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Saudi Health Council

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(SHC)

Enabling Standards-Based eHealth Interoperability

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Saudi eHealth Document Sharing Interoperability Specification

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Specification

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PREFACE

DOCUMENT PURPOSE

The purpose of this document is to support several Core Interoperability Specifications and their associated Use Cases, in a specific area of interoperability. This area is centered on the sharing of documents containing health records using the IHE Document Sharing family of integration profiles. The scope of this document is to specify the Saudi eHealth specific constraints when using the IHE Document Sharing integration profiles to support the sharing of documents containing health records. It complements these IHE Profiles. It also aligns with the Saudi e-Government Interoperability Standards (YEFI) to expedite national adoption.

This Supporting Interoperability Specification is applicable to existing and new information systems that are to be connected to a Health Information Exchange (HIE) Platform.

WHERE TO FIND INFORMATION

This document contains five normative sections, as well as informative appendices for your convenience. The document is structured as follows:

Section 1: Contains an introduction to the Interoperability Specification (IS). This section contains a summary of the IS purpose and assumptions, as well as other content to help orient the first time reader to the topic of the IS and how it relates to other specifications in the SeHE System.

Section 2: Establishes the Conformance Requirements for the Interoperability Specification

Section 3: Describes the Saudi specific extensions and constraints on the IHE Document Sharing profiles (XDS.b and XDM), including Saudi specific requirements for the IHE Patient Identity Source, Document Source, Document Consumer, Document Registry and Repository, and Integrated Document Source/Repository actors.

Section 4: Describes the Saudi specific constraints and extensions for the Document Metadata Subscription profile, including Saudi specific requirements for the IHE Document Metadata Notification Broker and Document Metadata Notification Recipient actors.

Section 5: Describes the related Saudi eHealth Interoperability Specifications, as well as the international standards which underpin this Interoperability Specification.

Appendix A: Provides sample messages for IHE Provider and Register, Registry Stored Query, and Document Metadata Notify transactions.

Appendix B: Provides a list of informative guidance for implementers to leverage IHE Document Sharing Metadata for queries.

ASSUMPTIONS

The reader of this Interoperability Specification is assumed to be familiar with the IHE Document Sharing Profiles, in particular the following concepts:

- IHE Document Sharing Actors, for example: Document Registry, Document Repository, Document Source, On-Demand Document Source, and Document Consumer.
- DSUB Actors such as Document Metadata Notification Broker, and Document Metadata Notification Recipient
- IHE Document Sharing Profile Options
- IHE Document Sharing Metadata

The IHE Document Sharing Profiles offer a number of options and the ability to assign specific coded value sets to certain IHE Document Sharing metadata attributes. These value sets are defined to enable definite and consistent choices throughout the KSA and to ensure effective interoperability between systems.

REFERENCES

This document is a Supporting Interoperability Specification that may be referenced by a number of Core Interoperability Specifications, as shown by example in *Figure i1 References to the Saudi eHealth Document Sharing Interoperability Specification*. It is a specification targeted to be testable unit of the Core Interoperability Specification for the technology developers, the compliance assessment testing and certification, and the purchaser of IT systems in terms of technical requirements that will ensure interoperability.

