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Abstract. IHE XDS-I profile proposes an architecture model for cross-enterprise medical image sharing, but there are only a few clinical implementations reported. Here, we investigate three pilot studies based on the IHE XDS-I profile to see whether we can use this architecture as a foundation for image sharing solutions in a variety of health-care settings. The first pilot study was image sharing for cross-enterprise health care with federated integration, which was implemented in Huadong Hospital and Shanghai Sixth People's Hospital within the Shanghai Shen-Kang Hospital Management Center; the second pilot study was XDS-I-based patient-controlled image sharing solution, which was implemented by the Radiological Society of North America (RSNA) team in the USA; and the third pilot study was collaborative imaging diagnosis with electronic health-care record integration in regional health care, which was implemented in two districts in Shanghai. In order to support these pilot studies, we designed and developed new image access methods, components, and data models such as RAD-69/WADO hybrid image retrieval, RSNA clearinghouse, and extension of metadata definitions in both the submission set and the cross-enterprise document sharing (XDS) registry. We identified several key issues that impact the implementation of XDS-I in practical applications, and conclude that the IHE XDS-I profile is a theoretically good architecture and a useful foundation for medical image sharing solutions across multiple regional health-care providers. © 2015 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: 10.1117/1.JMI.2.4.046501]

Keywords: IHE XDS-I profile; solutions for image sharing and exchange; regional health-care services; picture archiving and communication system.

Paper 15137PR received Jul. 8, 2015; accepted for publication Oct. 6, 2015; published online Nov. 12, 2015.

1 Introduction

Health-care professionals (e.g., referring physicians, radiologists, surgeons, oncologists, and so on) benefit from a coordinated method for locating, accessing, and archiving relevant medical documents including imaging information. The creation and subsequent use of these documents may span several care delivery organizations and may be performed separately over different time periods. Thus, there is a strong motivation to implement electronic health-care record (EHR) systems as information exchange platforms for regionally coordinated health-care services.¹

The major challenge with EHR implementations is the integration of different information systems with different information models and platforms. To solve this integration problem, the Integrating Healthcare Enterprise (IHE)² has defined an integration profile, known as cross-enterprise document sharing (XDS), to regulate medical record sharing, queries, and retrievals among different document source systems and end applications in a clinical affinity domain: a shared set of policies and infrastructure for exchanging documents.³ Research has been done on how to use the XDS profile to federate multiple clinical affinity domains,⁴ and how to enable the outsourcing of XDS architectural parts to a public domain with secured data exchange.⁵ The XDS for imaging (XDS-I) profile is a

supplement to the IHE XDS profile, which extends and specializes XDS to support exchanges of imaging “documents,” specifically sets of DICOM instances (including images, evidence documents, and presentation states) and diagnostic imaging reports, and provide them in a ready-for-display format.⁶ The IHE XDS-I profile proposed an architecture model for cross-enterprise medical image sharing almost 10 years ago with the release of version “a” in 2005, but very few clinical implementations of this model have been reported.

In the past few years, we studied implementation methods of the XDS-I profile and gave some preliminary results.⁷ In this paper, we systemically present our full study about image sharing and exchange solutions for three image sharing scenarios, based on the IHE XDS-I profile, and also evaluate these solutions to determine whether the IHE XDS-I profile can serve as a foundation for medical image-sharing solutions across different regional health-care providers. These three scenarios include: (a) long-term health-care management across multiple hospitals and clinics; (b) patient-controlled image exchange between health-care providers and image data end-users; (c) telecollaboration for image diagnosis across multiple regional hospitals. In order to support these pilot studies, we developed new image access methods, components, and data model such as RAD-69/WADO hybrid image retrieval, Radiological Society of North America (RSNA) clearinghouse, and the extension of metadata definitions in both the submission

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set and the XDS registry. In the following sections, we will present these three pilot studies and discuss some key issues which may impact clinical implementation of the XDS-I profile.

2 Brief Description of IHE XDS/XDS-I Profiles

One key technical problem for continuity of patient care is the identification of an appropriate method for sharing and exchanging patient records among various hospitals and health-care providers. To solve this integration problem, several different architectural approaches and programs have been developed; e.g., the National Program for IT, in the UK⁸ and Canada Health Infoway, in Canada.⁹ The IHE has defined an integration profile termed IHE XDS to standardize medical record publication, query, and retrieval among document source systems and consumer applications.

Currently, the IHE XDS integration profile has evolved to version “b,” due to the maturation of Web services standards for intra- and inter-enterprise integration and associated support from an increasing number of platforms and vendors, both commercial and open-source. The b-version presents a number of enhancements for image exchange, including metadata expressed in the eXtensible markup language used for electronic business, Registry 3.0,¹⁰ which is used for XDS transactions, and an updated simple object access protocol (SOAP 1.2).¹¹ It also retains the legacy SOAP 1.1, but it uses the W3C message transmission optimization mechanism with XML-binary optimized packaging (MTOM/XOP),¹² instead of the legacy SOAP with attachments mechanism, for providing and registering a document set “online.” In addition, it provides a new transaction with a SOAP binding that uses MTOM/XOP for retrieving XDS documents.^{11,12} Similarly, the XDS-I profile⁶ was updated to the b version (XDS-I.b). Figure 1 shows the diagram of actors and transactions used in the XDS-I.b profile.⁶

From Fig. 1, we can see that there are six key actors and five major transactions in the XDS-I.b profile.⁶ The six key actors are patient identify source, document registry, document repository, imaging document source, document consumer, and imaging document consumer. The five major transactions are provide and register document set-b (ITI-41), register document set-b (ITI-42), registry stored query (ITI-18), retrieve document set (ITI-43), and retrieve imaging document set (RAD-69). All of these key actors and transactions are clearly defined and described in the IHE XDS.b/XDS-I.b profiles.^{3,6}

In the following sections, we describe how to use the actors and transactions defined in the IHE XDS-I.b profile to design

and build different image-sharing solutions that meet the requirements of a variety of regional collaborative health-care services.

