

Enterprise Distribution of Medical Information Anywhere, At Anytime



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Treating patients at multiple healthcare facilities where each maintains their medical information in localized storage management systems and in many instances in proprietary application dependent formats is one of the greatest challenges to healthcare delivery and the emerging requirements for Health Information Exchange (HIE). To reduce the cost of healthcare, eliminate unnecessary clinical studies and streamline patient care, the patient's medical information must be available anywhere and at anytime to any authorized healthcare professional. This can be accomplished by registering medical information in standards-based enterprise storage management solutions that share data across any healthcare facility where a patient encounter occurs.

The implementation of a multi-enterprise standards-based medical informatics environment is beginning to evolve in Canada, Great Britain, Netherlands and elsewhere while in the United States a few localized HIE and Regional Health Information Organizations (RHIO) have been established. With the current investment from the US government through the American Recovery and Reinvestment Act (ARRA) initiative many healthcare providers will want to take advantage of this government incentive to participate in a unified network of Protected Health Information (PHI) to authorized users. Unfortunately the standards-based technical solutions are slow to being adopted in the United States making a regional or national network of medical information difficult to achieve.

Integrating the Healthcare Enterprise (IHE) started in 1997 to improve interoperability, utilizing existing standards, e.g. Health Level 7 (HL7), Digital Imaging and Communications in Medicine (DICOM), etc., between clinical applications. IHE's initial emphasis on Radiology has expanded to multiple clinical and IT domains and a global perspective (1). In 2003 (2) IHE initiated efforts on the healthcare infrastructure with Cross-Enterprise Document Sharing (XDS). In 2005 IHE began work on including images in XDS with XDS-I (3).

The information storage management system for clinical and related applications is central to providing swift and cost-effective healthcare at any healthcare facility. This system must deliver requested information seamlessly to any authorized user anywhere and at anytime. A standards-based enterprise storage management system that is independent of the application and transmits data (4) is critical to achieving the goals of:

- Interoperability between clinical applications
- Increased productivity
- Decreased operational cost and
- Facilitate implementation of an Electronic Health Record (EHR) system.



This solution will deliver benefits that will result in improved patient care while reducing healthcare costs.

InSite One, Inc. was founded in 1999 to provide standards-based application independent managed storage and disaster recovery solutions. These managed service offerings have evolved to include off- and on-site HIPAA compliant intelligent storage management, data migration, disaster recovery, business continuance and enterprise wide viewing of stored images. A decade later InSite One is managing over 40 million studies consisting of over 2.7 billion images from over 600 healthcare institutions. InSite One manages the largest inventory of medical studies maintained in standards-based vendor independent storage management system in the United States. Since InSite One's inception, the storage management system has operated without data loss and zero downtime.

Building upon this foundation, InSite One is introducing the Actors and Transactions in the IHE XDS and IT Infrastructure Domains including XDS-Imaging. These capabilities will allow current and future clients to image enable their EHR and provide the infrastructure to participate in HIEs and RHIOs. This whitepaper describes the role and manner in which this new technology will provide application and location independent data sharing that will improve patient care and outcomes while reducing healthcare cost.

Overview of Cross Enterprise Document Sharing (XDS)

XDS facilitates the registration, distribution and access across and within healthcare enterprises of patient healthcare information, both data and images which also includes Protected Health Information (5, 6). The objectives of the IHE XDS and IT Infrastructure functionality is to provide a specification for managing the sharing of documents between any healthcare enterprise including a physician office, clinic, acute care in-patient facility as well as personal health record systems. The definition of an XDS document is broad and specifies the means for sharing all kinds of healthcare information. IHE has developed IT Infrastructure Integration Profiles to facilitate patient identity, interoperability, storage as well as privacy and confidentiality of electronic information between healthcare enterprises.

