

XDS-I - CROSS-ENTERPRISE DOCUMENT SHARING FOR IMAGING

Physicians, nurses, administrators and other healthcare professionals foresee a day when vital information can flow seamlessly from system to system and be readily available at the point of care. IHE is intended to make this vision a reality by improving the condition of systems integration and eliminating barriers to optimal patient care.

IHE is a multi-year initiative undertaken by medical specialists, administrators, information technology professionals and manufacturers, sponsored by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS), whose sole purpose is to improve the way computer systems in healthcare share information.

IHE is not a standards organization. Instead, it promotes coordinated use of existing standards, such as DICOM and HL7, to develop workflow solutions for the healthcare enterprise. Systems designed in agreement with IHE profiles communicate better with one another, are easier to implement, and facilitate efficient access to information.

The IHE organization has been active within several clinical domains to analyze work processes since 1998. The common goal of these activities, supported by a large group

of users and vendors, is to identify issues that result from using clinical applications from different vendors. Everybody undoubtedly recognizes problems that result from trying to share (electronic) data between systems from different vendors.

Since the late 1990s, IHE has expanded from the radiology domain to various other clinical domains, such as cardiology, radiation therapy and eye care. A more IT-focused domain has also emerged known as IT infrastructure (ITI), which deals with IT-related problems rather than problems related to the clinical processes. One of the profiles within this domain deals with the problems associated with sharing clinical information between care professionals in different organizations. This profile is referred to as cross-enterprise sharing of documents (XDS).

This technical white paper was written in collaboration with Forcare B.V and addresses XDS in general and XDS-I Cross-enterprise Document Sharing of Images in particular.

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IHE - INTEGRATING THE HEALTHCARE ENTERPRISE

XDS overview

The XDS profile is basically a blueprint for a networked infrastructure in which:

- Information is selectively made available
- The availability of information is centrally indexed
- Healthcare IT systems can safely share information in a trusted network
- Audit records are kept of who accessed the data

Like other IHE profiles, XDS does not create new standards but relies on many well-known communication standards, such as DICOM, HL7, XML and http(s).

The XDS developments by IHE are the result of discussions on how to realize:

- An open, standards-based infrastructure that is relatively easy to implement by vendors in the healthcare IT domain
- A future-proof and scalable solution that can scale from small regional to large national-scope health information networks
- A content-neutral infrastructure that can be expanded into various clinical domains by adding content profiles

The XDS profile as defined in the IHE IT Infrastructure domain defines the generic architecture for how to share clinical information. Several content profiles created in the various IHE clinical domains define what information is actually shared and in what format. One such content profile is the XDS for Imaging (XDS-I) profile from the radiology domain. XDS for Imaging defines how radiology reports and image references can be shared through an XDS network.

Further information on XDS and XDS-I is presented in the following sections. It will become clear how existing RIS and PACS systems can be connected into an XDS infrastructure.

THE XDS ARCHITECTURE

Basic architecture

The XDS profile is a generic framework for publishing, registering, querying and retrieving standardized clinical information in document form. Documents vary from simple text-based formats to HL7 messages, but can also include well-formed and formatted patient statuses using HL7 v3 Clinical Document Architecture standard.

The XDS framework basically divides the world in five (abstract) system components. Each of these components is depicted below.

How vendors implement these abstract system components into their application is not something IHE dictates. IHE does not define products, such as RIS or PACS, but merely defines the roles and responsibilities of each of the XDS system components. A vendor that implements a component as part of a real-life product guarantees that this product takes up the same roles and responsibilities as described by the IHE profile.