3 Pilot Studies of Medical Image Sharing and Exchange for a Variety of Health-Care Services

3.1 Pilot Study 1: Image Sharing for Cross-Enterprise Health Care with Federated Integration

3.1.1 Background

The EHR provides an information exchange platform for regionally coordinated health-care services. Due to the rapid growth of Shanghai city to 20 million residents, the imbalance between health-care supply and demand has become an important issue. The local government intends to ameliorate this problem by developing an image-enabled EHR (iEHR) that allows sharing between specific hospitals. The challenges involved in designing and developing this iEHR system, are the complicated city health-care system, the different kinds of affinity domains, and the many different kinds of service models currently in the health-care system. Shanghai Shen-Kang Hospital Management Center (SSKPMC) is a hospital management organization (HMO) that manages 34 large hospitals in Shanghai. This HMO intends to build an iEHR system to enable sharing patient health-care information (PHI) among the 34 hospitals. To that end, we aimed to evaluate several different technical solutions.

The first candidate technical solution was to adopt the IHE XDS-I integration profile⁶ as a technical guide for building a prototype proof of concept (POC) iEHR with a federation model. For the POC, the iEHR must integrate with the hospital picture archive and communication system (PACS) and the radiological information system (RIS). In addition, it must consider security issues, the protocols for interfacing with different vendors’ PACS/RISs, and the operating models.

3.1.2 Image sharing architecture, components, and work flows

We chose Huadong Hospital and Shanghai Sixth People’s Hospital for testing within the SSKPMC to evaluate the design concept and implementation of an iEHR system based on the

Fig. 1 The diagram of actors (boxes) and transactions (lines) used in the XDS-I.b profile.

Fig. 2 The architecture, major components and work flows of an XDS-I-based iEHR for image sharing with federated integration.

IHE XDS-I.b profile. The architecture of the major components of the iEHR is shown in Fig. 2. The PACS/RIS used for pilot testing in Huadong Hospital was from a local PACS vendor, Simed Technologies Inc.,¹³ which provides DICOM C-Store SCU/SCP services for pilot testing. The PACS/RIS used for pilot testing in Sixth People's Hospital was GE Centricity PACS,¹⁴ which provided DICOM C-Store SCU/SCP services and also offered a Web access to DICOM objects (WADO) service for pilot testing. The pilot testing network was set up across Huadong Hospital, the Sixth People's Hospital, and the SSKHMC data center through a dedicated VPN with a bandwidth of 100 MB.

The designed system included typical XDS-I components, including the XDS.b registry, repository, patient identifier cross-referencing (PIX) manager, imaging document consumer (iEHR client), and an edge appliance. These components were deployed in a demilitarized zone (DMZ) and functioned as an imaging document source actor and a protocol interface adaptor for the hospital PACS/RIS and iEHR systems. All transactions of the IHE XDS-I.b were implemented in the iEHR and conformed to the standards of the National Institute of Standards and Technology Document-Sharing Test Facility.¹⁵

There were two methods for processing the submitted DICOM image data in the edge appliances. One method was to store the DICOM image data in the edge appliance for later direct retrieval, when requested from an iEHR client (imaging document source); this was called online retrieval. The other method was to delete the image data in the edge appliance, and then retrieve image data from the local PACS through IHE RAD-69 and DICOM WADO on-the-fly each time the iEHR client requested the image data from the edge appliance. The IHE RAD-69 and DICOM WADO hybrid retrieval was first developed specifically for this study in the edge appliance, and was called near-line retrieval.

The typical work flow for testing was to register the imaging document data (DICOM images and related reports) by transferring the data from the hospital PACS/RIS to the XDS-I sharing infrastructure. Then, using the iEHR client, we attempted to find and retrieve the Image document.

Image registering

1. DICOM image studies were sent from the PACS to the edge appliance through a DICOM C-Store service; reports (CDA R2/Plain text) were sent from the RIS through a HL7 message (Fig. 2). In edge appliance A at Huadong Hospital, the DICOM image studies were stored for later online retrieval, when requested from the iEHR client (imaging document source). In edge appliance B at the Sixth People's Hospital, the DICOM image studies are deleted after registering.
2. The edge appliance extracts specific metadata information (UIDs for patients/studies/series/images) from studies and reports and creates an image manifest defined in the DICOM key object selection (KOS).⁶ It also retrieves a global identifier (global ID) from the PIX manager and creates the submission set, which contains the manifest, DocEntry metadata, and submission set metadata defined by the XDS-I profile.⁶ Then, it submits the submission set to the XDS repository through ITI-41.
3. The XDS repository stores the DICOM manifest and DocEntry metadata in the database, creates the Object UID (OID) for each document in the submission set, and forwards the DocEntry metadata, OIDs, and URL of the repository to the XDS registry through ITI-42.