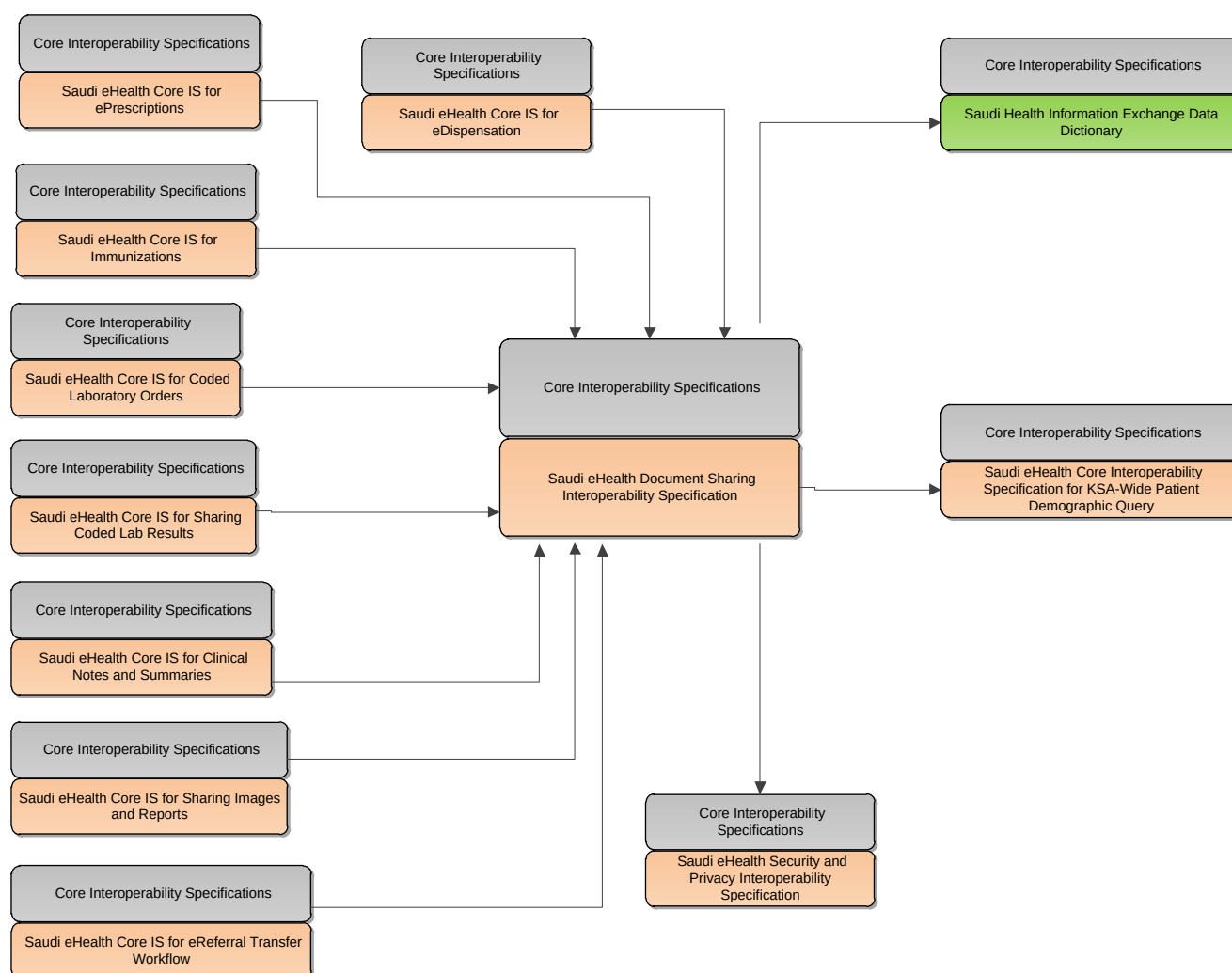


FIGURE 12 REFERENCES TO THE SAUDI EHEALTH DOCUMENT SHARING INTEROPERABILITY SPECIFICATION

DESCRIPTION

This Interoperability Specification describes the technical requirements for the interface to share healthcare based clinical documents via the Saudi Health Information Exchange (HIE). It is used in conjunction with multiple Core Interoperability Specifications that enable document exchange via the IHE XDS.b, XDM and DSUB Profiles. This Interoperability Specification specifies Saudi eHealth specific constraints to IHE XDS.b, XDM and DSUB.

METHODOLOGY

This Interoperability Specification has been developed with input from various Saudi stakeholders collected during several months through workshops and teleconferences.

DOCUMENT CONVENTIONS

Requirements numbering conventions:

All Saudi eHealth 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 purposes, and #### is the unique number for that requirement within the Interoperability Specification.
- “Where a specific value set or code is required to be used, it can be found in the “IS0200 Saudi Health Information Exchange Data Dictionary”. The location and process to access the Health Information Exchange Data Dictionary will be specified in mechanisms external to this document.

Saudi eHealth numbered requirements are the elements of the Interoperability Specification that the system can conform to. In other words, in order to implement a system that fully supports the Use Case and Interoperability Specification, the system shall be able to demonstrate that it conforms to every numbered requirement for the system actors to which it is claiming conformance.

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

Requirements language

Throughout this document the following conventions¹ are used to specify requirement levels:

SHALL: the definition is an absolute requirement of the specification. (Note: “SHALL IF KNOWN” means that the tag must be sent. However, if there were no information, then this tag should be sent with a <nullflavor>)

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 behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior 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 Definitions based upon RFC 2119

1. USE CASE OVERVIEW

1.1 SCOPE

In Scope:

The scope of this document is the specification of usage of the IHE XDS.b and supporting profiles within the HIE System.

The following topics are in scope for this Interoperability Specification:

- Definition of IHE XDS.b, XDM, DSUB and Metadata Update constraints for use in the HIE Platform and specification of document sharing common constraints

Out of scope:

The following is a list of content and specifications that are specifically out of scope for this Interoperability Specification:

- The means by which the Identity Source Actor for the KSA (identical to the KSA-Wide Demographics Supplier Actor) and the XDS Document Registry are synchronized with KSA-Wide Health IDs is out of scope for this Interoperability Specification. This is left up to the SeHE Internal Architecture design
- The IHE XDS.b Profile defines specific metadata requirements. These requirements are not restated by this Interoperability Specification. This Interoperability Specification focuses only on the Saudi eHealth specific constraints.
- The semantics associated with each clinical key word listed in this document are not defined by the IHE XDS.b Profile nor 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 clinical content associated with an On-Demand Document Source is not defined by the IHE XDS.b or XDM profiles, nor by this Interoperability Specification, as they are specific to the types of document content being shared (e.g., On-Demand Immunization histories, Medication histories, or iEHR summaries).

