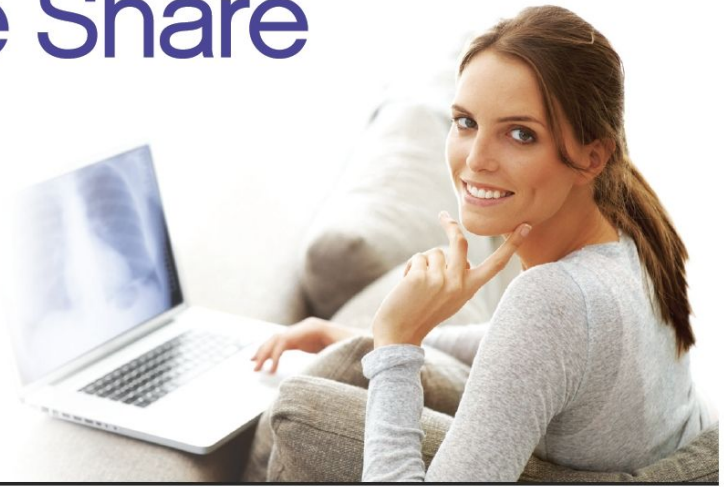


RSNA® Image Share

Letting patients
take control of their
medical images



Executive Overview

Version 4.0

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1. Introduction: RSNA Image Share Network

The RSNA Image Share Network (ISN) is a pilot project involving radiology sites and patients across the US, made possible by funding from the National Institute of Biomedical Imaging and Bioengineering. The goal of the project is to enable sharing of medical images under patient control.

The ISN relies on two key components:

1. A server called the **Edge Server**, which is installed at each participating site. It collects images and reports from the site's PACS and RIS and enables site personnel to send them to the network.
2. The **Image Clearinghouse**, which receives images and studies submitted from all sites in the network and enables other sites--medical centers, research centers, or the patient's Personal Health Record (PHR)--to retrieve them.

The ISN addresses three primary use cases:

1. **Patient-centric Image Transfer:** A patient ask site staff to make her imaging studies available. Staff submit her studies (images and reports) to the Image Clearinghouse. She later downloads her imaging studies from the Image Clearinghouse into a Personal Health Record (PHR) she has established on a system from an authorized imaging PHR system on the network, such as DICOM Grid's ImageShare, itMD or lifeIMAGE's LINCS.
2. **Clinical Site-to-Site Transfer:** A clinician sends a patient's imaging studies to another care center linked to the ISN. This site-to-site transfer can be used for a variety of clinical cases, including trauma cases.
3. **Research Site-to-Site Transfer:** A researcher sends anonymized imaging studies from a source site to a core lab in a multi-site research program.

A simplified view of the ISN is shown in Figure 1-1 below. Each site that produces DICOM images for clinical or research use uploads images to the Image Clearinghouse, which is provided by a commercial vendor, lifeIMAGE.

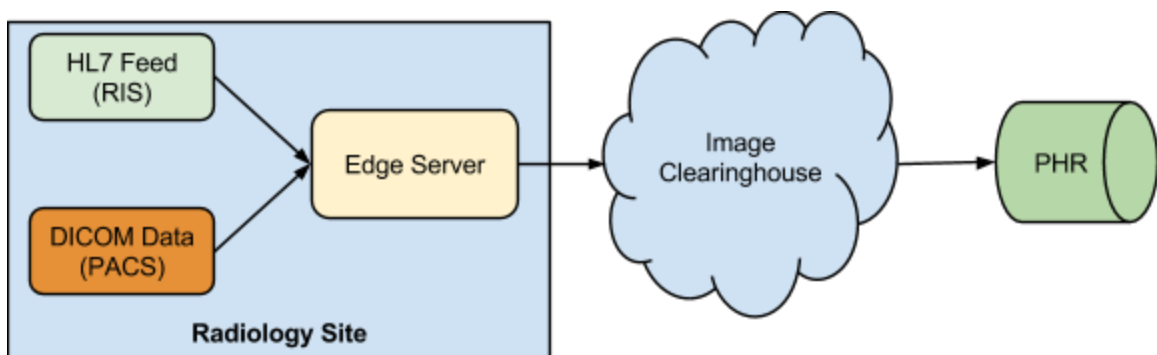


Figure 1-1: RSNA Image Share Network architecture for the patient-centric use case