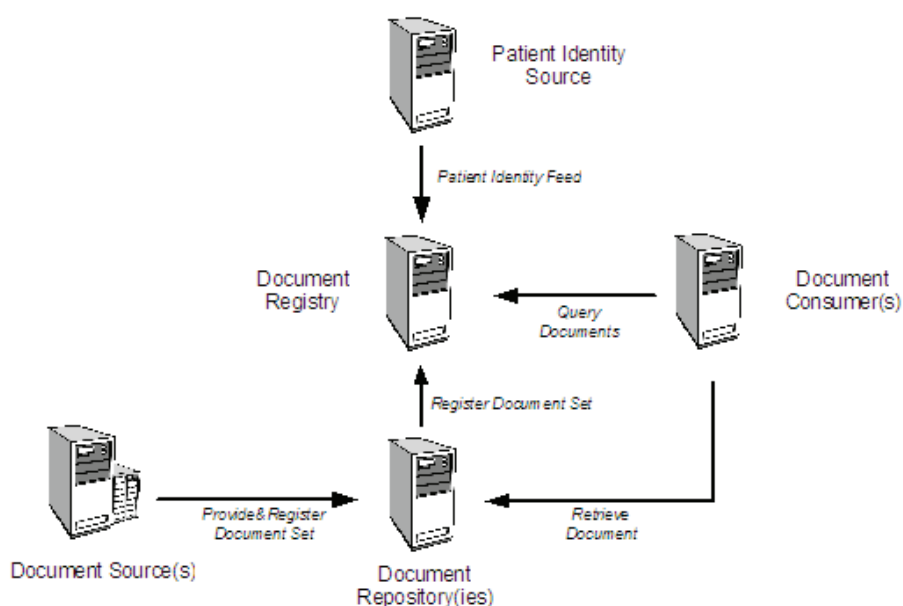
Actors and transactions

The abstract system components are referred to as “actors” in IHE terminology. Actors can be grouped in system architectures according to pre-defined patterns and may exchange information (data). This exchange is called a “transaction”.

In the following section, the XDS actors and transactions will be described.

Actors

The “Document Source” actor is the “system” providing clinical documents. A real-world user (or system) is responsible for selecting the set of information that is published to the XDS infrastructure. Typically, an XDS document contains a set of information that concludes a clinical act. For example, a radiology report with referenced images, a discharge summary or a medication list. The XDS document is provided to a “Document Repository” actor.



THE XDS ARCHITECTURE (CONT.)

The “Document Repository” takes care of safe and permanent document storage. The repository must always be available to “Document Consumer” actors to deliver documents on request. A document repository can be implemented as a standalone device or can be integrated with a “Document Registry” or “Document Source”. In the latter case, it is referred to as an “Embedded Repository”. An example of an embedded repository is a PACS system that, besides image storage, also takes care of the XDS-I document storage.

The “Document Registry” maintains an index of published documents. The registry contains a set of document attributes for each document stored. Such properties include patient name, document type and storage location. Part of the XDS profile defines the list of mandatory and optional document properties.

The “Document Consumer” represents a system that queries and retrieves documents from an XDS network. To do this, a document consumer will query the registry using query patterns defined by the XDS profile. The query returns a list of documents. From this list, a consumer (user) may select a document that is transferred from a repository to the consumer upon user request.

A fifth actor is the “Patient Identity Source”. This component is responsible for providing a unique patient ID to be used within the scope of a single XDS infrastructure.

Transactions

As mentioned above, the various XDS actors communicate according to pre-defined communication patterns or “transactions”. In XDS, these transactions are based on ebXML standards defined by OASIS. The ebXML is comparable to SOAP (a protocol for exchanging XML-based messages, normally using HTTP or HTTPS, in which SOAP forms the foundation layer of the web services protocol). XDS documents are data sets (also called “blobs”,

binary large objects) wrapped in an ebXML message. This can be compared with the paradigm of an envelope containing a letter. From the outside, you cannot determine what kind of letter is on the inside (private letter, official letter, merchandise spam, etc.). Once you open the envelope, you’ll find out. However, the envelope will tell you what type of information to expect, to whom it is addressed and the name of the sender.

The “Provide and Register Document Set” transaction is used to publish a document from a document source to a document repository. Once the document is received and accepted by the repository, the “Register Document Set” transaction is used to register the document with the document registry. In this transaction, the document properties (metadata) are handed to the registry as well as the “handle” to the location from which the document can be retrieved by document consumers. IHE clearly defines the set of document attributes. It also defines the allowed values per attribute. In many cases, these are coded values selected from a vocabulary that may be selected by IHE or agreed upon by users of the XDS infrastructure. The latter is referred to as an “Affinity Domain”.