Image query and retrieval

1. The iEHR client (imaging document consumer actor) uses the global ID (from the PIX manager) to query the XDS registry through an XDS query (ITI-18) transaction. Then, the XDS registry searches the registry database and returns a list of OIDs (created when the document was stored in the repository).
2. The iEHR client parses the queried results to allow the user to make a selection and to initiate the retrieval procedure (ITI-43, Fig. 2). The retrieval request is

sent to the XDS repository, which retrieves the image manifest (DICOM KOS) or the report, in clinical document architecture release 2 (CDA R2) format. Then, the iEHR client parses the manifests to obtain the UIDs of the studies/series/images and the URLs of edge appliances A or B (image source actors that store and manage the image studies). Then, the iEHR client initiates a RAD-69 transaction to retrieve images from edge appliances A or B.

- When edge appliance A is accessed by the iEHR client, it returns the image instances to the iEHR client through a RAD-69 response. When edge appliance B is accessed, it first converts the RAD-69 transaction request to a DICOM WADO request, then it retrieves the image instances from the PACS of the Sixth People's Hospital (GE Centricity PACS v.3.5), and sends the retrieved image instances to the iEHR client through a RAD-69 response.

3.1.3 Key issues identified in pilot testing

We successfully designed the architecture and work flows of XDS-I-based image sharing for cross-enterprise health care. However, we found some key issues that require evaluation and discussion before embarking on a clinical implementation.

Image sharing models. One issue is that the choice of image sharing model affects the strategy for integrating the XDS-I infrastructure with the local PACS. In the study, we tested two sharing models for exchanging data between the local PACS/RIS and the XDS-I image sharing infrastructure. The network settings and communication protocols of these two models are shown in Fig. 3.

One model used online sharing [Fig. 3(a)], which pushed or copied shared data from the local PACS/RIS to the edge appliance (edge appliance A in Fig. 2), and then, registered the data in the XDS-I registry and repository. In this model, the iEHR client could retrieve the image data from the edge appliance directly, with the RAD-69 transaction. In addition, the shared image data was stored in the local edge appliance located in the hospital DMZ, and it was fully managed by the XDS-I infrastructure. In this model, the local edge appliance was capable of storing and managing the image data for long-term use. However, this model increased the storage cost, because the image data was duplicated in the local PACS and edge appliance.

The second model used near-line sharing [Fig. 3(b)], which registered and stored the metadata and shared the image data manifest in the registry and repository. Thus, the iEHR client could only indirectly retrieve the image data stored in the local PACS/RIS by accessing it through the edge appliance [edge appliance B in Fig. 2] with a combined RAD-69 and WADO transaction. In this sharing model, the data was stored in the hospital, and fully managed by the hospital PACS. This model saved on storage cost, but it had the potential to impact image retrieval performance, because the images must be retrieved first from the local PACS and sent to the edge appliance, and then sent to remote consumers. Thus, the retrieval rate was affected by local PACS performance and the security settings.

Performance. Another key issue in designing image sharing solutions is the image transmission performance particularly the

Fig. 3 Protocols and data flows for: (a) online sharing model in edge appliance, and (b) near-line sharing model in edge appliance.

rate of image retrieval in on-demand mode of image transmission. For on-demand mode, most meaningful or important to measure the image transmission performance is to measure the interval time from requesting time to arriving time of first retrieved image, as this interval time is objective compared to measuring the retrieval time of the entire study transmission. In our IHE XDS-I-based image sharing design, we could expect the two sharing models to have different retrieval performances. Therefore, we compared their retrieval rates.

The hardware configuration of the edge appliance in the Huadong Hospital DMZ comprised a Dell Poweredge 2950 with dual 2.5-GHz CPUs, 8 GB of RAM, and dual network adapters. It was set up for the online sharing model; therefore, it stored the shared image studies in local storage, and preregistered the image studies in the registry and repository, located in the Shen-Kang data center, through ITI-41 and ITI-42. The edge appliance in the Sixth People's Hospital DMZ had the same hardware configuration as that at Huadong Hospital. It was set up for the near-line sharing model; therefore, it stored the shared image studies in a GE Centricity PACS server, and it preregistered the image studies in the registry and repository, located in the Shen-Kang data center, through ITI-41 and ITI-42. The iEHR client was also set up in a test site of the Shen-Kang HMO. For the testing, we collected one computed tomography (CT) study with one series of 200 DICOM images (image size = $512 \times 512 \times 2$ bytes), one magnetic resonance (MR) study with one series of 100 DICOM images (image size = $256 \times 256 \times 2$ bytes), one digital radiography (DR) study with one series of 2 DICOM images (image size = $2000 \times 2500 \times 2$ bytes), and one ultrasound (US) study with one series of 27 DICOM images (image size = $768 \times 1024 \times 1$ bytes).

For the testing procedures, the iEHR client performed an ITI-18 stored query, an ITI-43 document (image manifest)

Table 1 Time intervals for displaying the first image in a series after issuing a ITI-43 request in the online sharing model.

Modality	Time for 1st request(s)	Time for 2nd request(s)	Time for 3th request(s)	Average time for displaying 1st image (s)
MR	2.014	1.912	2.002	1.976
CT	2.386	2.376	2.381	2.381
DR	1.823	1.681	1.777	1.76
US	1.144	1.142	1.136	1.14

retrieval, and it extracted UIDs for studies/series/images. Then, it performed RAD-69 retrievals from the edge appliances of Huadong Hospital and the Sixth People's Hospital. We measured the time intervals between the ITI-43 request and the first retrieved image of a series through the RAD-69. For each study or series dataset, we performed three retrieval requests and measured the time intervals between the ITI-43 request and the first retrieved image of a series through the RAD-69. The time intervals of the three requests for each study were almost the same, so the testing results were reproducible. We averaged interval times of the three retrieval requests as retrieval performance results for each modality study. We compared the retrieval performances of the online and near-line sharing models. Tables 1, 2, and Fig. 4 show the results.

