An Integrated Document Source/Repository declares the Delayed Document Assembly option if it is able to register Stable Document Entries with size and hash zero to represent a stable document which content has not yet been assembled. It is capable to assemble the Document Content upon receipt of a Retrieve Document Set transaction and update the size and hash values by grouping with an XDS.b Document Administrator Actor in order to update the document entry using the Document Metadata Update Option.

3.5 Requirements for On-Demand Document Source Actor

On-Demand Document Source Actors are able to dynamically generate documents for a patient containing specific content to support various use cases. The On-Demand Document Source is required to register an entry for each patient for each kind of document it can generate.

Note: This on-demand document creation may be used for example for a patient summary aggregation service that performs its aggregation with the most current encounter and discharge summaries available at the time of the on-demand request.

To avoid the need for pre-populating the XDS document registry with these entries, this Interoperability Specification requires the XDS Document Registry be configurable to notify On-Demand Document Sources of queries for information for which the registry does not have an On-Demand document entry. The On-Demand Document source may, upon receiving this notification, register a new On-Demand Document type with the IHE XDS Document Registry actor prior to completing this transaction.

[IXDS-050] On-Demand Document Source actors shall be grouped with, and conform to all requirements specified for Document Source actors found in section 2.2 above.

[IXDS-051] On-Demand Document Source actors shall implement the Persistence of Retrieved Documents Option.

[IXDS-052] On-Demand Document Source actors shall only create and register new On-Demand documents when the clinical content of the new document differs from the last on-demand document of the same type created for the patient.

[IXDS-053] On-Demand Document Source actors shall register an On-Demand document entry for each patient for which on-demand data are available.

[IXDS-054] On-Demand Document Source actors shall register an On-Demand document type for a patient upon notification by the XDS Document Registry that such a document type was requested if relevant content is available for that OnDemand document type.

3.6 Requirements for Document Administrator Actor

The Document Administrator supports metadata update by issuing the Update Document Set [ITI-57] transaction to the Document Registry and shall be capable of generating at least one of the operations documented in ITI TF-2b: 3.57.4.1.3.3.

No specific requirement is defined for this actor.

4 Referenced documents and standards

The following documents and standards were referenced during the development of this Interoperability Specification.

TABLE 5-4-1 INTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
Core Interoperability Specification for Patient Identification Management	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide IHI numbers are used.
Irish Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of Health Information Exchange. The Health Information Exchange Policies apply to all individuals and organizations that have access to shared health records.

TABLE 5-4-2 EXTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IHE IT Infrastructure (ITI) Technical Framework – Volume 3 (ITI TF-3) Integrations Profiles, Section 4 Metadata used in Document Sharing profiles	Describes the metadata that is used in IHE profiles designed for sharing documents (Document Sharing profiles). The Document Sharing profiles are implementing the Document Sharing concept outlined in the ITI whitepaper entitled Health Information Exchange: Enabling Document Sharing Using IHE Profiles May be obtained at https://www.ihe.net/resources/technical_frameworks/#IT
IHE IT Infrastructure (ITI) Technical Framework – Volume1 (ITI TF-1) Integrations Profiles, Section 10 Cross-Enterprise Document Sharing (XDS.b)	Facilitates the registration, distribution and access across health enterprises of patient electronic health records. This profile 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. May be obtained at https://www.ihe.net/resources/technical_frameworks/#IT
IHE IT Infrastructure (ITI) Technical Framework Supplement – Metadata Update	Updates the XDS and XDR profiles to add support for the updating and deleting of metadata. One new actor and two new transactions are introduced. The Document Administrator actor is the source of the new transactions. The Update Document Set transaction carries metadata updates and the Delete Document Set transaction enables metadata deletion. These new capabilities are assigned to a new actor and new transactions to enable tighter authentication/authorization control over their use. May be obtained at https://www.ihe.net/resources/technical_frameworks/#IT
IHE IT Infrastructure (ITI) Technical Framework Supplement – On-Demand Documents	Updates the XDS and XCA profiles to support the sharing of dynamically created document content by adding an option for On-Demand Documents. On-Demand Documents are not specific to any type of content profile; it is expected that all document content profiles used by XDS and XCA may be shared using On-Demand Documents in the same way they are shared in the base XDS and XCA profiles. May be obtained at https://www.ihe.net/resources/technical_frameworks/#IT

5 Appendix A – Sample Messages

5.1 Sample Provide and Register Document Set

This example provides a sample transaction from the corresponding IHE Profile including the Irish customisations. It will be provided in a future update to this specification.