1.2 DESIGN CONSTRAINTS AND ASSUMPTIONS

It is expected that all services initiated or provided by these Actors operate in accordance to the Saudi eHealth Interoperability Policies.

This specification addresses design constraints that are to be used by all Core Interoperability Specification that exchange patient records using the IHE Document Sharing capabilities. The constraints are generic for document sharing and not specific to the Core Interoperability Specification. Each Core Interoperability Specification may override and/or provide additional constraints based upon the specific requirements of the Use Case.

2. CONFORMANCE TO THE SAUDI CONSTRAINTS FOR THE IHE DOCUMENT SHARING PROFILES

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.

3. SAUDI eHEALTH CONSTRAINTS FOR THE IHE DOCUMENT SHARING PROFILES

This Section specifies Saudi eHealth extensions and constraints to the IHE Cross-enterprise Document Sharing (XDS.b) and Cross-Enterprise Document Media Interchange (XDM) integration profiles. All details of the IHE XDS.b and XDM Profiles and transactions are specified in IHE ITI Technical Framework, beginning with Volume 1 chapter 10 (IHE ITI TF-1: 10) and chapter 16 (IHE ITI TF-1: 16). For more information on IHE Document Sharing Profiles, see Section 5 Referenced documents and standards.

3.1 REQUIREMENTS FOR IHE PATIENT IDENTITY SOURCE ACTOR

The Document Registry uses the KSA-Wide Health ID, as its patient ID against which documents may be published and queried.

[KXDS-001] – The XDS Profile Patient Identity Source Actor shall be grouped with the Patient Demographic Supplier Actor of IS0001 *KSA-Wide Patient Demographic Query Interoperability Specification*, see Figure 3.1-1 Flow of consistent Health IDs. 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 – Health IDs in this case). The Document Sharing patientId metadata attribute will always contain an existing and valid Health ID.

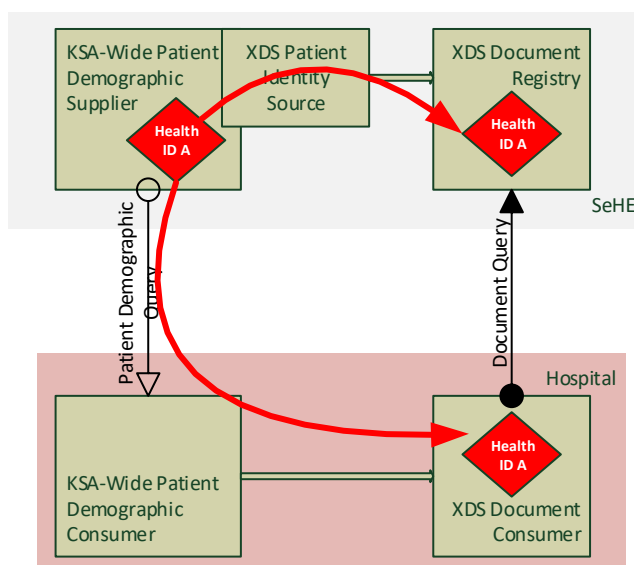


FIGURE 3.1-1 FLOW OF CONSISTENT HEALTH IDS

Note: The means by which the Identity Source Actor for the KSA (identical to the KSA-Wide Demographics Supplier Actor) and the XDS Document Registry are synchronized with KSA-Wide Health IDs is out of scope for this Interoperability Specification and is left up to the HIE Internal Architecture design.

3.2 REQUIREMENTS FOR IHE DOCUMENT SOURCE AND PORTABLE MEDIA CREATOR ACTORS

The Document Source actor of the IHE XDS.b Profile and the Portable Media Creator actor of the XDM Profile provide the capability enabling the transmission or publication of documents to another actor. The XDS.b Profile does so via transactions over a network based interaction, while the XDM Profile does so using media or e-mail as a means of conveying information.

3.2.1 Handling of Document Sharing Metadata

[KXDS-002] – Document Source and Portable Media Creator Actors are responsible to accurately create the metadata as per the specification of the IHE XDS.b and XDM Profiles in the IHE ITI Technical Framework Volume 3 (ITI TF-3: 4.2.3). An overview of the Document Sharing metadata is provided in Appendix D of this document.

The creation of metadata attributes requires specific attention to ensure consistency across all healthcare document submissions. These metadata attributes accurately reflect the specific content of the published documents. In particular, each value selected 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 and Media Creators should apply the same rigor in control and quality assurance for the metadata attributes as they apply for the clinical data they manage.

The IHE Document Sharing Profiles define specific metadata requirements. These requirements are not restated by this Interoperability Specification. This Interoperability Specification focuses only on the Saudi eHealth specific constraints.