The performance comparison from Tables 1 and 2 as well as Fig. 4 showed that the online sharing model had a faster image retrieval rate than the near-line sharing model for different kinds of images. However, the retrieval time difference between the online and near-line models were only 0.05 s for US and 0.34 s for CT data. This result can be explained, because it takes longer to transfer an image from the GE WADO to RAD-69 in the edge appliance than to read an image from a local disk in the edge appliance. Another interesting result from Fig. 4 is that the difference of interval times of retrieving DR/CR between online sharing and near-line sharing models was much larger than that of CT/MR/US. The explanation of this result is that it takes a longer time to retrieve one (first image in a series) DR/CR image from PACS by using WADO compared to CT/MR/US as the image size of a single DR/CR is larger than that of CT/MR/US.

Table 2 Time intervals for displaying the first image in a series after issuing an ITI-43 request in the near-line sharing model.

Modality	Time for 1st request(s)	Time for 2nd request(s)	Time for 3th request(s)	Average time for displaying 1st image (s)
MR	2.494	2.112	2.331	2.312
CT	2.783	2.762	2.621	2.721
DR	3.682	3.521	3.611	3.605
US	1.191	1.183	1.201	1.192

Fig. 4 Performance comparison of online and near-line sharing models. The time intervals (s) represented by vertical axes (time unit: s) for appearance of the first image of different data series after issuing an ITI-43 request in the IHE X-DS-I-based image sharing platform.

3.2 Pilot Study 2: XDS-I-Based Patient-Controlled Image Sharing Solution

3.2.1 Background

Most XDS-I-based image sharing solutions focus on image transfer between radiologists and physicians. However, it is also very common for patients to share imaging exams with doctors. Typically, patients receive copies of their medical imaging exams on a compact disc (CD). The intent is that patients give the CDs to specialists, who can then view the images on their personal computers. Sharing data through CDs has many disadvantages, including corruption, damage, loss, and incompatibility between operating systems, which causes difficulty and frustration. An online method could replace the CD approach.

Through a grant from the National Institute of Biomedical Imaging and Bioengineering, five academic sites, called the RSNA team in this paper: The Mayo Clinic, Mount Sinai Medical Center, University of Chicago, University of California San Francisco, and University of Maryland; collaborated together to implement a patient-centered image sharing solution (RSNA image sharing network [ISN]),¹⁶⁻¹⁸ which is based on the IHE XDS-I.b profile. This solution gives the patient control over how imaging exams are shared. It leverages a cloud-based “clearinghouse,” which we designed and developed collaboratively with LifeIMAGE Inc.¹⁹ The clearinghouse coordinates to transfer imaging exams from edge servers in hospitals/clinics to personal health record (PHR) systems.²⁰

3.2.2 RSNA image sharing network solution

The RSNA ISN solution has three major components (Fig. 5):²⁰ the edge server, clearinghouse, and PHR. The global ID of a patient in the RSNA ISN solution is a hash key, which comprises a PIN specified by the patient and an RSNA ID that is mapped to the local patient medical record number. Combining these values into a hash key ensures a high degree of security. Similarly, all transactions between the edge servers, clearinghouse, and

PHRs are encrypted with standard SSL, which provides secure communications over the public Internet.

The edge server is designed to receive the image study and reports from a hospital PACS and RIS through DICOM and HL7 services. It creates a document submission set that contains a report formatted in CDA R2, a DICOM KOS manifest, and DICOM objects. It submits this document set to the clearinghouse through an ITI-41 transaction.

The clearinghouse architecture is based on IHE XDS-I.b profile and shown in Fig. 5. The clearinghouse acts as an XDS.b document registry, document repository, XDS-I.b imaging document source, DICOM image manager, and a PIX manager. It receives the document submission set from the edge servers through ITI-41; it parses out the DICOM objects and stores them in the image manager; and it resets the manifest to make the pointers within the manifest point to the image manager (i.e., the internal source actor). Image data are encrypted with a 256-bit ASA algorithm. As per standard XDS, the PHR can query and retrieve data from the clearinghouse with standard IHE ITI-18, ITI-43, and RAD-69 transactions.

The clearinghouse has an audit and monitoring manager that tracks auditing events that ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA)²¹ and all ITI transactions; it also monitors source site connections, PHR connections, data volumes, the number of studies, the type of studies, and the volume of pixels stored in the clearinghouse. This audit and monitoring manager is very useful in managing the system from the perspectives of both clinical function and technical operation.

PHRs act as XDS.b document consumers and imaging document consumer actors. PHRs use the global ID to retrieve images from the clearinghouse, and they have an embedded viewer that allows patients, consulting physicians or specialists to review images. The PHRs also notify the clearinghouse PIX manager of any cross-referenced patient RSNA IDs.