Cross-Enterprise Document Sharing (XDS) Transaction Diagram

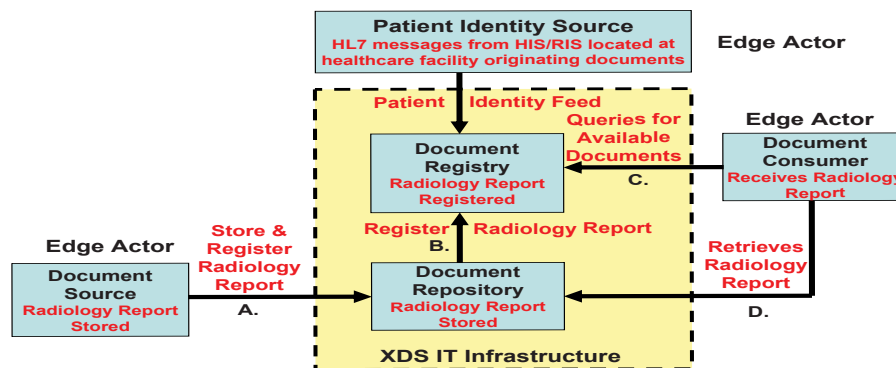


Figure 1. Cross-Enterprise Document Sharing (XDS) Transaction Diagram. The IHE XDS Actors are shown in rectangles, The Edge Actors (Document Source, Document Consumer and Patient Identity Source) are located on-site at the healthcare providers participating in the HIE. The patient is registered at the facility in the HIS/RIS and assigned a medical record number (MRN) if one does not currently exist. This information is sent to the Document Registry via HL7.

A. A document such as a radiology report is created and may be stored at the Document Source, e.g. an imaging center, and the primary copy is sent to the Document Repository of the HIE (Affinity Domain) to which this imaging center belongs.

B. The Document Repository registers the radiology report in the Document Registry of the HIE.

C. A Document Consumer at another healthcare entity in the HIE needs the patient's radiology report of the stored study to compare with the results of a current study. The Document Consumer queries the Document Registry for a list of the patient's documents and where they are located, i.e. which Document Repository.

D. The user (at the Document Consumer) selects the desired document, radiology report, and the Document Consumer retrieves the report from the Document Repository.

The role these Actors play is as follows:

- **Document Source Actor** generates and manages documents that it may already be storing, i.e. lab results, audio files, images, etc. They are located at the various healthcare providers, such as hospitals, healthcare clinics, imaging centers, etc. in the healthcare Affinity Domain that have agreed to share ePHI. They also provide the patient identity information and create the descriptive data (metadata) related to the documents to be stored. The Source Actor submits the documents and associated description of the data (metadata) to the Document Repository for storage.
- **Document Consumer Actor** is the authorized user of the documents and queries the XDS IT Infrastructure for specified patient records and to display/access registered documents.



- **Document Repository Actor** accepts documents and associated metadata and stores the documents and forwards the metadata to the Registry Actor. When requested by a Consumer Actor, it serves up to the Consumer to retrieve the document.
- **Document Registry Actor** indexes document associated metadata from the Repository. When queried, it returns up a list of relevant document for the specified patient and their Repository locations.
- **Patient Identity Source Actor** provides patient identifying information and status changes typically from the HIS/RIS which it receives as HL7 messages.

IHE IT Infrastructure Integration Profiles

The primary IT Infrastructure Integration Profiles are:

- **Patient Identifier Cross-referencing (PIX)** reconciles patient information on patients from different sources within or across hospitals, healthcare providers, HIEs or RHIOs to a single, cross referenced set of IDs for each patient. This integration profile PIX provides the functionality of the enterprise Master Patient Index (eMPI). The PIX Integration Profile is critical for matching a patient who is being seen at multiple sites within a healthcare enterprise, HIE or RHIO. A healthcare provider identifies a patient with a medical record number (MRN) that may or may not be unique for that patient within the healthcare enterprise or within the HIE or RHIO along with demographic data such as birth date, birth city, gender, first and last name, etc. when ePHI is generated for that patient.

The identifying data for a patient may differ between healthcare providers as a result of the clinical applications in use. As an example, if the two hospitals have separate servers for their Hospital Information System (HIS), different MRNs will be generated for the same patient or the birth date or name may be formatted differently. A patient's last name may change resulting from marriage or divorce. The critical role of the PIX Integration Profile is to ensure that all of the patient documents are associated with the patient irrespective of where healthcare was provided to the patient and how each healthcare provider identifies that patient.