To obtain the images that have been submitted to the Image Clearinghouse, a site (DICOM Image Destination) or PHR queries the Image Clearinghouse using the security information (patient DOB and a system generated, study-specific twenty character Access Code) sent with the submission and retrieves the matching studies. This centralized design allows sending and receiving sites to configure a single connection to the network rather than maintaining a number of different point-to-point connections.

The Image Clearinghouse is designed as a temporary storage area for images. Image studies are retained for thirty days and then deleted. (They remain available, of course, at their source site.) This provides sufficient time for patients to load images into their own PHRs and for clinical and research sites to transfer images.

Communication between sending and receiving sites and the Image Clearinghouse is based on the IHE XDS-I.b profile. The Edge Server is designed to provide an interface to RIS and PACS, transmitting image studies and reports to the Image Clearinghouse.

Benefits of Connecting to the Image Share Network

Installing an Edge Server and connecting to the ISN enables a site to:

- Offer patients the ability to get copies of their image studies electronically by retrieving them into PHR accounts
- Send clinical studies to, and receive them from, partner institutions through the Image Share Network
- Send de-identified research studies to, and receive them from, partner institutions through the Image Share Network

The Edge Server requires a connection to a feed for HL7 order and report messages (typically a site's RIS). Sites without a RIS, or which may not be able to access HL7 messages are not able to use the Edge Server effectively. Sites whose only image communication need is sending or receiving research images may find other tools (such as the RSNA Clinical Trials Processor [CTP] software available [here](#)) simpler to use for this purpose.

Further detail on the use cases addressed by the ISN, as well as security and other operational considerations, is provided below. Important information on installing and using the Edge Server and participating in the ISN is provided in two additional publications that should be read by site technical administrators and staff who will use these systems:

- [RSNA Image Share Network Edge Server Installation, Upgrade and Administration Manual v 4.0](#)
- [RSNA Image Share Quick Start User Guide v 4.0](#)

2. Use Case Details

2.1 Patient-Controlled Image Transfer

Figure 2-1 illustrates the workflow in the patient-controlled use case.