3.2.1.1 classCode

[KXDS-003] – The code specifying the particular kind of document at a coarse-grained level. classCode **SHALL** have a single value and the value **SHALL** be one of the values from the "KSA Class Code" .

3.2.1.2 confidentialityCode

[KXDS-004] – The code specifying the level of confidentiality of the document. confidentialityCode **SHALL** have one or more values, and the values **SHALL** be one of the values from the "KSA Confidentiality Code" .

3.2.1.3 eventCodeList

[KXDS-005] – This list of codes represents the main clinical “key words” that may be added for certain types of documents and used for associated queries. eventCodeList **SHALL** have zero or more values. The codingScheme for each eventCode **SHALL** use the OID of the value set related to the specific eventCode.

Note: The semantics associated with each key word are not defined by either IHE XDS.b or XDM 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 eventCode elements (Coding Scheme, Code value and Code meaning)

are specific to the various documents shared using the IHE Document Sharing Profiles. Therefore, the eventCode value sets are defined in the relevant Core Interoperability Specifications.

3.2.1.4 healthcareFacilityTypeCode

[KXDS-006] – This code represents the type of organization (and type of care) where the clinical encounter during which the documented act occurred. healthcareFacilityTypeCode **SHALL** have a single value, and the value **SHALL** be one of the values from the "Healthcare Facility Type of Care" Values Set .

3.2.1.5 practiceSettingCode

[KXDS-007] – The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Intensive Care, Laboratory, Radiology). This practiceSettingCode **SHALL** be a single value from one of the values of the "Facility Medical Units and Departments Identifier"

3.2.1.6 typeCode

[KXDS-008] – The code specifying the precise kind of document at a fine-grained level (e.g., Pulmonary History and Physical, Discharge Summary, Ultrasound Report). This code **SHALL** have a single value.

Note: The document typeCode value sets are specific to the content of various documents being shared by using the IHE Document Sharing Profiles. See the specific Interoperability Specifications for Saudi eHealth Constraints on document content referenced by the Core Interoperability Specification that referenced this Document Sharing IS.

3.2.1.7 formatCode

[KXDS-010] – The code specifying the syntactic encoding of the document as defined by the Interoperability Specification on the document content. This formatCode **SHALL** have a single value from the "KSA Format Code"

Note: The document formatCode values are specific to the content of each documents being shared by using the IHE Document Sharing Profiles. For selecting the relevant value, see the specific Interoperability Specifications for Saudi eHealth constraints on document content referenced by the Core Interoperability Specification that references this Document Sharing IS.

3.2.1.8 mimeType

[KXDS-011] – The code specifying the MIME type as defined by the Interoperability Specification on the document content. The code **SHALL** have a single value from the "MIME Type"

Note: The document mimeType values are specific to the content of various documents being shared by using the IHE Document Sharing Profiles. For selecting the relevant value, see the specific Interoperability Specifications for Saudi eHealth constraints on document content referenced by the Core Interoperability Specification that referenced this Document Sharing IS.

3.2.1.9 patientId

[KXDS-013] – The patientId values used in the DocumentEntry, SubmissionSet and Folder Metadata shall contain a Health ID (An Id with a Registration Authority OID with a value of 2.16.840.1.113883.3.3731.1.1.100.1) that has been verified with the Patient Demographics Supplier Actor. The Actor grouping requirements for the flow of consistent Health IDs applies between the Document Source or Portable Media Creator, 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), or stored on media.

Note: It is outside the scope of this specification to define the technical means by which this flow of consistent Health IDs is achieved.

3.2.1.10 sourcePatientId, sourcePatientInfo, legalAuthenticator

[KXDS-014] – The sourcePatientId, the sourcePatientInfo, and the legalAuthenticator metadata Attributes **SHALL** be empty.

3.2.1.11 INTENDED RECIPIENT

[KXDS-080] – The intendedRecipient attribute **SHALL** be supported with the ability to convey configured values defined by the HIE platform (See Section 4.1). The intendedRecipient attribute **MAY** be empty if no notification is to be issued to a Document Consumer for a specific document.

3.2.2 Document Replacement (Document Source only)

[KXDS-020] – This option (see IHE ITI TF-1 10.2.1) **SHALL** be supported by all Document Source Actors to ensure that all published documents may be updated if a correction is needed. Further details about such situations are specified in the referring Core Interoperability Specification.

3.2.3 Document Addendum (Document Source only)

[KXDS-021] – The Document Addendum option (see ITI TF-1: 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 3.2.2 above).

3.2.4 Document Transformation (Document Source only)

[KXDS-022] – This option (see ITI TF-1: 10.2.2) **SHALL** be supported by Document Source Actors, in scenarios when required by the referring Core Interoperability Specification.

3.2.5 Folder Management (Document Source Only)

[KXDS-023] – This option (see ITI TF-1: 10.2.2) **SHALL** be supported by Document Source Actors, in scenarios when required by the referring Core Interoperability Specification.