3.2.3 Patient-controlled work flow in the RSNA image sharing network

1. Patients are asked whether they want to use the RSNA ISN to obtain image studies, and which exams they want to push to the network. They are either given an RSNA ID or they use a previously assigned RSNA ID. The patient is asked to provide a PIN to associate with the specific imaging studies. Finally, they are asked to provide a contact email for notification.¹⁸
2. Order information is sent to the edge server via HL7. This order information is maintained in the edge server database and allows an on-site staff member to search for and select the imaging exam that the patient wants to submit to the clearinghouse. This exam is queued up for submission to the clearinghouse.
3. Once all the requested exams and results are queued up, the edge server retrieves the images from the local PACS and the reports from the exam database.
4. The edge server creates a document submission set, which contains a CDA-formatted report, a DICOM KOS manifest, and DICOM objects. The edge server transmits the dataset to the clearinghouse. At the same time, an email is sent to the patient to notify him or her that images are available.
5. Upon receipt of the email, the patient logs in to his or her PHR account and uses the RSNA ID and PIN to retrieve his or her images and reports from the clearinghouse. The material is deposited into his or her PHR account.
6. After a fixed period of time, the images and reports are deleted from the clearinghouse.

Fig. 5 The architecture, major components, and data flows of the RSNA image sharing network solution.

3.2.4 Key features of the RSNA image sharing network solution

The RSNA image sharing network solution has a number of key features that differentiate it from standard XDS-I solutions, like the one used in the federated integration model described earlier. These key RSNA ISN features are:

1. A patient determines whether a study is transferred to the PHR. In the federation model, patients do not have control over what is submitted and shared.
2. Imaging exams must be explicitly submitted to the clearinghouse by an on-site user. In the federation model, all studies are always uploaded automatically.
3. ITI-41 is used to transfer reports, manifests, and DICOM objects. In a standard XDS-I domain, like the federation model, only manifests and reports are submitted (with ITI-41) to the document repository/registry. The DICOM objects (images) remain with the imaging document source.
4. The clearinghouse is unique, because it groups the XDS registry and repository actors with an image manager and an imaging document source actor. In contrast, standard XDS-I domains separate the document repository from the image manager and imaging document source actors.
5. A secure global ID is used as a token that comprises the RSNA ID and a user-specified PIN. This ensures that only patients (or individuals that know the PIN) can discover and retrieve patient information. In a standardized XDS-I domain, like the federated model, the global ID is generated by the PIX manager, but it is mapped to a local medical record number, and thus, it is open to all users.
6. A transient storage infrastructure is implemented that only stores patient exam information for a limited period of time. The assumption is that information transferred to a PHR can be permanently stored by the patient. Standard XDS-I domains, like the federation model, provide permanent access to patient information; they lack a mechanism for deleting data.

The clearinghouse is hosted by lifeIMAGE, in a HIPAA-compliant data center, in the United States. It went into production in 2011, and it has successfully transferred many patient exams over the Internet from large institutions to patient PHRs. It has proven to be extremely reliable, and it has gained acceptance in more than five institutions.

3.3 Pilot Study 3: Collaborative Imaging Diagnosis with Electronic Health-Care Record Integration in Regional Health Care

3.3.1 Background

In medium or large population cities in China, there are multiple administration districts. In each district, the health administration typically manages public hospitals that are small (around 50 beds) or medium-sized (200 to 800 beds). In general, the

large hospitals have higher service quality and more medical expert resources than smaller hospitals. However, small hospital service quality may not be recognized, even though they are equipped with high-quality imaging modalities. With the rapid growth of city populations, balancing health-care supply and demand has become a serious issue. Most patients prefer to go to large hospitals to see doctors when they are sick, despite the high cost. This results in overloading the large hospitals and neglecting the smaller hospitals.

To improve health-care service quality, to balance health-care resources between large and small hospitals, and to reduce costs, each district health administration has begun to build iEHR systems. This undertaking will allow hospitals to share patient medical records and encourage patients to visit small hospitals for initial evaluations and preliminary diagnoses. For example, they can have an imaging examination at the small hospital; then, senior radiologists in large hospitals can make the final imaging diagnosis through a regional health-care information exchange platform, like the iEHR system.

In each district, large hospitals provide collaborative diagnostic services to multiple small hospitals; thus, those hospitals form a collaborative health-care service group. There may be multiple collaborative health-care service groups in one district. Thus, image sharing and collaborative systems must support multiple imaging service groups to provide collaborative imaging services in one health administration domain with one iEHR system.

We designed a method and implementation solution for iEHR systems, based on the IHE XDS-I integration profile, combined with the grid concept.²² This grid-based-XDS-I image sharing system was used to provide collaborative diagnostic service among four hospitals (one large and three small hospitals) in the Zhabei district of Shanghai city. In this paper, we present a study about the extension of data models for XDS/XDS-I transactions to meet the new requirements of regional collaborative imaging diagnosis with multiple service groups. In addition, we integrated the XDS-I-based image sharing system with an existing EHR system to achieve iEHR systems in two districts of Shanghai.

3.3.2 XDS-I-based regional collaborative imaging sharing solution with an existing electronic health-care record system

We designed the new XDS-I-based image sharing and collaborative system to fulfill the following requirements:

1. It should provide the same work flows for each imaging service group as the previous EHR system.
2. Access to patient imaging studies, before their final report delivery, should only be available to hospitals that are peers to the diagnostic service requester and service provider; then later, they can be published to other hospitals in the same district.
3. The same interfacing component (edge appliance) should be used to interface and communicate with hospital PACS/RIS.²²
4. It should be integrated with the district iEHR system.