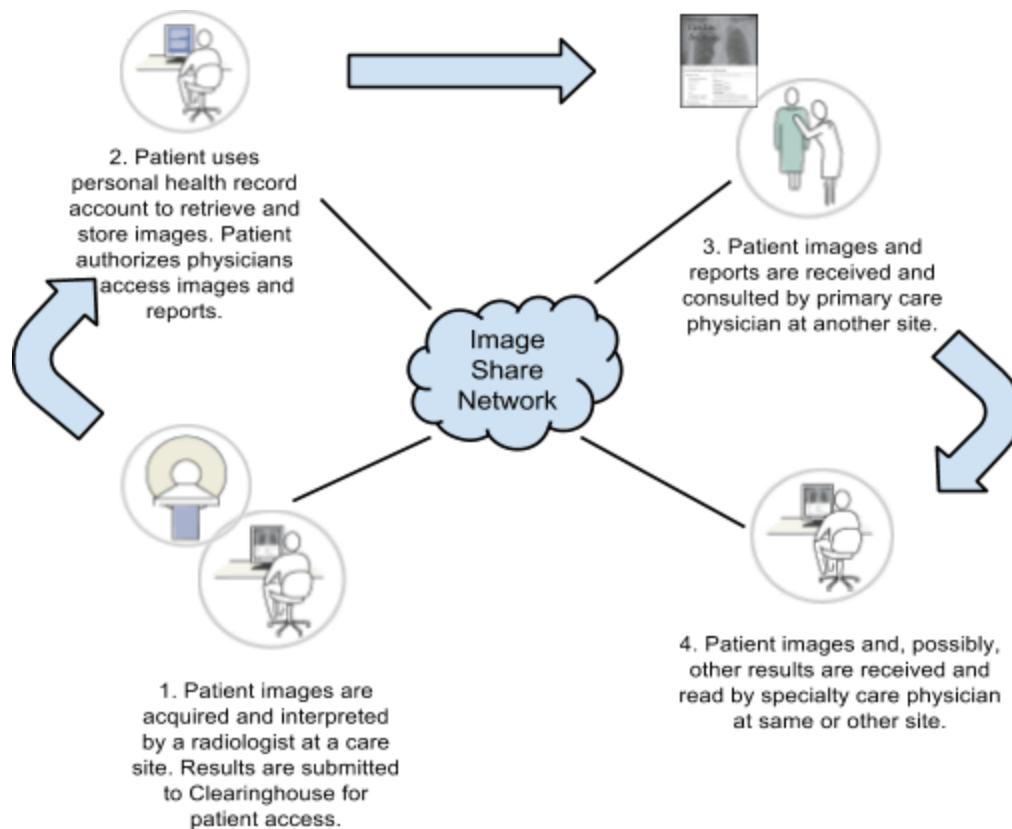


Figure 2-1: Image Sharing Workflow: Patient-Controlled Use Case

1. A patient undergoes an imaging procedure at a clinical site, and a radiologist associated with the facility interprets the images and generates a report. Site personnel use the Edge Server to submit the patient's images and report to the Image Clearinghouse. The images and report are protected by encryption in transmission and storage. They can only be retrieved through an authorized PHR system using an access code that is controlled by the patient.
2. The patient logs into a PHR that is authorized to use the Image Share Network. The patient uses the access code to retrieve the images and report from the Image Clearinghouse into his or her PHR account. The patient's information is now safely stored in the PHR under their control, and they can grant access to physicians and others as they find appropriate.
3. A primary physician with access to the patient's PHR can retrieve both the images and report. If the PHR software does not support direct physician retrieval, the patient can login at the physician office and give access to the physician.
4. Finally, the patient images, radiology report and possibly other test results store in the PHR can be reviewed by other clinicians or specialists.

In this model, a site establishes a business relationship and network connection with the Image Clearinghouse. All data are shared through that one relationship, eliminating the need to develop multiple point-to-point connections.

2.1.1 Patient Enrollment Process

The Image Share network is designed to supplement or replace existing processes for providing images to patients on removable media (CD, DVD). Patient enrollment involves some direct interaction with the patient

and use of the browser-based Edge Server application. Dedicated staff, typically those currently responsible for burning CDs (such as “film or digital library” staff), and dedicated hardware, typically a desktop PC with a Web browser and network access to the Edge Server device.

The process steps in the enrollment process are outlined in Figure 2-2. The primary staff activities specifically related to initiating sharing of images with the patient are step number 4,5 and 6. Note that step number 6, in which staff create the patient’s submission set, can be initiated at any time after the imaging procedure is scheduled.