3.2.6 Basic Patient Privacy Enforcement ITI TF-2b:3.41.4.1.3.1 and ITI TF-2b:3.32.4.1.4.1

The requirements for this option (See IHE ITI TF-2b:3.41.4.1.3.1 and IHE ITI TF-2b:3.32.4.1.4.1) and the associated Saudi eHealth constraints are specified in IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*– See Section 3.7. This applies both to Document Source actors using XDS.b and Portable Media Creator Actors using XDM.

3.2.7 Asynchronous Web Services Exchange (Document Source Only)

[KXDS-024] – This option **MAY** be supported by Document Source Actors (See IHE ITI TF-1: 10.2.5).

3.2.8 Metadata Update (Document Source Only)

[KXDS-071] – Document Source Actors **SHALL** support a Document Administrator Actor as defined by the Metadata Update Supplement to the Document Sharing Profiles.

[KXDS-072] – The grouped Document Administrator Actor **SHALL** support the Delete Option [ITI-62 Delete Document Set Transaction] to support removal of documents filed in error for the wrong patient.

3.2.9 Language Content (Portable Media Creator only)

[KXDS-090] – The contents of INDEX.HTM and README.TXT files on portable media must appear in both Arabic and English.

3.3 REQUIREMENTS FOR IHE DOCUMENT CONSUMER ACTOR

3.3.1 Handling of Document Sharing Metadata

[KXDS-030] – 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 in [Section 3.2.1](#). 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).

3.3.2 Basic Patient Privacy Enforcement Option ITI TF-2b:3.41.4.1.3.1

The requirements for this option and the associated Saudi eHealth constraints are specified in IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*– See Section 3.7.

3.3.3 Basic Patient Privacy Proof Option ITI TF-2a: 3.18.4.1.3.6

The requirements for this option and the associated Saudi eHealth constraints are specified in IS0101 *Saudi eHealth Security and Privacy Interoperability Specification*– See Section 3.7.

3.3.4 Asynchronous Web Services Exchange Option ITI TF-1: 10.2.5

[KXDS-031] – This option **MAY** be supported by Document Source Actors (See IHE ITI TF-1: 10.2.5).

3.3.5 Keeping cached documents current

[KXDS-081] – If a Document Consumer is locally accessing the content of a document previously retrieved from the Document Repository and locally imported, the Document Consumer **SHALL** perform a Registry Stored Query [ITI-18] to detect if the document has been deprecated. If this is the case, the Document Consumer **SHALL** offer the ability to the user to retrieve the current version of the document.

3.3.6 On-Demand Documents Option

[KXDS-091] – The On-Demand Documents Option **MAY** be supported by Document Consumer Actors.

3.4 REQUIREMENTS FOR DOCUMENT REGISTRY AND REPOSITORY

3.4.1 Handling of Document Sharing metadata

[KXDS-040] – The XDS Document Registry Actor shall verify at document registration time that only codes from the value sets defined in Section 3.2.1 Handling of Document Sharing Metadata **SHALL** be used. Use of unknown code values **SHALL** result in rejection of the [ITI-42] Register Document Set – b (and related [ITI-41] Provide and RegisterDocument Set-b Transaction).

[KXDS-073] – The Document Registry Actor shall support the Delete Option ([ITI-62] Delete Document Set transaction) specified in the Metadata Update Profile Supplement.

Note: Core Interoperability Specifications referencing this Interoperability Specification may require specific additional metadata (e.g. eventCodeList). Such specific additional metadata will be specified in the Core IS.

3.4.2 Patient Identity Feed (Note 1) ITI TF-2a: 3.8

This option is not defined in this Interoperability Specification. The means by which the Identity Source Actor for the KSA (identical to the Patient Demographics Supplier Actor) and the XDS Document Registry are synchronized about patients are beyond the scope of this Interoperability Specification and are part of the internal HIE architecture design decisions.

3.4.3 Patient Identity Feed HL7v3 (Note 1) ITI TF-2b: 3.44

This option is not defined in this Interoperability Specification. The means by which the Identity Source Actor for the KSA (identical to the Patient Demographics Supplier Actor) and the XDS Document Registry are synchronized about patients are beyond the scope this Interoperability Specification and are part of the internal HIE architecture design decisions.

3.4.4 Asynchronous Web Services Exchange ITI TF-1: 10.2.5

[KXDS-042] – This option **MAY** be supported by Document Source Actors (See IHE ITI TF-1: 10.2.5).

3.4.5 Document Replacement

[KXDS-043] – The XDS Document Registry **SHALL** enforce that only the Document Source Actor that has published a document is authorized to replace it (based on sourceId in metadata).

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

3.4.6 On-Demand Documents

[KXDS-092] – The XDS Document Registry **SHALL** support the On-Demand Documents option.