- **Patient Demographic Query (PDQ)** is the Integration Profile that returns demographic information and identifiers for patients based on the specified demographic criteria. PDQ provides the functionality to the Consumer Actor who queries the Registry Actor to retrieve a patient's demographic, visit information and related documents that is equivalent to a worklist.
- **Audit Trail and Node Authentication (ATNA)** is the Integration Profile that provides the security and authentication systems using certificates and transmitting ePHI-related audit events to the Repository. ATNA receives audit records from other Actors and securely stores them for audit purposes. It also authenticates peer-nodes and encrypts communications.
- **Basic Patient Privacy Consents (BPPC)** Integration Profile records patient privacy consent, including opt-in and opt-out; marks documents with the privacy consent, enforces the permission for the intended use and controls access to the documents.

XDS-I Integration Profile

The XDS integration Profile was extended to better manage imaging documents due to the complexity of storing large datasets of large objects. The extended standard, XDS-I (3, 7) now includes an Image Document Source and Image Document Consumer (Figure 2). The key difference between a Document Source and an Image Document Source is that the Image Document Source provides the Document Repository with a reference to the document (image[s]) as opposed to the document itself. This alleviates the storage management burden from the Document Repository and places it on the Image Document Source (typically the PACS or the Image Archive) itself. The Image Document Consumer is unique in that it knows how to interpret the reference to the images and can request the actual images directly from the Image Document Source making it ideal for sharing.

DICOM objects (images, structured reports, etc.) and the Document Source is well suited for handling diagnostic imaging reports provided in a ready-for-display-format such as Portable Document Format (PDF) and Clinical Document Architecture (CDA) documents.

Cross-Enterprise Document Sharing (XDS-I) Transaction Diagram

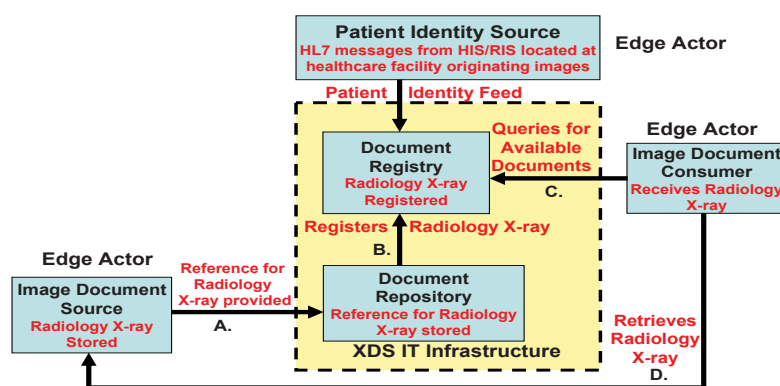


Figure 2. Cross-Enterprise Document Sharing (XDS-I) Transaction Diagram. The XDS Integration Profile was extended to better manage imaging documents. Two new Edge Actors (Image Document Source, Image Document Consumer and Patient Identity Source) are located on-site at the healthcare providers participating in the HIE. The key difference between the Document Source and the Image Document Source is that the Image Document Source provides the Document Repository a reference to the document (images) as opposed to the images themselves. The Image Document Consumer can interpret the reference to the images and retrieve them directly from the Image Document Source. The patient is registered at the facility in the HIS/RIS and assigned a medical record number (MRN) if one does not currently exist. This information is sent to the Document Registry via HL7.

A. X-ray images are created and are stored at the Image Document Source, e.g. an imaging center, and the reference to the X-rays is sent to the Document Repository of the HIE to which this imaging center belongs.

B. The Document Repository registers the X-rays in the Document Registry of the HIE.

C. An Image Document Consumer at another healthcare entity in the HIE needs the patient's prior X-rays to compare with the results of a current study on that patient. The Image Document Consumer queries the Document Registry for a list of the patient's documents and where they are located, i.e. which Document Repository.

D. The user (at the Document Consumer) selects the desired document, the X-rays, and the Image Document Consumer retrieves the X-ray reference from the Document Repository, extracts the reference to determine where (which Image Document Source) the X-rays are located, and retrieves the X-rays from the Image Document Source.

