

Integrating the Healthcare Enterprise



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IHE IT Infrastructure (ITI) Technical Framework Supplement 2009-2010

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Cross-Enterprise Document Reliable Interchange (XDR)

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Trial Implementation Supplement

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1 Foreword

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.ihe.net/Technical_Framework.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,

85 standards-based transactions. It describes this body of transactions in progressively greater depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

90 This IHE IT Infrastructure Technical Framework Supplement was initially issued for Trial Implementation in August 2006. It was updated in July 2007 to account for alignment of the Provide and Register Transaction (Web Services and ebRS 3.0 schema) with the release of the XDS.b Supplement for Trial Implementation. It is therefore re-issued for Trial Implementation through March 2010. Based on implementation feedback, it is reissued for a fourth trial implementation through March 2010.

95 Comments and change proposals arising from Trial Implementation may be submitted to <http://forums.rsna.org> under the forum:

“Integrating the Healthcare Enterprise”

Select the sub-forum:

“IHE IT Infrastructure 2009-2010 Supplement for Trial Implementation”

100 The IHE IT Infrastructure Technical Committee will address these comments resulting from implementation, Connectathon testing, and demonstrations such as HIMSS 2010. Final text is expected to be published in June 2010.

2 Introduction

105 This Supplement introduces a new IHE Integration Profile that facilitates interchange across health enterprises of electronic documents.

This Integration Profile, referred to as XDR (for Cross-Enterprise Document Reliable Interchange), is focused on providing a standards-based specification for managing the interchange of documents that healthcare enterprises (anywhere from a private physician to a clinic to an acute care in-patient facility) have decided to explicitly exchange using a reliable point-to-point network communication. This also enables better interoperability between Electronic Health Records (EHRs), Personal Health Records (PHRs) and other Healthcare IT Systems. It is a natural complement to the IHE ITI XDS Integration Profile (for cross-enterprise document sharing) when a sharing infrastructure (repositories and registry) is not needed.

115 2.1 Background

Cross-Enterprise communication of medical information is increasingly required in the Healthcare domain. In parallel to "publish and pull" oriented mechanisms, such as XDS, "push" communication is required. Several standards (i.e. HL7, DICOM, OASIS...) have defined three kinds of mechanisms for conveying such information:

- 120 1. Specific workflow messages, as an extension of the Intra-Enterprise messaging format (HL7 messages for lab results, DICOM store).
2. Encapsulation of standardized documents/objects in MIME, in the context of a "push" communication between parties (peer-to-peer), described in the present XDR profile.
- 125 3. Specification of a document interchange format for the transfer of clinical images via portable media (i.e. non-networked based), in the context of a "sneaker" net communication between parties whereby the patient is the often the mode of transport. Such mechanisms are described in the XDM profile.

Similar to what has been developed in the XDS profile, a generic standards based mechanism for conveying a set of medical documents in a point to point networked based communication, staying "neutral" vis-à-vis the document content, is needed. The proposed approach results from the analysis of a number of specific solutions, used in various countries around the world, in particular the one based on the concept of a "patient based electronic envelope of documents" originated by EDISanté (working group GT11) in 1998, with a format/protocol called MMF/MXF.

135 2.2 Proposed solution

The present XDR Integration Profile proposes to interchange a set of documents related to a particular patient and the associated metadata using a networked based secure protocol over HTTP/SOAP. It re-uses the metadata and the messages defined by the XDS (Cross-Enterprise Document Sharing) Integration Profile.

140 This profile aims to be fully consistent and complementary with the XDS.b Integration Profile, re-using the same transaction "Provide and Register Document Set-b".

2.3 Scope of Supplement

145 This supplement extends the existing IHE IT Infrastructure Technical framework and assumes that the reader is familiar with the IHE process and methodology in defining Integration Profiles, as well as familiar with other related IHE Integration profiles defined by the IHE Technical Frameworks available at <http://www.ihe.net>.

150 The XDR Integration Profile is not intended to address all cross-enterprise EHR communication needs. Some may require the use of other IHE Integration profiles, such as Patient Identifier Cross-Referencing, Audit Trail & Node Authentication, Retrieve Information for Display, etc. Others may be only partially supported. Others may require future IHE Integration profiles, which will be defined by IHE as soon as the necessary base standards are available.