[KXDS-093] – 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 3.6 Requirements for On-Demand Document Source Actor for more details on this requirement.

3.5 INTEGRATED DOCUMENT SOURCE/REPOSITORY

[KXDS-050] – The combining of the Document Source and Document Repository Actors **MAY** be supported as an Option if specified in the referring Core Interoperability Specification.

3.6 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.

To avoid the need for prepopulating the 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.

[KXDS-094] – On-Demand Document Source actors **SHALL** be grouped with, and conform to all requirements specified for Document Source actors found in section 3.2 above.

- [KXDS-095] – On-Demand Document Source actors **SHALL** implement the Persistence of Retrieved Documents Option.
- [KXDS-096] – 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.
- [KXDS-097] – On-Demand Document Source actors **SHALL** register an On-Demand document entry for each patient for which on-demand data are available.
- [KXDS-098] – On-Demand Document Source actors **SHALL** register an On-Demand document type for a patient upon notification by the registry that such a document type was requested if relevant content is available for that On-Demand document type.

4. SAUDI EHEALTH CONSTRAINTS FOR THE DOCUMENT METADATA SUBSCRIPTION INTEGRATION (IHE-DSUB) PROFILE

This Appendix specifies Saudi eHealth extensions and constraints to the IHE Document Metadata Subscription Integration Profile. All details of the IHE DSUB Profile and transactions are specified in IHE ITI TF-1: 10. See Table 5-2 External references for a description of the DSUB Supplement for trial implementation.

4.1 REQUIREMENTS FOR IHE DOCUMENT METADATA NOTIFICATION BROKER ACTOR

[KXDS-060] – The IHE DSUB Document Metadata Notification Broker Actor is grouped with the IHE XDS Document Registry Actor. The IHE DSUB Document Metadata Notification Broker Actor **SHALL** process the stream of XDS Registration events against which the existing subscriptions are matched. Based on the metadata associated with document registrations, this actor sends notifications to interested subscribers.

[KXDS-061] – The IHE DSUB Document Metadata Notification Broker Actor **SHALL** support configuration at installation for subscription request (implied grouping with a Document Metadata Subscriber). It keeps track of all subscriptions in the Metadata Notification domain (same as XDS Affinity Domain managed by the XDS Registry- See KXDS-060).The subscription configuration will contain:

A list of web service end-points of Notification Recipient Actor that is configured to receive DSUB notification using the [ITI-53] Document Metadata Notify transaction

For each configured web service end-point, the value of the XDS intendedRecipient (ihe:SubmissionSetMetadata subscription topic) to be matched on every Document Registration received by the XDS Registry grouped with the DSUB Document Metadata Notification Broker,

KXDS-062] – If a configured intendedRecipient value matches, a [ITI-53] Document Metadata Notify transaction is sent to the corresponding webservice end-point. If no intendedRecipient value is received in a Document Set Registration, or if the received value does not match one of the configured values, action **SHALL NOT** be taken.

Note: As a consequence of KXDS-60, KXDS-061, and KXDS-062, the [ITI-52] Document Metadata Subscribe transaction **MAY** be supported by the IHE Document Metadata Notification Broker.

[KXDS-063] – When an IHE DSUB Document Metadata Notification Broker Actor attempts to send an [ITI-53] Document Metadata Notify transaction and fails to open a TCP/IP connection to the IHE Document Metadata Recipient Actor, the IHE DSUB Document Metadata Notification Broker Actor **SHALL** keep track of these non-delivered notifications and queue them for periodic retries. A retry timeout and a minimum length of time during which retries are performed **SHALL** be configurable on the IHE DSUB Document Metadata Notification Broker Actor, before an [ITI-53] Document Metadata Notify transaction is declared failed.

4.2 REQUIREMENTS FOR DOCUMENT METADATA NOTIFICATION RECIPIENT ACTOR

[KXDS-070] – The IHE DSUB Document Metadata Notification Recipient Actor is grouped with an IHE XDS Document Consumer Actor, and **SHALL** process the [ITI-52] Document Metadata Notify transaction as defined by the Core Interoperability Specification referencing this Document Sharing IS.