Document Repository (Storage) Models in the XDS Environment

There are three basic Document Repository Models used in the XDS environment, the Federated Clinical Affinity Domain Model and Centralized Model or a combination of both models, a hybrid model, depending on the client's infrastructure and functionality desired by the client and/or the health exchange. In the Federated or Peer-to-Peer Model, each healthcare entity maintains its own Document Repository and has secure communications with all members of the healthcare enterprise. There is a centralized Document Registry, but no one entity necessarily has all the data for individual patients.

With the Centralized Model, all documents for a patient are stored in one or more Document Repositories and Registry in a centralized domain with all healthcare providers securely transmitting documents to the centralized domain and registering with the centralized Document Registry. As in the case with the Federated Model, the healthcare enterprise, HIE or RHIO may require a hybrid model, however, there will still be a single Document Registry. Another example of a hybrid model would be the case of multiple HIEs that have a working relationship, i.e. the ability to share documents with authorized users in multiple registries in different HIEs.

IHE XDS, XDS-I and IT Infrastructure Compliant Offerings by InSite One

Registering Existing Stored Objects as XDS-I Compliant Objects

The client's studies and related documents (DICOM objects) currently residing in InSite One's standards-based vendor independent storage management system and client's on-site document storage systems will be registered in the Image Document Source and Document Repository Actors as XDS-I compliant documents. InSite One can generate XDS-I documents for historical studies efficiently without referencing each underlying image file by quickly processing metadata in its DICOM database. InSite One can also provide its Universal Viewer as the Image Document Consumer. The thin client Universal Viewer can be readily integrated to existing applications and portals.

Cross-Enterprise Availability of Medical Images

InSite One registers client images (including images from an existing HIE that are not image enabled) as XDS-I documents in InSite One's and the client's Image Document Source and Repository. The original stored DICOM objects remain unaltered. The document is made available to an



XDS environment by creating a manifest specifying the contents of the clinical study along with pointers indicating the location of the original DICOM objects and related metadata. The manifest is stored in the Image Document Source and is registered in the Document Registry. The DICOM objects remain located at the client's site, at InSite One's secure data center or both. They are not relocated to the Document Repository, significantly reducing storage requirements and thus cost. When an Image Document Consumer queries the Document Registry for an Image Document, the Registry retrieves the associated document manifest from the Image Document Source and the document is retrieved from either the client's storage system or InSite One's secure data center.

InSite One can also provide an XDS Document Consumer Universal Viewer which can be integrated into the client's portal, e.g. EMR, etc. This enables the client to share and view images throughout the healthcare enterprise. As an added advantage, this offering would provide existing InSite One clients the ability to be XDS standards-based "ready" to join an HIE.

The storage model for this offering would, for the most part, be Federated, but for healthcare enterprises with providers that generate varying quantities of documents, a Centralized or Hybrid Model may be more appropriate since many smaller healthcare facilities may not want to support the DICOM object storage management system.

Hosted Registry and Repository for Clients Medical Information

InSite One's also offers to manage and provide the IT infrastructure for the HIE infrastructure and a central Document Registry. This service would include registration of the client's patients and documents into XDS compliant format as described above and implementing the full complement of XDS Actors and XDS Infrastructure Integration Protocols as previously described (i.e., Image Document Source and Registry, PIX, PDQ, ATNA and BPPC) along with the optional Document Consumer Universal Viewer that can be integrated into the client's portal.

Depending on the infrastructure and resources of the client, InSite One can provide as much or as little of the required infrastructure as needed. The primary infrastructure component provided by InSite One at a client document source, e.g. an outpatient imaging center or physician office "edge sites" would be InSite One's Intelligent Management Gateway (IMG). The hardware, storage capacity and software of the IMG located at each of the client's sites would be based on the individual site requirement.

The IMG, federated at “edge sites,” combined with the centralized Document Sources and Repositories, bring to market a true, hybrid architecture, dynamically utilizing the optimal mix of storage and network resources to store and exchange clinical information in the most cost effective and sustainable manner.