A document consumer issues the “Query Documents” transaction to discover the availability of documents. The query transaction typically uses the Patient ID as its indexing key. Accordingly, the Patient ID is one of the most important identifying attributes in an affinity domain. Either an affinity domain uses one unique key per patient or it provides some form of a Master Patient Index where all locally used patient IDs can be found and mapped to a unique ID for the affinity domain.

Once a document consumer decides what document to retrieve, it issues the “Retrieve Document” transaction to retrieve the XDS document from the repository identified by the registry.

THE XDS ARCHITECTURE (CONT.)

To “populate” the index with patient information, the “Patient Identity Feed” transaction is used. This transaction consists of an HL7 ADT feed to register new patients, update patient information and merge patients. This information is typically provided by an overall service providing the affinity domain with Patient information (or example, an HIS).

Affinity Domain Policy

The XDS profile not only dictates transactions needed for the exchange of information within an affinity domain, but also formatting, naming conventions and agreed working policies. How to handle attributes and data and how to store them in the Document Registry is defined by the affinity domain policy. Attributes must be populated by the Document Source and Repository upon submission in order to be used as query parameters by the Document Consumers. Thus, agreement by all stakeholders of an XDS Affinity Domain on metadata information is essential in assuring that all members can interpret exchanged information correctly. Within radiology, examples of this could be naming of examinations, exam code structures, reporting formats and patient ID formats. This set of common rules and agreements is called an XDS Affinity Domain Policy.

Other XDS concepts

As described above, an XDS infrastructure allows for sharing of clinical documents. Three concepts are relevant with respect to the clinical information exchanged.

- XDS Document
- XDS Submission Set
- XDS Folder

An “XDS document” consists of a coherent set of clinical information typically related to a clinical act. Depending on the specific clinical domain, the XDS document technically can be an HL7 v3 CDA document, a PDF document, plain text or a DICOM Key Object Selection (KOS) document.

The various data formats allow sharing of both structured (HL7 CDA, DICOM KOS) and unstructured (PDF, plain text) information. Since most information exchanged in healthcare today is unstructured (for example, referral letters, radiology reports, ECG registrations), XDS provides a pragmatic approach to start sharing clinical information. However, with progressing developments in HL7, XDS also provides a future-proof solution when semantically exchanging information.

An “XDS Submission Set” is used to share one or more documents from a single patient that somehow are related. For example, the result of a radiology procedure typically includes a report and images, both of which are individual XDS-I documents. Providing both documents in a single Submission Set makes it clear to the registry that both documents have a relationship.

The third concept is that of an “XDS Folder”. A folder is defined as a logical collection (or category) of documents. For example, if a patient care process includes multiple visits to several departments, it is likely that multiple documents will be published to a repository. To “group” these documents together, the “XDS Folder” can be used. A document can be a member of multiple folders. As such, the folder concept is a form of categorizing the documents.

BUILT-IN FLEXIBILITY

Flexible architecture

One of the strengths of XDS is that it basically is a distributed architecture, better known as a Service Oriented Architecture (SOA). This provides vendors with different implementation choices for how to XDS-enable their products. For example, a combination of a Document Source and Document Consumer may be relevant for systems like PACS or RIS. Other systems may only implement the document source actor and delegate the responsibility for storage to another system.

The picture below demonstrates an arbitrary combination of XDS actors and clinical domains. Depending on the vendor's choice, it becomes clear which "transactions" are used to communicate within an XDS infrastructure.