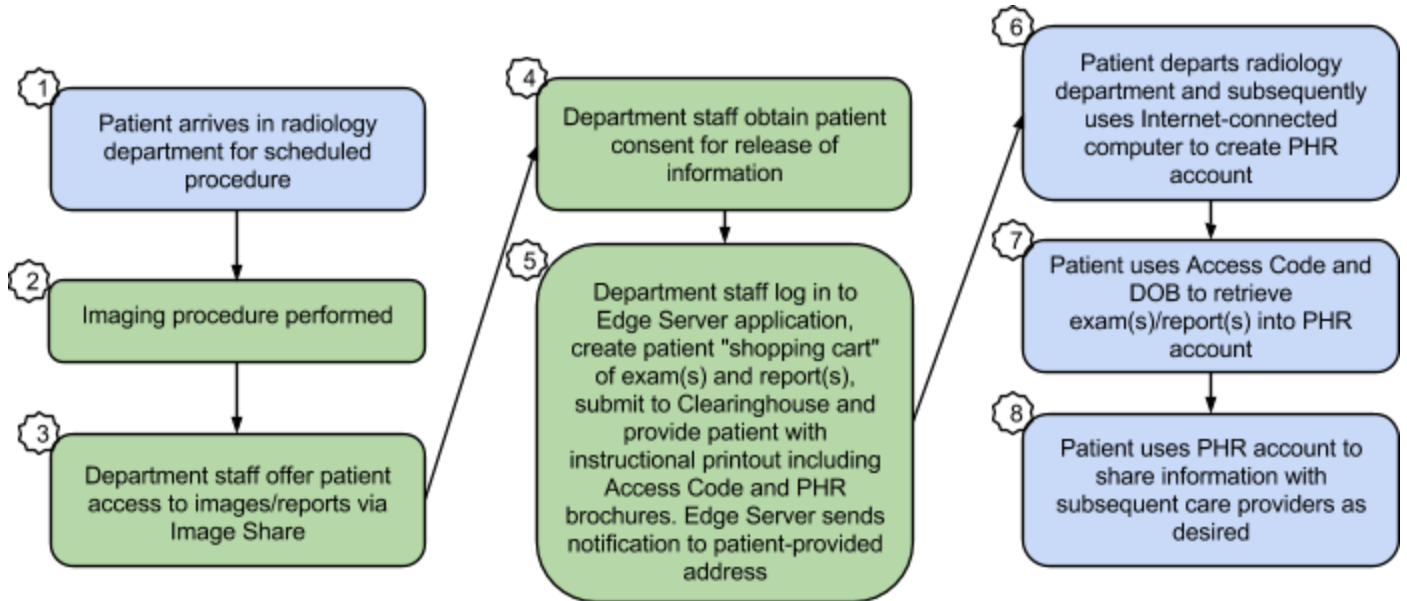


Figure 2-2: Patient Enrollment Process Steps: Patient-Controlled Use Case

2.2 Site-to-Site Transfer for Clinical Care

In this use case, two sites have decided in advance to share data for clinical reasons. A common situation would be a trauma case that requires remote consultation. For sites that have a number of partners and specialists distributed among dispersed sites, the Image Share Network simplifies the configuration and transmission of images as follows:

1. A patient is seen at clinical site A and has one or more imaging studies.
2. Physicians at site A decide they need a radiologist at site B to interpret the images. A staff member at site A transmits the imaging study to the Image Clearinghouse without waiting for a report to be generated.
3. A radiologist at site B queries the Image Clearinghouse for the imaging study for the patient. The radiologist retrieves the images, imports them into the local PACS, reads the images and consults with the physicians at site A.
4. Images remain fully identified to support clinical care.

2.3 Site-to-Site Transfer for Research

In imaging based clinical trials, imaging centers submit de-identified images to an imaging core where data analysis, image interpretation and/or reader studies occur. Different imaging cores use different

de-identification software and transmission mechanisms, requiring imaging centers to maintain multiple applications. The Image Sharing Network provides a single solution for imaging sites and allows sites to share de-identified images with multiple imaging cores.

1. A research participant is seen at an imaging center and has one or more imaging studies.
2. A staff member at the imaging center initiates a data transfer to the Image Clearinghouse that de-identifies the image data and associate the data with the proper clinical trial.
3. An automated process at the imaging core polls the Image Clearinghouses and retrieves imaging data intended for that imaging core.

3. Security and Legal Considerations

In the research use case described above, protected health information (PHI) is anonymized before images are sent beyond the site's firewall. To understand how PHI is protected in the remaining two use cases, it is useful to examine the security design of the ISN system as a whole and the Edge Server's interfaces in greater detail.

3.1 Detailed View of ISN Interfaces

Figure 3-1 below shows the general model of the Edge Server (in sending modes) in relationship to your existing systems and the Image Clearinghouse that will receive, store and ultimately distribute images for patient requested transfers, clinical transfers between sites and research transfers between sites. The RIS shown in the figure is needed to provide exam orders and reports for PHI containing sends. Non-PHI studies (i.e. anonymized research sends) do not require the HL7 feed and can be addressed by direct pushes from the PACS to a special module of the Edge server.