5. REFERENCED DOCUMENTS AND STANDARDS

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

TABLE 5-1 INTERNAL REFERENCES

DOCUMENT OR STANDARD	DESCRIPTION
IS0001 Saudi eHealth Core Interoperability Specification for KSA-Wide Patient Demographic Query	Documents the specifications required to obtain patient IDs and demographic information for the patient. It is used to ensure that the nationwide Health ID is used to register laboratory orders for the correct patient.
IS0003 Saudi eHealth Core IS for Sharing Coded Lab Results	Describes the technical requirements for the interface to share coded Laboratory Results Reports via the Saudi eHealth Information Exchange (SeHe). These laboratory test results are generally used by primary and hospital care providers but may also be used by Business Applications, including public health/business organizations. Note that policies may require that patient information be pseudonymized for use in business applications.
IS0004 Saudi eHealth Core IS for Coded Lab Orders	Establishes the initiation of a coded laboratory order and making the order accessible via the HIE platform. It addresses two types of laboratory orders: Laboratory Orders that are created by primary care providers and Healthcare Organizations to perform laboratory tests on their patients. Laboratory test facilities (i.e. hospital, private and national laboratory centers) access the coded orders and fulfill the order. Laboratory Orders created by laboratories that rely on other laboratories to perform tests that cannot be performed locally. For example, small Healthcare Organization laboratories typically only perform common tests and use a regional or national lab for advanced tests.
IS0005 Saudi eHealth Core IS for Sharing Images and Reports	Describes the technical requirements for the interface to share imaging reports and images via the Saudi eHealth Information Exchange (HIE). This includes reports and images acquired on a broad range of imaging modalities. Two common examples are to store images and reports about a patient's current imaging procedure and the ability to access images/reports from imaging studies previously performed for that patient.
IS0007 Saudi eHealth Core Interoperability Specification for Clinical Notes and Summaries	Describes the technical interface requirements for sharing Clinical Notes and Summaries documents as well as access to clinical data through the Health Information Exchange (HIE). This capability is accessible to various "edge" applications including point of care systems and business applications
IS0008 Saudi eHealth Core IS for ePrescriptions	Enables Healthcare Providers to record a prescription in an outpatient environment. The prescription conveys information necessary to ensure dispensers have the proper data to fulfill the dispensation including dosing information and additional clinical information to document the rationale behind the prescription as well as to support drug interaction checking.
IS0009 Saudi eHealth core IS for eDispensation	Describes the technical interface requirements that enable Healthcare Providers to record a medication dispensation to a patient in an outpatient environment or at the time of an in-patient discharge.
IS0010 Saudi eHealth Core IS for Immunization	Enable Healthcare Providers to record a medication dispensation to a patient in an outpatient environment or at the time of an in-patient discharge

DOCUMENT OR STANDARD	DESCRIPTION
IS0011 Saudi eHealth Core IS for eReferral and eTransfer Workflow	Describes the technical interface requirements to enable Healthcare Providers and facilities to electronically refer and/or transfer patients to other healthcare facilities. This includes KSA healthcare organizations, such as Primary Healthcare Centers (PHC), Hospitals, Specialty Centers, Long-term Care, etc. It covers MOH facilities but also other governmental organizations (such as National Guard and Military) and private healthcare systems. This information is published and is accessible via the Health Information Exchange (HIE). This enables access to the information by various "edge" applications including point of care systems and business applications.
IS0101 Saudi eHealth Security and Privacy Interoperability Specification	Specifies the interoperability standards and profiles along with the Saudi specific constraints that are required to provide the technical security measures, data protection, and privacy management that will facilitate the implementation of the Saudi eHealth Policies for Health Information Exchange in the Kingdom of Saudi Arabia among communicating IT systems.
IS0200 Saudi Health Information Exchange Data Dictionary	Specifies the terminology concepts and associated coded value sets for data elements used throughout the Saudi eHealth Interoperability Specifications.
IS0303 Saudi Health Information Exchange Policies	Contains the policies and supporting definitions that support the security and privacy aspects of the Saudi Health Information Exchange. The Saudi Health Information Exchange Policies apply to all individuals and organizations that have access to the Saudi Health Information Exchange managed health records, including those connected to the Saudi Health Information Exchange, their Business Associates, as well as any subcontractors of Business Associates. These policies apply to all information provided to or retrieved from the Saudi Health Information Exchange.

TABLE 5-2 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 http://www.ihe.net/Technical_Frameworks/#it
IHE IT Infrastructure (ITI) Technical Framework – Volume1 (ITI TF-1) Integrations Profiles – Section 16 Cross-Enterprise Document Media Interchange (XDM)	This profile provides document interchange using a common file and directory structure over several standard media types. This permits the patient to use physical media to carry medical documents. This also permits the use of person-to-person email to convey medical documents. XDM supports the transfer of data about multiple patients within one data exchange. May be obtained at http://www.ihe.net/Technical_Frameworks/#it

DOCUMENT OR STANDARD	DESCRIPTION
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 in-patient facility. May be obtained at http://www.ihe.net/Technical_Frameworks/#it
IHE IT Infrastructure (ITI) Technical Framework – Volume1 (ITI TF-1) Integrations Profiles – Section 26 Document Metadata Subscription (DSUB)	Describes the use of 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. May be obtained at http://www.ihe.net/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 http://www.ihe.net/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 http://www.ihe.net/Technical_Frameworks/#it

8.1 COPYRIGHT PERMISSIONS

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6. APPENDIX A – SAMPLE MESSAGES

6.1 SAMPLE PROVIDE AND REGISTER DOCUMENT SET

This example provides a sample transaction from the corresponding IHE Profile including the customizations for KSA specifics. It will be provided in a future update to this specification.