The development of this IHE Integration Profile relies on considerable work and standards development activities that have been performed in this domain in many countries around the world (e.g. OASIS-ebRS, HL7 CDA, CEN ENV 13606, EDISANTE MMF/MXF, IETF, etc.).

155 2.4 Open Issues and Questions

1. None

2.5 Closed Issues

- 160 1. How to associate this profile with PIX, XDS, and how to convey images on the same “Provide and Register Document Set” message, using the (pending) DICOM Email. Done in appendix E.
2. Recipient addresses in off-line and on-line. Optional because a default value shall exist when absent.
- 165 3. The XDS metadata have been extended to contain the intendedRecipient(s) as an update of the Register Document Set transaction, advising it is required for XDR and optional for XDS? Add it in the XDS metadata definition as an optional attribute.
4. Shall ATNA Audit Trails be used in all the cases? Document Source only? Document Recipient only? It is required for all.
5. What to do on the Document Recipient if a required metadata does not exist or is void? Depending of the agreement between the creator and the recipient
- 170 6. What to do on the Document Recipient with the coding schemes / codes enforcement Idem?
7. Should the Multiple Document Management be an option for the Document Recipient? And if so, what it does when receiving multiple documents and it does not support this option. => optional on the Document Source side, Required on the Document Recipient side
- 175 8. Idem for Lifecycle Management => not supported by this profile (for the moment). The Document Recipient has to send a negative acknowledgment if the action is not a “new document”.

180 Idem for Folder Management => not supported by this version. The Document Recipient has to accept the metadata containing folder information but ignore such information.

9. Approach 1 (add recipient slot) vs. approach 2 (add existing rim:user and rim:organization objects) for the XDR specific metadata. => retain the simplest one (approach 1).

185 With the release of the XDS.b Supplement for Trial Implementation in August 2007, XDS.b is aligned on ebRS V3.0. To avoid introducing a long-term discrepancy between XDR and XDS.b which is expected to become widely adopted; it is suggested to update XDR from ebRS 2.0 to ebRS3.0. This introduces no functional differences only a slightly different XML structure.

3 Profile Abstract

190 This Integration Profile, referred to as XDR (for Cross-Enterprise Document Reliable
Interchange), is focused on providing a standards-based specification for managing the
interchange of documents that healthcare enterprises (anywhere from a private physician to a
clinic to an acute care in-patient facility) have decided to explicitly exchange using a reliable
point-to-point network communication. This also enables better interoperability between
Electronic Health Records (EHRs), Personal Health Records (PHRs) and other Healthcare IT
195 Systems. It is a natural complement to the IHE ITI XDS Integration Profile (for cross-enterprise
document sharing) when a sharing infrastructure (repositories and registry) is not needed.

Volume I – Integration Profiles

200 <This section describes the changes required in Volume I of the Technical Framework that result from including this Integration Profile.>

Changes to Sections 1 – 1.X

1.7 History of Annual Changes

Add the following bullet to the end of the bullet list in Section 1.7

- 205
- Added the **Cross-Enterprise Document Reliable Interchange (XDR)**, which provides document interchange using a reliable messaging system. This permits direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS.

Add the following section to Table 2-1 Integration Profiles Dependencies in Section 2.1

Cross-Enterprise Document Reliable Interchange (XDR)	ATNA	Each XDR Actor shall be grouped with Secure Node or Secure Application Actor	Requires secure communication and audit trails.
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210

Add the following section to Section 2.2

2.2.15 Cross-Enterprise Document Reliable Interchange (XDR)

215 *Cross-Enterprise Document Reliable Interchange (XDR)* provides document interchange using a reliable messaging system. This permits direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.

Add the following Section 15

15 XDR Integration Profile

220 Cross-Enterprise Document Reliable Interchange (XDR) provides document interchange using a reliable messaging system. This permits direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document sharing infrastructure such as XDS Registry and Repositories.

225 XDR provides a reliable and automatic transfer of documents and metadata for one patient between EHR systems even in the absence of an XDS infrastructure. XDR supports the reuse of the Provide and Register Set transaction-b with Web-Services as transport. Transfer is direct from source to consumer, no repository or registry actors are involved.