5.2 Sample Registry Stored Query

This example provides a sample transaction from the corresponding IHE Profile including the Irish customisations. It will be provided in a future update to this specification.

5.3 Sample Document Metadata Notify transaction

This example provides a sample transaction from the corresponding IHE Profile including the Irish customisations. It will be provided in a future update to this specification.

6 Appendix B –IHE Document Sharing metadata

TABLE 6-1Metadata Overview Table – Document Entry provides the list of the metadata that may be associated with documents stored and shared within an XDS affinity domain.

This Appendix does not specify any additional interoperability requirements beyond those included in the above sections. However, it provides guidance for implementers of interoperable applications leveraging the Document Sharing metadata for queries.

The table qualifies the various metadata elements into four types of usage:

- Primary Filtering: Metadata attributes primarily used for querying documents and submission sets (Registry Stored Query).This may be a narrowly targeted query (looking for a specific or small set of documents) or a broad query intended to select a manageable set of likely relevant documents.
- Secondary filtering: Metadata attributes intended to be returned with the matches of a primary query and allow a human (or application) to filter, out among the returned candidates, the ones that are not relevant and need not be retrieved.
- Third-level filtering: Once the relevant documents have been retrieved the content may be processed (aggregated, displayed, etc.) and relevant information extracted. This third level is not included in the metadata table as metadata are not used for this third-level filtering.
- Technical: Metadata attributes critical for the operation of the queries, but generally not visible to the clinical user. They are used for integrity verification, performance management, configuration, etc.

TABLE 6-1 METADATA OVERVIEW TABLE – DOCUMENTENTRY

XDS METADATA ATTRIBUTE	ATTRIBUTE DEFINITION	INTENDED USE	CODED QUERY KEYS
METADATA USE FOR BROAD SEARCHES			
Patient Id	The patient Id represents the subject of care of the document. It contains the Irish IHI number with its two parts: • Authority Domain Id (OID enforced by the Registry) • An Id in the above domain issued by the National Patient Register	Primary Query	No
Service Start Time	Represents the start time the service being documented took place (clinically significant, but not necessarily when the document was	Primary Query	No

	produced or approved).		
Service Stop Time	Represents the stop time the service being documented took place. Same details as service Start Time	Primary Query	No
Class Code	The code specifying the particular kind of document. Shall have a single value. Coded with a coarse level of granularity.	Primary Query	Yes
Practice Setting Code	The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Intensive care, Laboratory, Radiology). Coarse level of granularity. Has a single value.	Primary Query	Yes
METADATA FOR TARGETTED SEARCH			
Healthcare Facility Type Code	This code represents the type of organizational where the clinical encounter during which the documented act occurred. The value chosen in the value set need to avoid conflict with the value used in the type Code, as such a conflict would create an ambiguous situation. Has a single value.	Primary Query	Yes
Availability Status	An XDS Document shall have one of two availability statuses: • Approved: available for patient care • Deprecated: obsolete	Primary Query	No

Confidentiality Code	The code specifying the level of confidentiality of the document. Has one or more values.	Primary Query	Yes
Unique Id	The globally unique identifier assigned by the document creator to this document. This unique identifier may be used in the body of other documents to reference this document. The structure and format of this Id is consistent with the document content Interoperability Specification, in particular with the format Code attribute. Has a single value.	Primary Query	No
Event Code List	This list of codes represents the main clinical “key words” for queries specific to certain document content (e.g. test panel code for laboratory results). The value chosen shall	Primary Query (second level- Use Case specific)	Yes

	not conflict with the values selected in the class Code, practice Setting Code or Type Code; as such a conflict would create an ambiguous situation. This value list may have zero or more values.		
Reference Id List	This list contains zero or more Identifiers. These Identifiers may be internal or external identifiers, E.g., Identifiers may be Accession Numbers, Order Numbers, Referral Request Identifiers, XDW Workflow Instance Identifiers, etc.	Primary Query (second level-Use Case specific)	No
METADATA FOR FILTERING QUERY RESPONSES BEFORE RETRIEVING			
Title	Represents the title of the document and is encoded in UTF-8.	Secondary Filtering	No
Type Code	The code specifying the precise kind of document (e.g., Pulmonary History and Physical, Discharge Summary, Ultrasound Report). Shall have a single value.	Secondary Filtering	Yes
Author	Represents the humans and/or machines that authored the document and contains the following sub-attributes: • Author Institution • Author Person • Author Telecommunication	Secondary Filtering	No
Comments	Comments associated with the Document. Free-form text.	Secondary Filtering	No
Creation Time	Represents the time the author created the document in the Document Source. Shall have a single value	Secondary Filtering	No
SPECIAL PURPOSE METADATA			
Entry UUID	This globally unique identifier is primarily intended for use as a document registry management identifier. It is not meant to be an external reference (outside of the Document Registry) for documents (e.g., in links within other documents).	Technical	No
Format Code	Code globally uniquely specifying the format of the document. Along with the type Code, it provides sufficient information to allow any potential Document Consumer to know if it	Technical	No