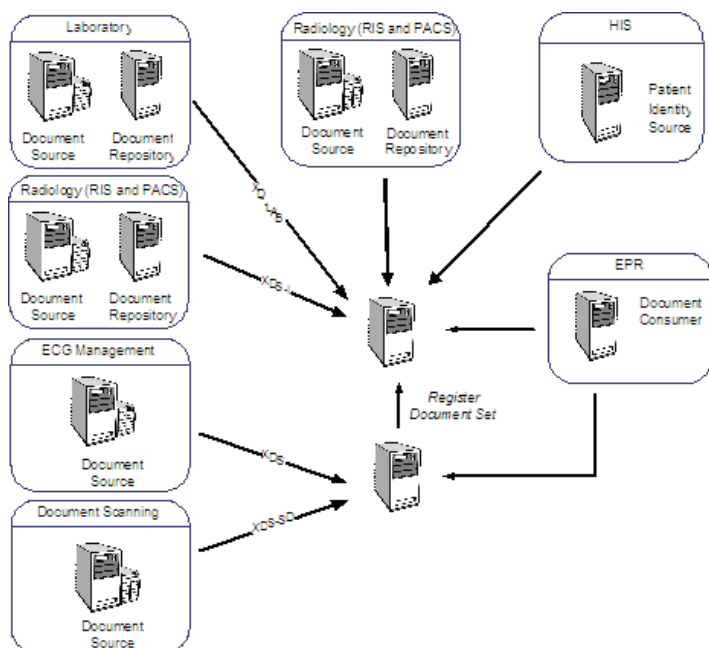
The XDS actors can belong to different hospitals or chains of hospitals. The XDS framework also handles different patient identity domains within the affinity domain through the use of the IHE PIX (Patient Identifier Cross-referencing) profile.

However, each affinity domain only has one Document Registry and there should be no discussion about uniqueness of a global patient identifier at the affinity domain level.

There are also other IHE profiles covering how to handle cross-enterprise user assertion (XUA), cross-community access to other domains (XCA), as well as frameworks for handling Basic Patient Privacy Consents (BPPC). Details about these profiles, including uniqueness of patient identifiers and cross referencing, go beyond the scope of this paper.

XDS for Imaging (XDS-I)

In 2005, a first content profile was developed for XDS within the radiology domain. This XDS for Imaging (XDS-I) content profile describes how to share radiology reports and references to images. The latter is important since it prevents duplication of image data. Typically, image storage in an average hospital exceeds many terabytes. It is quite common today for image sharing to be carried out



Example of XDS actors within an affinity domain

BUILT-IN FLEXIBILITY (CONT.)

by means of copying images to a CD, then transported to another facility and imported into a local PACS.

The XDS-I profile allows for sharing:

- The radiology reports either as a plain text document, a PDF (Portable Document Format) document or as an HL7 v3 CDA document. The first two typically contain unstructured text and easily map to existing message-based exchange networks. The latter allows for structured and well-formed documents.
- DICOM Key Object Selection (KOS) documents. KOS objects are small DICOM objects that contain a list of UID references instead of image data. The XDS-I profile describes how an Imaging Document Consumer should follow these UID references to the source PACS and retrieve image data.

In the aforementioned retrieve step, images can be imported as either simple JPEG compressed images (non-diagnostic use case) or as full uncompressed DICOM images (diagnostic use case). XDS-I mandates the use of the DICOM Web Access to Persistent DICOM Objects (WADO) standard or the use of other DICOM communication protocols, such as DICOM Query/Retrieve.

XDS Medical Summary

Another main category of content profiles is found in the Patient Care Coordination domain. This domain is mainly concerned with a document class called “Medical Summaries”. Medical summaries include such document types as:

- Referral letters
- Discharge letters
- Medication lists
- Emergency department referral letters
- Basic Patient Privacy Consents
- Pre-procedure, History and Physical

Each of these documents is based on the HL7v3 Clinical

Document Architecture (CDA) document standard. An HL7v3 CDA document is basically an XML document that adheres to a common data model allowing for inclusion of narrative text, as well as highly structured and machine-processable data entries. The latter makes CDA a strong choice for interoperability between information systems in healthcare.

XDS Laboratory

More recently, the IHE Laboratory domain has defined a series of XD-Lab use cases. All use cases are about the exchange of lab test results from a Lab Information System to other information systems (such as EPR or a GP’s system). The document format chosen by the IHE-Lab community is also HL7v3 CDA and is basically an extension of the documents created within the PCC domain.