XDR is document format agnostic, supporting the same document content as XDS and XDM. Document content is described in XDS Document Content Profiles. Examples are XDS-MS, XD-LAB, XPHR, and XDS-SD.

230 XDR defines no new metadata or message formats. It leverages XDS metadata with emphasis on patient identification, document identification, description, and relationships.

15.1 Actors/ Transactions

235 Figure 15.1-1 shows the actors directly involved in the XDR Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in XDS, PIX or XUA are not shown.

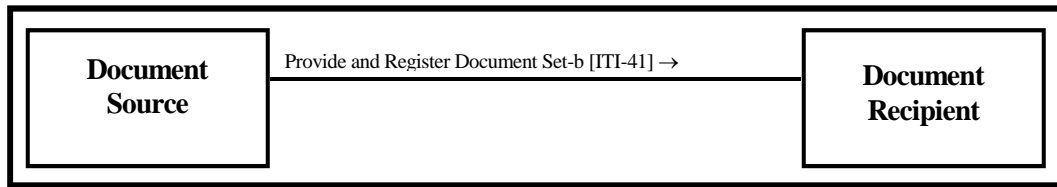


Figure 15.1-1 XDR Actor Diagram

240 Table 15.1-1 lists the transactions for each actor directly involved in the XDR Profile. In order to claim support of this Integration Profile with one or more actors, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume I, Section 15.2.

245 **Table 15.1-1 XDR Integration Profile - Actors and Transactions**

Actors	Transactions	Optionality	Section in Vol. 2
Document Source	Provide and Register Document Set-b [ITI-41]	R	ITI TF-2:3.41
Document Recipient	Provide and Register Document Set –b [ITI-41]	R	ITI TF-2:3.41

15.2 XDR Integration Profile Options

250 Options that may be selected for this Integration Profile are listed in Table 15.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 15.2-1 XDR - Actors and Options

Actor	Options	Vol & Section
Document Source	<i>Multiple Document Submission</i>	ITI TF-1: 15.2.1

Actor	Options	Vol & Section
	<i>Basic Patient Privacy Enforcement</i>	ITI-TF-2b: 3.41.4.1.3.1
Document Recipient	<i>Basic Patient Privacy Enforcement</i>	ITI-TF-2b: 3.41.4.1.3.1

15.2.1 Multiple Documents Submission Option

In this option the Document Source offers the ability to include multiple documents in a single Submission Request.

255 15.2.2 Basic Patient Privacy Enforcement Option

For this option, see ITI-TF-2b: 3.41.4.1.3.1

15.2.3 Folder Option Issue

The Document Source may include Folders in metadata. The Document Recipient may ignore them.

260 15.3 XDR Process Flow

XDR describes the exchange of a set of a patient’s documents between healthcare providers, such as: physicians, hospitals, special care networks, or other healthcare professionals.

Where XDS Registry/Repositories are not yet implemented or available for the exchange of information, XDR is the viable approach.

265 In a situation where the information is going to an automated application or robust system capable of automated storage or processing of documents relative to one patient, XDR is the appropriate profile.

The XDR integration profile is intended only for exchange of patient related medical documents and not intended to address all cross-enterprise EHR communication needs.

270 Use Cases:

1. Dr. Primary refers his aging patient Mr. Robinson to his first appointment with a gastroenterology specialist.

275 Since there is no XDS repository available at the gastro clinic, Dr. Primary cannot use XDS to communicate the XDS-MS referral to Dr. Gastro. Also, since there is no affinity domain linking Dr. Primary and Dr. Gastro, XDR is preferable to XDS for the exchange of Mr. Robinson’s referral information. XDR is also appropriate for Dr. Gastro’s documents communication to Dr. Primary.

2. Mabel is transferred from a hospital setting to her retirement home for long-term care. XDR: Mabel’s information can be transferred from the hospital to the long-term care facility’s EHR application for future review by her attending physicians and nurses, through XDR.

280

- 285
3. Stanley’s recent MRI has generated unusual results that Stanley’s primary physician would like to consult with another specialist in a specialized cancer facility located across the state. Since there is not likely to be an affinity domain between the remote health environments, XDR can be used instead.
 4. Mrs. Sweettooth has been diagnosed with adult diabetes and her specialized circle of care has not yet gotten organized to provide shared access to a common repository. Until they do, they will need to exchange her information peer-to-peer using XDR.