	will be able to process/display the document by identifying an encoding, structure and template		
Hash	Hash key of the document itself. This value is computed by the Document Repository and used by the Document Registry for detecting tampering or the improper resubmission of documents .Has a single value.	Technical	No
Home Community Id	A globally unique identifier for a community. Configured in every document source, consumer, repository, or registry actor to enable cross community access between multiple XDS affinity domains.	Technical	No
Mime Type	MIME type of the document in the Repository. Shall have a single value.	Technical	No
Repository Unique Id	The globally unique identifier of the repository where the document is stored, assigned by each Document Repository. Has a single value.	Technical	No
Size	Size in bytes of the byte stream of the document that was provided in the [ITI-42] Provide and Register – b Transaction and stored by the XDS Document Repository.	Technical	No
Language Code	Specifies the human language of character data in the document. The values of the attribute are language identifiers as described by the IETF (Internet Engineering Task Force) RFC 3066. Has a single value.	Secondary Filtering	No
Source Patient Id	The source Patient Id represents the subject of care medical record Identifier (e.g., Patient Id) in the local patient Identifier Domain of the Document Source. If used, it contains two parts: • Authority Domain Id • An Id in the local domain (e.g., Patient Id). It is only intended as an audit/checking mechanism and has occasional use for Document Consumer Actors.	Not Used	N/A
Source Patient Info	This attribute should contain demographics information of the patient to whose medical record this document belongs, as the Document Source knew it at the time of Submission. It is only intended as an audit/checking	Not Used	N/A

	mechanism and has occasional use for Document Consumer actors.		
Legal Authenticator	Represents a participant who has legally authenticated or attested the document within the author Institution. Legal authentication implies that a document has been signed manually or electronically by the legal Authenticator. This attribute may be absent if not applicable. If present, shall have a single value	Not Used	N/A

A Submission Set plays the role of an “envelope” within which one or more documents have to be placed for submission and registration. Such a concept is clinically important, as it represents semantics, not only about the concurrent sharing of a document set, but also about the clinical significance of their grouping (e.g. a hospital discharge summary along with attached laboratory and cardiology reports). The metadata attributes related to a Submission Set and their use for queries is presented in Table 6-2Metadata Overview Table – Submission Set.

TABLE 6-2 METADATA OVERVIEW TABLE – SUBMISSIONSET

XDS METADATA ATTRIBUTE	ATTRIBUTE DEFINITION	INTENDED USE	PRIMARY QUERY CODES
Availability Status	A Submission Set has one of two availability statuses: • Deprecated: this document has been replaced • Approved: available for patient care if present, has a single value.	Primary Query	No
Content Type Code	The code specifying the type of clinical activity that resulted in placing these documents in this Submission Set. Has a single value.	Primary Query	Yes
Entry UUID	This globally unique identifier is primarily intended for use as a document registry management identifier. It is not meant to be an external reference (outside of the Document Registry) for documents (e.g., in links within other documents).	Primary Query	No
Intended Recipient	Represents the organization(s) or person(s)	Primary	No

	for whom the Submission Set is intended.	Query	
Patient Id	The patient Id (IHI number) represents the medical record identifier of subject of care whose longitudinal record is being maintained. Has a single value.	Primary Query	No
Source Id	OID identifying the instance of the Document Source that contributed the Submission Set. When a "broker" is involved in sending submission sets from a collection of client systems, it should use a different source ID for submissions from each separate system to allow for tracking.	Primary Query	No
Submission Time	Point in Time at the Document Source when the Submission Set was created and issued for registration to the Document Registry. Has a single value.	Primary Query	No
Unique Id	Globally unique identifier for the submission-set instance assigned by the Document Source in OID format. Has a single value.	Primary Query	N/A
Title	Represents the title of the Submission Set .If present, has a single value.	Secondary Filtering	No
Comments	Comments associated with the Submission Set. Free form text with an XDS Affinity Domain specified usage.	Secondary Filtering	No
Author	Represents the humans and/or machines that authored the document. This attribute contains the following sub-attributes: • Author Institution • Author Person • Author Telecommunication	Secondary Filtering	No
Home Community Id	A globally unique identifier for a community.	Technical	No