GE Healthcare

# How does your image management approach stack up?

## Multi-layered neutrality: A new standards-based framework for unifying medical images and clinical documents across the enterprise

*Priyank Sharma, Senior Marketing Manager – Global Solutions*
*Lawrence White, Senior Marketing Manager – Radiology*

**SYNOPSIS:**
As the diagnostic capabilities and availability of medical imaging continue to advance, healthcare IT executives are faced with the increasingly daunting task of managing the vast amounts of data created by the modalities and devices in their facilities across the network. And the challenges will continue to mount as care providers ask for more comprehensive patient information, not just imaging but multi-ology data such as dermatology, hematology, pathology, and ophthalmology at the point of care. Each of these -ologies introduces its own set of storage and management requirements and frequently incorporates different technology vendors, formats, and standards. Today, this siloed information runs counter to the general expectations of "integrated anywhere, anytime" data access.

There is a growing urgency to create a patient-centric record by integrating, managing, and sharing imaging and other departmental data for the care providers to make more informed decisions at lower cost. There are offerings available from storage vendors, niche migration companies, PACS providers, and full-service healthcare IT companies to solve this challenge, but given the wide range of technology options available, it is important for healthcare IT executives to pick the right technology and approach for a long-term sustainable solution delivering the desired performance and ROI.

This paper proposes that a key aspect of long-term sustenance of such multi-vendor, multi-department-ready solutions is "industry standards compliance," which in some cases is also referred to as "vendor neutrality." While the industry has started to discuss and adopt vendor-neutral archives/repositories to migrate from multiple proprietary departmental repositories, it is important to look at "vendor neutrality" more holistically. The solution required is much more than just an archive/repository, and this paper evaluates a multi-layered approach including storage infrastructure, middle-ware, transport, and the presentation layer. It proposes that neutrality at each layer is critical to optimize performance and ensure sustainability of the overall solution.

## BRINGING MEANING TO DISPARATE CLINICAL DATA

Today, volumes of mission-critical patient data live in departmental silos that are expensive to manage. This complexity makes it difficult to provide access to the right images and documents at the right time throughout different stages of patient care. Migrating from multiple proprietary departmental repositories to a Vendor-Neutral Archive (VNA) is essential for optimal sharing of information and workflow across the healthcare system.

As the diagnostic capabilities and availability of medical imaging continue to advance, healthcare IT executives are faced with the increasingly daunting task of managing the vast amounts of data created by the modalities in their facilities at lower cost. And the challenges will continue to mount. Consider just a few trends:

- **Increased demand for storage capacity** – The Advisory Board, in one of their webinars[1], noted that new data volume is expected to grow at a CAGR of 42% from 2010-2015. In addition to the rising volume, long-term retention requirements are a significant factor influencing storage capacity concerns. KLAS noted in their recent enterprise imaging study[2] that 59% of respondents plan to keep their images forever.
- **Increasing complexities of data management** – In the same webinar[1], the Advisory Board also informed that in their survey of hospitals with over 100 beds, over 84% of respondents have PACS implemented in multiple locations, and newer specialties like ophthalmology, orthopedics, pathology, neurology, oncology, and dermatology are implementing departmental archives and image management solutions increasing the complexity of data management in the enterprise.
- **Increased use of imaging** – A study[3] that examined the health records of millions of patients in several western and Midwestern states of the USA showed a dramatic increase in the use of medical imaging from 1996 to 2010. During that time period, the number of ultrasound examinations doubled, the number of CT exams tripled, and the number of MRI studies quadrupled.[3] With the shift to a fee-for-performance model, imaging growth is expected to slow or show decline.
- **Declining imaging reimbursement** – A new analysis of Medicare data,[4] released by the Medical Imaging & Technology Alliance (MITA) in September 2012, confirms that the spending on imaging services for each Medicare beneficiary has dropped 16.7 percent since 2006—the last year before the implementation of significant imaging-specific reimbursement cuts from the Deficit Reduction Act.