290 This profile is only defining the digital transport mechanism used for such use cases, content transported will be detailed by Content Profiles such as the ones defined by the IHE PCC (Patient Care Coordination) domain.

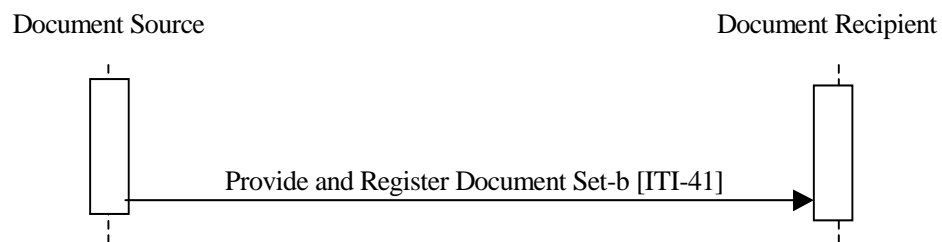


Figure 15.3-1 Process Flow in XDR Profile

295 **15.4 Digital communication**

It is a web service based HTTP message.

15.5 Security Considerations

300 The Profile assumes that the health organizations that are using Document Source and Document Recipient have an agreement defining when they can interchange PHI. This may require an explicit patient consent (depending on the regulation) and an agreement on how to manage the potential inconsistency between the security policies. The main aspects that should be covered by this agreement are similar to XDS – See Appendix L. In the case of XDR, the EHR-to-EHR (or PHR) communication is a transient XDS Affinity Domain. In addition, the following aspects should be covered:

- 305
- Management of Patient identification in order to perform patient reconciliation correctly upon importation of the documents.

Both Actors for this Profile require a grouping with Secure Node.

<Appendix A> Actor Descriptions

Add the following Actor Descriptions in Appendix A

- 310 **Document Recipient:** This actor receives a set of documents sent by another actor. Typically this document set will be made available to the intended recipient who will choose to either view it or integrate it into a Health Record.

<Appendix E> Cross Profile Considerations

Add the following Section to the existing Appendix E

315 **A.1 XDR Integration with XDS, Content Integration Profiles, PIX, and DSG**

A.1.1 XDR Integration with XDS

The XDR profile and the XDS profile are both similar and complementary.

- 320 Both profiles are document content neutral, conveying documents without modification and managing the same set of metadata. They both enable a Document Source to transmit a set of documents to another IHE Actor, using a HTTP based on-line mode or a SMTP based off-line mode.

- 325 But they do differ in some important ways. XDS is a centralized profile with “servers” (Registry and possibly Repository) and “clients” (Source and Consumer). XDR is more symmetrical (Source and Recipient).

If the Document Source and the Document Recipient belong to the same Affinity Domain, the metadata shall respect the rules defined for this Affinity Domain (patientId, assigning Authority, encoding schemes...).

- 330 In case the actors are not all part of the same Affinity Domain, the following options should be considered:

- If the Document Source is sending the Document Set to a Document Repository while sending it to the Document Recipient(s) at the same “time” (consequent network on-line messages), then the rules defined in the Affinity Domain which includes the Document Source and the Document Repository shall be used.
- 335 • In the other cases:
 - If the Document Source and the Document Recipient(s) have agreed on the rules to use (for example using a “regional patientId” accessible through a PIX compliant server), then these rules shall be used.

Note: it is highly recommended to define such “mutual agreement”

- 340 • If not, the rules available on the Document Source side will be used, and so, the Document Recipient has to transpose the patientId and the codes to follow its local rules.

345 The Cross-enterprise Document Reliable Interchange (XDR) Integration Profile may be used in conjunction with the XDS Integration Profile to provide both a cross-enterprise sharing capability and a targeted sending of a set of documents to one or more specific receivers. This is illustrated in the figure below, when the Document Source Actor supports both the XDS and the XDR Integration Profiles.