As shown in the figure, images intended for patient transfer or clinical use are sent to the Image Clearinghouse with protected health information (PHI) intact. Images that are intended for research use are de-identified by the Edge Server before transmission to the Image Clearinghouse. Unshaded actors lie within the medical center's firewall. The Image Clearinghouse (shaded) lies in the Internet. Interfaces (HL7 and DICOM) among unshaded actors are unencrypted. Interfaces between shaded and unshaded actors (i.e. that enter/leave the open internet) are over HTTPS encrypted interfaces.

To protect PHI, the system creates an SHA 256-bit hash, single-use identifier (which is never seen by the patient or other system users) called the RSNA-ID. The RSNA-ID is computed as a hash of two values:

- A unique twenty-character string called the Access Code, which is generated by the Edge Server software for the submission set
- Patient date of birth

This hashed value cannot be reverse engineered or decrypted into its components. Each submission set to the Image Clearinghouse is secured by a different, single-use Access Code.

The Image Clearinghouse maintains each patient's images for 30 days, indexed by the RSNA-ID. For the patient sharing use case (images to be downloaded to a PHR), the patient provides the two values (Access Code and Date of Birth) to the PHR. The PHR computes the RSNA-ID using the same hash algorithm as the Edge Server and presents the resulting RSNA-ID to the Image Clearinghouse. If the Image Clearinghouse finds that the RSNA-ID from the PHR matches the value it has stored, it will allow the PHR to download the

image set.

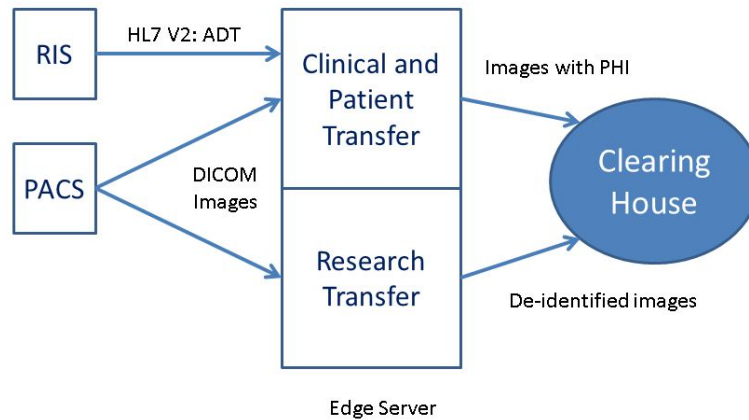


Figure 3-1: Edge Server Model.

In the diagram above, the arrows on the left are inside the site's firewall. The arrows to the Image Clearinghouse that pierce the site firewall, are created and destroyed per session (during each sending job) and are encrypted. The ClearingHouse and Edge Server authenticate each other with previously exchanged cryptographic certificates. The transactions used are: IHE ITI8pix (over port 8888), ITI8reg (over port 8890) and IHE ITI41 (over https port 443).

There are three different transfer scenarios permitted: the patient-centric, site-to-site transfer and research transfer use cases. The sending configurations for the Clinical and Patient transfers are identical.

1. Clinical / Patient transfers require an HL7 feed from your RIS (to provide exam orders and reports) and a DICOM feed from your PACS (to provide the actual images). **NOTE:** the RSNA Edge Server does not store images. It requests the image(s) from the PACS based on the request and sends them to the Clearinghouse.
2. Research transfers use only a DICOM feed from your PACS.
3. The studies on PACS are *pulled* by the Edge server based on the exams selected by the Edge server operator.

As mentioned above, the sending configuration for de-identified studies is different. The studies are *pushed* from the PACS to a separate module on the Edge server called CTP.