Figure 6 shows the architecture of this grid-based, XDS-I image sharing system for regional imaging collaborative

Fig. 6 The architecture of the grid-based XDS-I image sharing system for regional imaging collaborative diagnosis, integrated with an existing electronic health-care record (EHR) system. There are two service groups (#1 and #2) in this diagram. The collaborating relationship in service group #1 is that hospitals A and C are the requesting hospitals for imaging diagnosis, and hospital B is the responding hospital to perform the final diagnosis. It is the same in service group #2, in which hospital K is the requesting hospital for imaging diagnosis, and hospital F is the responding hospital to perform the final diagnosis. The radiologists in hospitals B and F perform the final reporting. The image manager is the central storage archive, which provides image archiving functions to all hospitals in one district.

diagnosis. The interfaces between the edge appliance and local PACS/RIS and the operating work flows of this system were presented in a previous publication.²² Here, we extended the data models for XDS/XDS-I transactions to support collaborative diagnoses between peer hospital radiologists of multiple service groups, and we integrated imaging documents into an existing EHR system.

The XDS affinity domains described in XDS/XDS-I.b profiles allow all facilities, hospitals, and service providers equal access to published patient medical records, when there is no specific access control role applied to documents. We extended the data model for the XDS provide and register document set-b

(ITI-41) to support peer-to-peer collaborative imaging diagnoses across multiple service groups (Fig. 7). These data models are related to the submission of preliminary and final reporting datasets during a collaborative diagnosis.

The preliminary submission set for the provide and register document set-b in the collaborative diagnosis model includes an examination folder, document entries of image KOS (DICOM KOS), a preliminary report and order, and a document entry access control. The access control was created based on extensible access control markup language (XACML). It possesses the properties of an access control policy, for a remote subject (hospital/radiologist), who should take action (perform final

Fig. 7 The data models for the cross-enterprise document sharing (XDS) provide and register document set-b. The models are related to submitting the preliminary and final reporting datasets.

Fig. 8 The two new communication services in the interface integration between the grid-based XDS-I image sharing system and the existing EHR system. (a) The image readiness notification allows information to flow from the XDS registry to an existing EHR system. (b) Different mechanisms are shown for a Web-based EHR portal client to access published images from the grid-based XDS-I image sharing system, which is integrated with an existing EHR system.

reporting) on a resource (reference to an image KOS and preliminary report). The access control is referenced when accessing an image KOS and preliminary report.

After the image was downloaded to a remote site or hospital, and a final report was performed by a senior radiologist,²² the final report was submitted to the XDS repository and registry, through the IT-41. Moreover, it was associated with an image KOS, it replaced the preliminary report previously submitted to repository and registry, and it was included in the examination folder of the preliminary submission set.

The final report and related image KOS could be published and integrated into the regional, existing EHR system by changing the access control policy, and sending metadata to the EHR system through the image readiness notification Web service. The metadata included the patient global UID (e.g., Social Security number), the preliminary submission set UID, and the document entry UID of the examination record or imaging document.

Figure 8 shows the interface integration between the grid-based XDS-I image sharing system and the existing EHR system. There are two new communication services in this integration. Figure 8(a) shows the image readiness notification service sending communications from the XDS registry to the existing EHR system. Figure 8(b) shows the Web-based image access service sending communications from an EHR portal client to the grid-based XDS-I image sharing system.

After the image readiness notification is sent to an existing EHR system, an EHR portal client can query the patient record list from the EHR system, select image records from the list, and retrieve the reports or image studies from the grid-based, XDS-I image sharing system.

3.3.3 Imaging sharing implementation for collaborative diagnosis and integration with existing electronic health-care record

We implemented this new XDS-I-based image sharing solution for multiple collaborative imaging diagnostic centers in two districts of Shanghai city; the Zhabei district and Xuhui district.

The Zhabei district has 10 community hospitals that perform preliminary reports on radiological examinations and two central hospitals that perform final diagnostic reports upon request from the 10 community hospitals. The Xuhui district has 18 community hospitals that perform radiological imaging examinations, but all preliminary and final reports are currently performed by one of four central hospitals. The image sharing processes of the two districts are logically the same, but there is a difference in the submission set. The content of the preliminary submission set in Zhabei district is the same as that described in Fig. 7. However, the preliminary submission set in Xuhui district is different, because it only contains the examination folder, the image KOS, the order, and the access control document; it does not contain the preliminary report.

Figure 9 shows the monthly statistical chart of numbers of imaging studies generated in 18 community hospitals of Xuhui district and the number of studies sent to a remote central hospital for both preliminary and final reporting through the iEHR system from January to December in 2014. From Fig. 9, we see that almost 90% (84% to 100%) of studies had been sent to remote senior radiologists for final reporting through the iEHR system except for March (64%), when there were 2163 studies done for screening purposes and did not need final reporting according to the agreement between community hospitals and central hospitals in Xuehui district.

We designed XDS-I-based image sharing systems in both Zhabei and Xuhui districts for integration with an existing EHR system, which were built by a third party. Now, both the new XDS-I-based image sharing system for multiple collaborative imaging diagnosis and the integration with the existing EHR system have been in clinical operation for more than two years.

4 Results

In this paper, we presented three pilot studies of image sharing for cross-enterprise health care that were based on the IHE XDS-I profile. In order to support these pilot studies, we developed new image access methods: RAD-69/WADO hybrid image retrieval, new components of the RSNA clearinghouse,

Fig. 9 Monthly statistical chart of numbers of imaging studies generated in 18 community hospitals in Xuhui district and the number of studies sent to a remote central hospital for both preliminary and final reporting through the iEHR system from January to December in 2014.

and a data model that extends the metadata definitions in both the submission set and the XDS registry.