Flexible Infrastructure: Sharing, Reliable Interchange, and Media

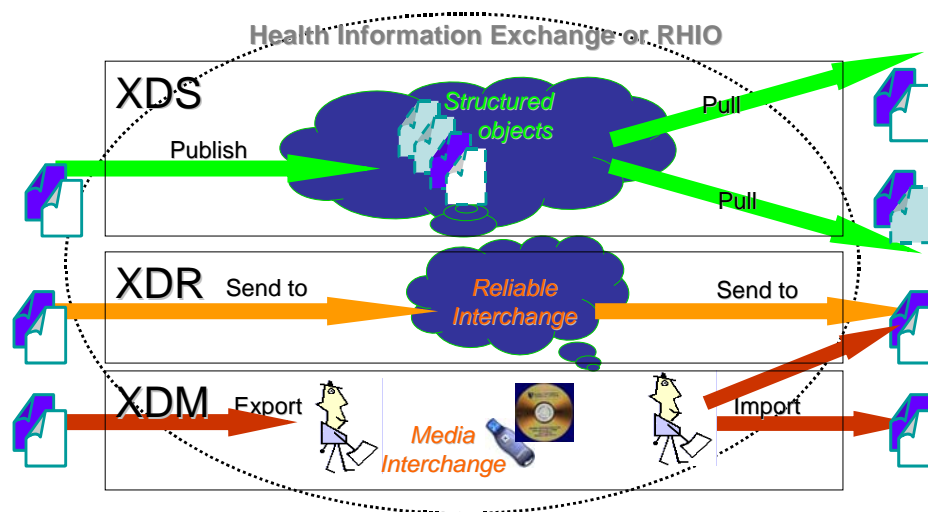


Figure E.6-1 Associated XDS, XDR, and XDM Profiles

350 A.1.2 XDR Integration with XDS Content Integration Profiles

355 The Cross-enterprise Document Reliable Interchange (XDR) Integration Profile is intended to be used in conjunction with any number of XDS Content Integration Profiles to provide an interoperable specification for the content of the documents interchanged. Any XDS Content Integration Profile such as a XDS-SD for scanned documents (See IT Infrastructure Technical Framework) or XDS-MS for medical summaries (See Patient Care Coordination Technical Framework) are examples of document content Integration Profiles that may be integrated along with XDR. One should note that although these Content Integration Profiles are called XDS-Scan or XDS-MS, the use of the XDS in their name does not imply that their use is restricted to XDS. It is equally intended for XDR, for point-to-point interchange.

360 A.1.3 XDR Integration with PIX

365 The Cross-enterprise Document Reliable Interchange (XDR) Integration Profile may be used in conjunction with the PIX Integration Profile to provide the cross-referencing or linkage of the patient identifier used by the Document Source with that of the Document Receiver. This Integrated use requires the grouping of the XDR Document Source and of the XDR Document Receiver with a PIX Patient Identity Source, so that the PIX Manager is fed with the patient

identities in the Document Source and the Document Receiver identification domains. In addition, the Document Recipient shall be grouped with a PIX Patient Identifier Consumer Actor, so that when a patient Identifier is received in the XDS Document Metadata of the XDR Provide and Register Document Set transaction, it may invoke the services of the PIX Manager Actor to cross-reference the received patient identifier to a patient identifier of the Document Recipient Identification Domain.

A.2 XDM/XDR Distinction

Both XDR and XDM describe the exchange of a set of patient's documents between healthcare providers. They are relevant in situations where XDS is not yet implemented or available at one of the participating organizations or where point-to-point (versus sharing through a registry) interaction is desired.

XDM is applicable in situations where the information receiver is an individual who will manually interpret or examine the data and associated documents. XDM allows for one exchange which contains documents relating to multiple patients and can be used in situations where no continuous networking capability is available on one or both of the participating healthcare providers..

XDR is applicable in situation where the information exchanged is going to an automated application or robust system capable of automated storage or process of documents relative to one patient. XDR requires continuous networking capability between the healthcare providers exchanging data.

Volume 2b - Transactions

The following section 3.41 is only included here for guiding the reader to ITI TF-2b Supplement, where this transaction ITI-41 specification may be found when used by this XDR Supplement

390 **3.41 Provide and Register Document Set-b**

The reader will find this transaction in ITI TF-2b.