The receiving side of all the use cases follows the pattern shown in Figure 3-2. There are two possible receivers: the patient's PHR that fetches PHI studies from the Image Clearinghouse, and/or an Edge Server that fetches either PHI or anonymized studies from the Image Clearinghouse. In the case of the Edge Server fetch, the data transferred from the Image Clearinghouse depend on the RSNA-ID used. If the Edge Server polls for a study based on a single-use RSNA-ID, those studies contain PHI. If polling on a multi-use RSNA-ID, the pulled studies are anonymized imaging studies and do not retain PHI. That decision of which

type of RSNA-ID was used was made by the sending site when the images were sent to the Image Clearinghouse.

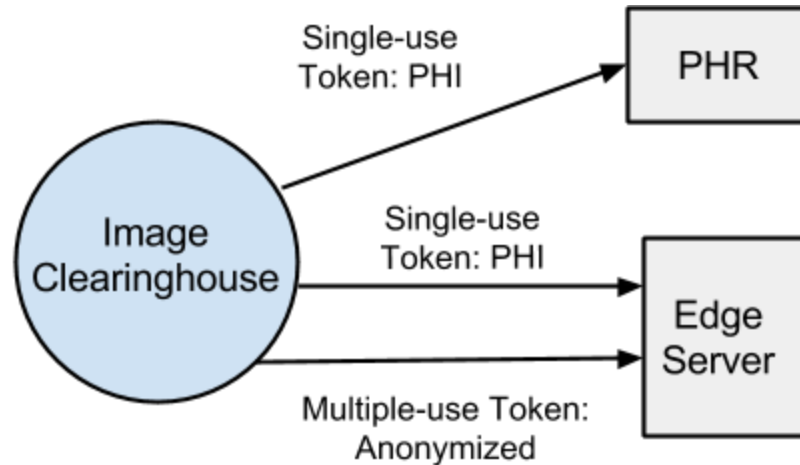


Figure 3-2: Data flow to the Receivers for the Patient, Clinical or Research Use Cases

3.2 Interface Specific Details

RIS to Edge Server (HL7):

Exams orders and results are sent asynchronously and unencrypted over the medical center's internal network to the Edge Server. These data are the basis for building the patient list and study list (for a given patient) within the Edge Server user interface

PACS to Edge Server (DICOM):

Patient-centric and site-to-site clinical use cases (containing PHI) are initiated as a pull from the PACS by the Edge. De-identified (research studies) are pushed to the Edge server from the PACS. Both transactions are via unencrypted DICOM services.

Edge Server Sends Submission Set to the Image Clearinghouse (HTTPS):

When a job is submitted on the Edge server, the relevant DICOM studies and reports are collected into a "submission set" that is encrypted with the RSNA-ID. The submission set is then sent over an encrypted Web interface, through the medical center's firewall, to the Image Clearinghouse. The Image Clearinghouse and Edge server also authenticate each other via private certificates that they exchanged (this assures that an imposter cannot masquerade as an Edge server to the Image Clearinghouse, or as an Image Clearinghouse to the medical center's Edge server).

3.3 Legal Issues

As stated above, the Image Clearinghouse allows communications only from authorized sites to authorized PHR systems. Likewise, the Edge Server will only send submission sets to a pre-configured destination. A principal security feature of the ISN architecture is that all agents that communicate with the Image

Clearinghouse have exchanged encrypted certificates with the hosting vendor. That is to say, a representative of the medical center, and one from the Image Clearinghouse meet and exchange cryptographic certificates from their respective sites. This in effect says when the Edge server and the Image Clearinghouse make a network association, "You, Image Clearinghouse, can trust that it is really me ABC Hospital, because I know the secret handshake." And vice versa.

Before security certificates are exchanged, a Business Associate Agreement (BAA) is contracted between the medical center and the Clearinghouse vendor. In the process of contracting the BAA, both sides agree to the safeguards that will be implemented, policies, liability sharing and other issues that may arise. This process is exactly analogous to the BAA process one would engage in when contracting a vendor for supporting the site's Electronic Medical Record (for example), or forming a Health Information Exchange (HIE) with other medical centers.

For further information contact RSNA staff at imageshare@rsna.org.