XDS Scanned Documents

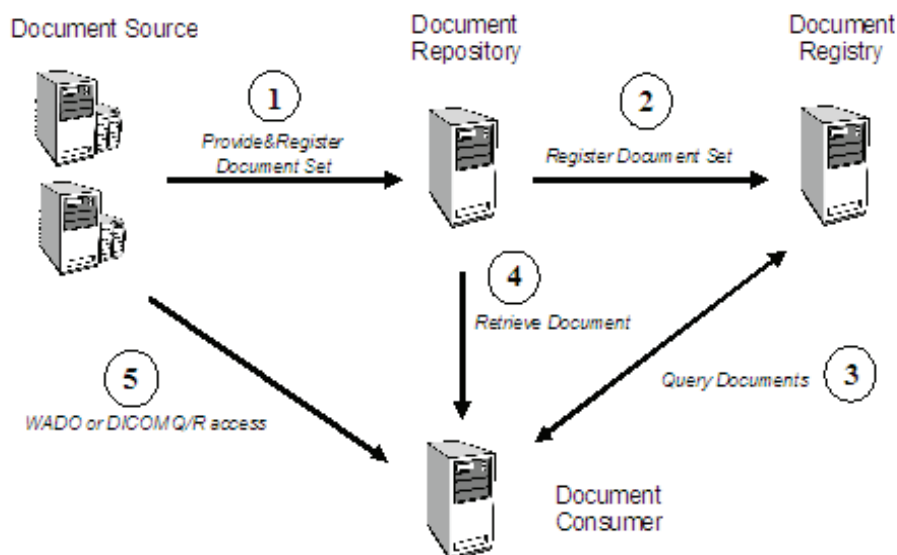
Another pragmatic content profile is XDS-SD. This profile offers a solution for how to include digitized paper records in an XDS infrastructure. The approach taken is very similar to how analog film was digitized when the first generation of PACS emerged. The XDS-SD profile chooses PDF as a “scanned file format”. The PDF is wrapped into an HL7 v3 CDA document to add document attributes that tell which patient the document is from and what type of document was scanned.

THE XDS-I WORKFLOW

Example of XDS-I workflow with RIS and PACS

To understand the implementation of XDS in general and XDS-I in particular together with a RIS and PACS, a simple workflow example is given below. The Document Consumer and Document Source can be from any vendor as long as they fulfill the XDS-I profile:

1. The Document Source (in this example, it could be a Sectra RIS and PACS) decides to share an examination and a radiology report to the XDS framework. This is done through a Provide and Register Document Set transaction to the Repository, where a report is sent from the RIS and a DICOM KOS object is sent from the PACS. The DICOM KOS object is a small object containing a list of UID references to the images instead of image data itself.
2. The document repository updates the Document Registry with a “Register Document Set” transaction to register the documents with the Document Registry. In this transaction, the document properties (metadata) about the report and the KOS object is handed
3. A Document Consumer (in this example, it could be a Sectra IDS7 workstation) requires access to a patient’s shared history within the connected systems in the XDS framework and issues a “Query Documents” transaction to discover the availability of documents. A list of matching documents is sent back to the Document Consumer. Among these documents, information about the radiology report and the examination is found.
4. The Document Consumer retrieves the report from the Document Repository itself, as well as the KOS object for the examination. This is handled through the Retrieve Document transaction.
5. The final step for the Document Consumer is to examine the KOS object to obtain references to the imaging data. It is accessed from the Document Source through either a WADO or DICOM Q/R transaction.



THE XDS-I WORKFLOW (CONT.)

Clinical use of XDS

The major benefit when working in an XDS-enabled environment is the possibility to easily access clinical information from various care providers within an enterprise or within a cluster of enterprises. The XDS-I framework serves as a solid infrastructure on which solutions for several clinical needs can be built, including the following examples:

- Access to imaging results by clinicians outside the local hospital organization. Clinicians can have instant access to shared radiology results regardless of where the patient's examinations were performed.

- Second opinion. Radiology (or other clinical) information can be shared between different physicians to enable an efficient second opinion workflow.

- Referral from one specialist to another. Already performed examinations can be shared with other specialists when referred to another hospital or clinic.



CONCLUSION

The XDS profile, in combination with the various XDS content profiles, offers a solid basis for developing cross-enterprise health information networks in order to share clinical information in a region. XDS allows for sharing of both structured and unstructured data. Thus, it provides a practical way to share information from information systems existing in healthcare today.