4.1 Pilot Study 1: Image Sharing for Cross-Enterprise Health Care with Federated Integration

We chose Huadong Hospital and Shanghai Sixth People's Hospital for testing of image sharing for cross-enterprise health care with federated integration within the Shen-Kang Hospital Management Center to evaluate the design concept and implementation of an iEHR system based on IHE XDS-I.b profile. In order to securely retrieve image studies stored in the local PACS from outside the hospital, the IHE RAD-69 and DICOM WADO hybrid retrieval method was developed in the edge appliance to support near-line sharing model.

We designed and developed major components and system architecture of image sharing with federated integration, and tested image transmission performance of two sharing models, online sharing model and near-line sharing model, for exchanging data between the local PACS/RIS and the XDS-I image sharing infrastructure. The performance comparison showed that the online sharing model had a faster image retrieval rate than the near-line sharing model for different kinds of images due to the protocol of WADO being used in near-line sharing. However, the retrieval time difference between the online and near-line models was only less than one second for most types of image data.

4.2 Pilot Study 2: XDS-I-Based Patient-Controlled Image Sharing Solution

We investigated a patient-centered image sharing solution (RSNA ISN), which was implemented by an RSNA team.¹⁶⁻¹⁸ The RSNA ISN was designed based on the IHE XDS-I.b profile, and leveraged a cloud-based clearinghouse developed through collaboration with LifeIMAGE Inc. From analyzing work and data flows, system components and architecture, as well as the transactions used for RSNA ISN, we identified a number of key features that differentiate RSNA ISN from standard XDS-I solutions, like the one used in the federated integration model described earlier. This solution gives the patient control

over how imaging exams are shared. It leverages a cloud-based "clearinghouse" to transfer imaging exams from hospitals/clinics to PHR systems.

4.3 Pilot Study 3: Collaborative Imaging Diagnosis with Electronic Health-Care Record Integration in Regional Health Care

We designed a method and implementation solution to support multiple imaging service groups to provide collaborative imaging services in one health administration domain with one iEHR system.

In this study, we extended the data model for the XDS provide and register document set-b (ITI-41) with an access control on the shared image objects and reports based on XACML to support peer-to-peer collaborative imaging diagnoses across multiple service groups. These data models are related to the submission of preliminary and final reporting datasets during a collaborative diagnosis. We defined two interfaces to integrate the grid-based XDS-I image sharing system with the existing EHR system. These two services guarantee seamless communications between an EHR server, EHR portal clients and the grid-based XDS-I image sharing system. We implemented this new XDS-I-based image sharing solution for multiple collaborative imaging diagnostic centers in two districts of Shanghai city, the Zhabei district and Xuhui district, and integrated with an existing EHR systems, which were built by a third party. Both the new XDS-I-based image sharing system for multiple collaborative imaging diagnosis and the integration with the existing EHR system have been in clinical operation for more than two years. According to the statistical study in Xuhui district in 2014, almost 90% (84% to 100%) of imaging studies scanned in community hospitals have been sent to remote senior radiologists for final reporting through the new XDS-I-based image sharing system.

5 Discussion

We presented and investigated methods and results of how to customize the architecture model of IHE XDS-I-based image sharing into practical solutions through three scenarios of image sharing applications. We identified several issues that must be addressed when implementing these sharing solutions,

including security issues, issues in image sharing across communities, and issues in using XDS-I for regional image sharing.

5.1 Comparisons of Three Pilot Studies

We evaluated three pilot studies of image sharing for cross-enterprise health care that were based on the IHE XDS-I profile. There were some differences in these three applications in implementation of IHE XDS-I proposed image sharing architecture model. Therefore, we created a table (Table 3) to compare these three pilot studies from the point of view of data flow, PACS interface, and implementation of IHE XDS-I.b actors and transactions. From Table 3, we can see that in pilot study 1, the image upload data flow was automatically set to send the manifest of image studies to the repository and register in registry, and image query and retrieval was controlled based on user on-demand mode. All of the transactions of pilot study 1 were implemented using standard ITI transactions. The major differences of pilot study 1 to pilot study 2 and 3 were interfaces with the PACS and the image sharing models between PACS and edge appliance. There were two sharing models, online sharing and near-line sharing in pilot study 1.

In pilot study 2, the data flows of image upload and query/retrieval were controlled by patients. The ITI-41 transaction was customized to transfer both manifest and DICOM image data from the local edge server to the clearinghouse. All of the other transactions were standard implementations. The interface service of the local PACS to edge server was DICOM C-Store.

In pilot study 3, the data flows of image upload and query/retrieval were driven by collaboration work flows between local and remote hospitals. The metadata model of the registry and ITI-41/18 transactions were customized to support collaboration requirements. All other transactions used standard ITI transactions. The interfacing services of local PACS to edge server was

DICOM C-Move and C-Store which were triggered by collaboration events.

5.2 Security Issues

Security issues typically involve privacy, authentication, data integrity, traceability, verifiability, reliability, and so on. In health-care information exchange, the most important security issue is to protect PHI during image data sharing. Protection is generally implemented with SSL-based secure communication and data encryption for data transmission and management, when public networks are used for data exchanges.