Impact of Deploying IHE XDS, XDS-I and IT Infrastructure Integration Profiles

There are five major issues that enable organizations to share of data across enterprise boundaries face: - patient identification, security, privacy, economics and document retention. An XDS enabled storage management system can address the first three with ease and possibly facilitate resolving the latter two. The requirements of unique patient identification and security and privacy of the electronic information (images and documents) are insufficient using existing DICOM standards both from regulatory and functionality perspectives.

There is no unique patient identifier universally available in the United States since it was deleted from the HIPAA of 1996. The IHE IT Infrastructure Integration Profile PIX describes how applications may utilize patient identity feeds from within an enterprise and with related entities in the associated HIEs and RHIOs. The PIX utilizes patient matching logic to link all local identifiers for a single patient together across multiple applications and institutions. By becoming aware of the other identifiers for the patient, other relevant documents can now be shared across institutional boundaries. This functionality provides access to the complete inventory of patient clinical information to authorized users who participate in this sharing of information.

Based on a security survey from the Healthcare Information and Management Systems Society (HIMSS) (8), United States healthcare organizations may not be adequately prepared to deal with security challenges and the requirements of the ARRA to maintain privacy and security of patient health data. Security of the data remains the number one issue as seen by the daily reports of data breaches.

The delicate balance of sharing clinical information must be maintained in a distributed environment that is both secure and patient privacy maintained. Many applications, including DICOM compliant applications do not provide the necessary security and privacy functionality. The IHE IT Infrastructure Integration Profiles ATNA and BPPC begin to provide this functionality.

Healthcare enterprises are being given economic incentives by the ARRA initiative to exchange clinical results that includes images and data both within their own enterprise, but not necessarily with other healthcare entities that are part of other HIEs and RHIOs. There is also the question of funding after the ARRA initial funding ceases. Answers to these issues must be responded to if HIEs and RHIOs are to be successful in the United States.

One of the common responses from healthcare providers is that sharing of patient clinical information to potential authorized users outside of your enterprise will impact the utilization of your services. This is a two-edged sword. If your institution provides exceptional clinical service with positive outcomes for both patient and referring physicians in your service area and other institutions do not match your level of service, your institution will benefit. Of course, the opposite is also true.

The issue of data retention and deletion or unavailability is a separate and more difficult issue to resolve especially for the federated storage model. The retention period for protected health information is mandated by federal, state and local statutes as well as a healthcare institution's retention policy. In the federated model a healthcare entity (Document Source) can create document "A" and store "A" in the Document Repository. Document "A" can be used diagnostically by another healthcare entity (Document Consumer) for patient care. Based on the document retention policy at the Document Source institution, or if that institution leaves the HIE, document "A" previously used by the Document Consumer is no longer available which may be in violation of the Document Consumer's retention policy for protected health information.

This data retention issue creates an enormous data management challenge that is not addressed by the IHE integration profile nor is there any regulatory guidance. To resolve this retention issue, healthcare entities using documents from other entities in the HIE may copy documents they use from other institutions into their Document Repository resulting in a duplicate entry in the HIE's Document Registry.

Alternatively, documents used diagnostically by institutions other than the one originating the document may be required to be kept in a centralized HIE Document Repository. How to manage data long-term in a federated storage model such as cost and storage management are operational issues. An alternative managed storage service solution can provide a cost-effective compromise such as InSite One's IHE XDS enabled application independent storage management system with IHE IT Infrastructure functionality and XDS-I, image enablement. This will mitigate future integration risks and provide a cost-effective solution.

The combination of InSite One's application independent DICOM-compliant storage management system, suite of managed services and now, XDS IT Infrastructure will allow a healthcare enterprise to share both data and images seamlessly within their enterprise and with any HIE or RHIO they join resulting in cost-reductions and more effective healthcare for their patients.

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Acknowledgement

The author would like to acknowledge the technical assistance of Robert Porper, Senior Vice President Product Development, InSite One, Inc. and Mitchell Goldburgh, Senior Vice President Marketing & Business Development, InSite One, Inc. for their editorial suggestions.

Biography

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