6.2 SAMPLE REGISTRY STORED QUERY

This example provides a sample transaction from the corresponding IHE Profile including the customizations for KSA specifics. It will be provided in a future update to this specification.

6.3 SAMPLE DOCUMENT METADATA NOTIFY TRANSACTION

This example provides a sample transaction from the corresponding IHE Profile including the customizations for KSA specifics. It will be provided in a future update to this specification.

7. APPENDIX B – IHE DOCUMENT SHARING METADATA

Table 7-1 Metadata Overview Table – DocumentEntry provides the list of the metadata that may be associated with documents stored and shared within an XDS affinity domain or stored on portable media created using the XDM Profile.

This Appendix does not specify any additional interoperability requirements beyond those include 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 7-1 METADATA OVERVIEW TABLE – DOCUMENTENTRY

XDS METADATA ATTRIBUTE	ATTRIBUTE DEFINITION	INTENDED USE	CODED QUERY KEYS
METADATA USE FOR BROAD SEARCHES			
patientId	The patientId represents the subject of care of the document. It contains the KSA-Wide Health ID with its two parts: • Authority Domain Id (OID enforced by the Registry) • An Id in the above domain issued by the PDQ Supplier Actor.	Primary Query	No
serviceStartTime	Represents the start time the service being documented took place (clinically significant, but not necessarily when the document was produced or approved).	Primary Query	No
serviceStopTime	Represents the stop time the service being documented took place. Same details as serviceStartTime	Primary Query	No

classCode	The code specifying the particular kind of document. Shall have a single value. Coded with a coarse level of granularity.	Primary Query	Yes
practiceSettingCode	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			
healthcareFacility TypeCode	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 typeCode, as such a conflict would create an ambiguous situation. Has a single value.	Primary Query	Yes
availabilityStatus	An XDS Document shall have one of two availability statuses: - Approved: available for patient care - Deprecated: obsolete	Primary Query	No
confidentialityCode	The code specifying the level of confidentiality of the document. Has one or more values..	Primary Query	Yes
uniqueId	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.	Primary Query	No
eventCodeList	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 not conflict with the values selected in the classCode, practiceSettingCode or typeCode, as such a conflict would create an ambiguous situation. This value list may have zero or more values.	Primary Query(second level-Use Case specific)	Yes
referenceIdList	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
typeCode	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: - authorInstitution - authorPerson - authorTelecommunication	Secondary Filtering	No
comments	Comments associated with the Document. Free-form text.	Secondary Filtering	No
creationTime	Represents the time the author created the document in the Document Source. Shall have a single value	Secondary Filtering	No

SPECIAL PURPOSE METADATA			
entryUUID	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
formatCode	Code globally uniquely specifying the format of the document. Along with the typeCode, it provides sufficient information to allow any potential Document Consumer to know if it will be able to process/display the document by identifying an encoding, structure and template	Technical	No
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
homeCommunityId	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
contentType	MIME type of the document in the Repository. Shall have a single value.	Technical	No
repositoryUniqueId	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
languageCode	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
sourcePatientId	The sourcePatientId 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
sourcePatientInfo	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 mechanism and has occasional use for Document Consumer actors.	Not Used	N/A
legalAuthenticator	Represents a participant who has legally authenticated or attested the document within the authorInstitution. Legal authentication implies that a document has been signed manually or electronically by the legalAuthenticator. This attribute may be absent if not applicable. If present, shall have a single value	Not Used	N/A

A SubmissionSet 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 SubmissionSet and their use for queries is presented in Table 7-2 Metadata Overview Table – SubmissionSet.

TABLE 7-2 METADATA OVERVIEW TABLE – SUBMISSIONSET

XDS METADATA ATTRIBUTE	ATTRIBUTE DEFINITION	INTENDED USE	PRIMARY QUERY CODES
availabilityStatus	A SubmissionSet 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
contentTypeCode	The code specifying the type of clinical activity that resulted in placing these documents in this SubmissionSet. Has a single value.	Primary Query	Yes
entryUUID	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
intendedRecipient	Represents the organization(s) or person(s) for whom the SubmissionSet is intended.	Primary Query	No
patientId	The patientId (i.e., KSA-wide Health ID) represents the medical record identifier of subject of care whose longitudinal record is being maintained. Has a single value.	Primary Query	No
sourceId	OID identifying the instance of the Document Source that contributed the SubmissionSet. 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
submissionTime	Point in Time at the Document Source when the SubmissionSet was created and issued for registration to the Document Registry. Has a single value.	Primary Query	No
uniqueId	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 SubmissionSet .If present, has a single value.	Secondary Filtering	No
comments	Comments associated with the SubmissionSet. 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: - authorInstitution - authorPerson - authorTelecommunication	Secondary Filtering	No
homeCommunityId	A globally unique identifier for a community.	Technical	No