The XDS-I.b profile adopted a Web service-based data transmission protocol, like MTOM/XOP, for ITI/RAD-transactions.^{11,12} These protocols facilitate the use of SSL-based secure communication channels for transactions between the participating actors defined in the XDS-I.b profile. The RSNA team and LifeIMAGE implemented SSL-based transactions for ITI-9/ITI-18/41/43/RAD-69 in the XDS-I-based clearinghouse for patient-controlled image sharing. The SSL authentication is bidirectional between the clearinghouse, edge servers, and PHR.

Also, for security reasons, hospital PACS/RIS are typically not allowed to be accessed directly by outside applications, like the iEHR client. Therefore, to integrate the local PACS/RIS and XDS-I infrastructures with security features, the edge appliances were located in a DMZ, where they function as imaging document source actors (Figs. 2 and 3).

5.3 Performance and Storage

In the federation solution of XDS-I-based image sharing, the online sharing model achieved faster image data retrieval and had more secure features than the near-line sharing model. However, these features were possible because the image data were duplicated and stored in the edge appliance. This

Table 3 Comparisons of three pilot studies in work flows, PACS interfacing, implementation of IHE XDS-I actors and transactions (S = standard implementation, C = customized implementation).

Work flows, interfaces, IHE XDS-I actors and transactions		Pilot study 1	Pilot study 2	Pilot study 3
Image upload		Automatic	Patient-control	Work flow-driven
Image query/retrieval		On-demand	Patient-control	Work flow-driven
PACS interfacing Services		DICOM C-Store/WADO	DICOM C-Store	DICOM C-Move/C-Store
XDS.b registry	MetaData Model	S	S	C
	ITI-18 Trans.	S	S	C
XDS.b repository	ITI-41	S	C	C
	ITI-42	S	S	S
	ITI-43	S	S	S
Imaging doc. source	ITI-41	S	C	C
	RAD-69	S	S	S
Imaging doc. consumer	ITI-43	S	S	S
	RAD-69	S	S	S

duplication represents an issue for long-term archiving and sharing across multiple health-care enterprises in a big city, like Shanghai. In contrast, the near-line sharing model does not require extra storage, but performance may be reduced compared to the online sharing model. Also, the security of the near-line sharing model may be weaker than that of the online sharing model, because the local PACS must be accessed by the edge appliance. Thus, an internal firewall must be set up to support bidirectional communications between the local PACS network and the DMZ network.

5.4 Extension of XDS-I Profile–Based Image Sharing

In large population cities or districts, there are multiple health-care groups with close imaging collaborations between individuals in each group, and these health-care groups are managed by a single administration. Therefore, to implement regional image sharing, the work flow or data flow should be compatible with the existing health-care infrastructure. Unfortunately, the XDS-I profile does not provide a work flow management description or scenario; thus, it is difficult to apply the XDS-I profile directly in designing an image sharing system for a specific set of source actors and consumer actors.

This study presented a new approach that extended the XDS-I profile to support different image sharing scenarios. For example, we extended the metadata model of the XDS-I profile, and combined this extension with a grid-based implementation of XDS-I²² to support collaborative image diagnosis work flows between peer hospital radiologists in multiple service groups. We also integrated the imaging document metadata into an existing EHR system. The primary advantage of this new design was that the regional image sharing infrastructure was consistent with the XDS-I profile. Thus, most transactions could use the IHE ITI standard transactions, but some privately defined metadata and slots were included in the XDS registry and submission set.

In the context of the RSNA ISN, we investigated several specific designs in both the metadata and the ITI transactions based on the XDS-I image sharing solution. These designs ensured that the solution met both the requirements of patient-controlled sharing and the requirements of HIPAA compliance in the Internet operating environment.

Our results demonstrated that XDS-I–based image sharing designs and implementations were successful in three scenarios of image sharing applications. Thus, we showed that the XDS-I profile was flexible, and that it could be extended to suit a variety of image sharing applications for regional health care.

6 Conclusions

In this paper, we present two new methods (pilot study 1 and 3) for how to customize the architecture model of IHE XDS-I–based image sharing into practical solutions and a new RSNA clearinghouse (pilot 2) to support XDS-I cloud-based imaging sharing. In order to securely retrieve image studies stored in local PACS from outside a hospital, IHE RAD-69 and DICOM WADO hybrid retrieval methods were developed in the edge appliance, as part of pilot study 1, to support near-line sharing model. In pilot study 3, we extended the data model for the XDS provide and register document set-b (ITI-41) with access control on the shared image objects and reports, based on XACML, to support peer-to-peer collaborative

imaging diagnoses across multiple service groups. With this new XDS-I–based image sharing system, almost 90% (84% to 100%) of imaging studies scanned in community hospitals in one district of Shanghai have been collaboratively diagnosed by remote senior radiologists.

From the presented testing and evaluation results, we can conclude that the IHE XDS-I profile is a theoretically good architecture and useful foundation for medical image sharing solutions across different regional health-care services. In order to use this profile and architecture efficiently, some customization work needs to be done during the system design and implementation. In the presented solutions, special considerations were identified to achieve success. These considerations included several key issues, which impacted the performance and security strategy of implementation, localized metadata definitions in both the submission set and the XDS registry, and extensions of the standard ITI transactions.

Acknowledgments

The project is supported by the grant from the Chinese Academy of Sciences (Project No.: KGZD-EW-T03). Thanks for the IT departments of Shen-Kang Hospital Management Center, Huadong Hospital and Shanghai Sixth People Hospital for their supporting on pilot testing, as well as LifeIMAGE's collaboration related to RSNA Clearinghouse.

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