Adoption of the XDS profile is progressing very quickly. An increasing number of clinical domains have created XDS content profiles. Also, in many nationwide initiatives, the use of XDS is investigated as a future-proof solution that improves the quality of healthcare and increases the level of service to the patient.

XDS-I makes it possible to share radiology reports and images. Image data is not duplicated. Instead, XDS-I docu-

ments include references to the image storage locations. Given the compliance of most RIS and PACS systems with HL7 and DICOM, realizing an XDS-I network has become a straightforward task.

Even though the XDS framework provides a standardized way of sharing data between different organizations and facilities, it still requires implementation of rules and guidelines through an XDS Affinity Domain Policy. This needs to be thoroughly defined and adhered to for a successful implementation.

The Sectra RIS and PACS product portfolio is designed to be IHE compliant and has made considerable progress with the implementation of the XDS profile. Sectra has demonstrated compliance with the XDS-I integration profile at Connectathon meetings arranged by IHE.



FREQUENTLY ASKED QUESTIONS

Q: Can the XDS repository be seen as a traditional PACS archive?

A: No, since the XDS-I content profile dictates that only metadata about the imaging information (the DICOM KOS object) is stored in the repository, there will be no imaging data stored. Instead, imaging data (can be both short-term and long-term data) is accessed directly from the Imaging Document Source. XDS-I can provide a standardized and extended method for image access across multiple existing PACS archives without the need for extensive data migration or major changes to already deployed systems.

Q: How is security, encryption and traceability maintained within an XDS domain?

A: XDS mandates the use of the IHE ATNA (Audit Node and Node Authentication) profile. In short, the ATNA profile defines two major actors: Secure Node – The Secure Node actor ensures that all transactions between involved servers are carried out securely and only with other trusted nodes in the network. Secure Nodes make use of the Transport Layer Security (TLS) protocol to encrypt data being exchanged over an insecure network. Audit Record Repository – The Audit Record Repository is responsible for the receipt and persistent storage of audit log events within the affinity domain. Audit events are required whenever an application imports, exports or queries protected health information.

Q: Do I need a Sectra RIS or PACS to participate in an XDS framework provided by Sectra?

A: No, the XDS and XDS-I framework is completely vendor neutral, which is one of the major benefits of implementing such infrastructure. The solution becomes future proof through the possibility of adding additional actors within various domains. However, to “XDS-enable” legacy RIS and PACS systems, interface products can easily connect such system to an XDS infrastructure. Examples of such tools are the Forcare forConnect and forView products.

Q: What are the requirements for a non-Sectra RIS to participate in an XDS-I environment?

A: The RIS needs to be able to post reports to an XDS repository. If the RIS does not have native XDS support, Sectra can provide software solutions that can convert an HL7 report-feed into an XDS Provide and Register document set transaction. If it is desirable to display other systems’ reports within the RIS, the RIS must also support being a Document Consumer. Initially, if this is not the case, XDS web viewing components can be used to browse and access the registry, both for images and reports. Examples of such solutions are the Forcare forConnect and forView products.

Q: What are the requirements for a non-Sectra PACS to participate in an XDS-I environment?

A: Unless the PACS has native XDS-I support, Sectra can provide software solutions that can act as a DICOM C-Store SCP converting received images into a KOS object that is posted to the Repository. The same goes for web viewing components that can be used to browse and access the registry, both for images and reports.

RELATED LINKS

General information on IHE:

<http://www.ihe.net>

Vendor's IHE information:

<http://www.sectra.com/medical/IHE>

Vendor's DICOM Conformance Statement:

<http://www.sectra.com/medical/DICOM>

forcare homepage:

<http://www.forcare.nl>

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Sectra provides industry-leading RIS/PACS, mammography and orthopaedic solutions. We are committed to transforming your needs into efficient medical imaging solutions. With more than 20 years of leading innovation, Sectra maintains its position at the forefront of medical IT development thanks to close cooperation with top research centers and more than 1,000 customers. This is how we provide the solutions you need, today and tomorrow. For more information about Sectra's radiology solutions please visit sectra.com/medical.

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