The growth in imaging volume comes not only from the expected areas of care, such as radiology and cardiology, but also from disciplines that are beginning to integrate digital imaging into their care protocols, such as dermatology, hematology, pathology, and ophthalmology. Each of these –ologies introduces its own set of storage and management requirements and frequently incorporates different technology vendors, formats, and standards.

The result is often a series of independent "silos" of information, each operating autonomously, and each requiring its own support and maintenance. In some cases, the images from non-traditional care areas may reside on cameras, laptops, or USB drives and thus not even be included in a managed solution. Data silos increase the complexity and cost of managing storage, complicate disaster recovery planning, and present significant security concerns with regard to HIPAA compliance.

More problematic, however, is that the data is not accessible to attending and referring physicians throughout—and beyond—the facility. Without a comprehensive view of a patient, vital connections may be missed at key decision points and meaningful collaboration among physicians is hindered. This lack of availability also runs counter to the general expectations society has developed in this digital information age of "anywhere, anytime" data access.

Ideally, physicians should have seamless access to information across all the disparate silos, presented in a format best suited to meet the needs of their specialty in a single viewing application integrated with the EMR.

In addition, facilities are mindful that future reimbursement levels and care quality may be positively impacted by sharing patient and population data across the care continuum, both within their organization and with other organizations. This may precipitate the desire to form or become part of an integrated delivery organization or image exchange, adding another layer of requirements and standards to their storage management protocols.[5]

## THE SEARCH FOR A TRULY UNIFIED SOLUTION

There is a growing urgency to manage clinical images and other documents at the enterprise level and make meaningful connections between the disparate data sources and the physicians who require access to them. This has led many HCIT executives to search for solutions that offer a unified approach combining both flexibility and a high degree of control for the internal IT team. But the solution landscape in this area is still evolving, and the sheer variety of options available can make progress toward the goal of unified patient data difficult.

Adopting a phased approach that connects the EMR with an enterprise imaging solution today with an eye towards an integrated care infrastructure across communities or regions for the future can provide a competitive advantage through increased information availability and potentially avoid having to reimplement a solution down the road.

Given the range of offerings available from storage vendors, niche migration companies, PACS providers, and full-service healthcare IT companies, it can be challenging to find the appropriate integrated solution for a facility's image management needs.

Some enterprise software vendors suggest avoiding best-of-breed solutions for each area of care to maximize economies of scale and consolidation. However, adopting a one-size-fits-all approach often concerns department heads who fear that the specialized needs of their departments won't be met; they are justifiably concerned about sacrificing quality of care and productivity for the sake of enterprise connectivity.

Choosing the right solution requires evaluating a number of factors, including the facility's current infrastructure, plans for growth in imaging volume, anticipated new sources of imaging, the unique needs of individual departments, and requirements for providing physicians with seamless access.

Organizational events also affect the timing and direction of the decision around enterprise image management. For example:

- **Replacing a PACS** — Given the complexities involved in a PACS data migration, finding a long-term solution for image management can eliminate or mitigate future migrations.
- **Joining an integrated care community** — The need to meet new standards for the exchange of images may make it an opportune time to re-evaluate image storage and management.

- **Accommodating new sources of images** — When a new department plans to integrate clinical imaging, it is advisable to consider an enterprise approach to image management rather than create another silo.
- **Impending mergers, acquisitions, and associations** — As provider networks continue to consolidate, the need for enterprise connectivity is becoming increasingly important.
- **Storage convergence** — To lower storage TCO, the organization may consider consolidating legacy storage fabric from multiple vendors or multiple fabrics to a single vendor or single fabric.
- **Centralized management** — Organizations with multiple facilities may achieve lower TCO by transitioning from a heterogeneous, decentralized model to centralized image management, leveraging key subject matter experts and freeing "spoke" resources to focus on innovation or competitive differentiation.

## A NEW FRAMEWORK TO EVALUATE ENTERPRISE-WIDE DATA MANAGEMENT OPTIONS

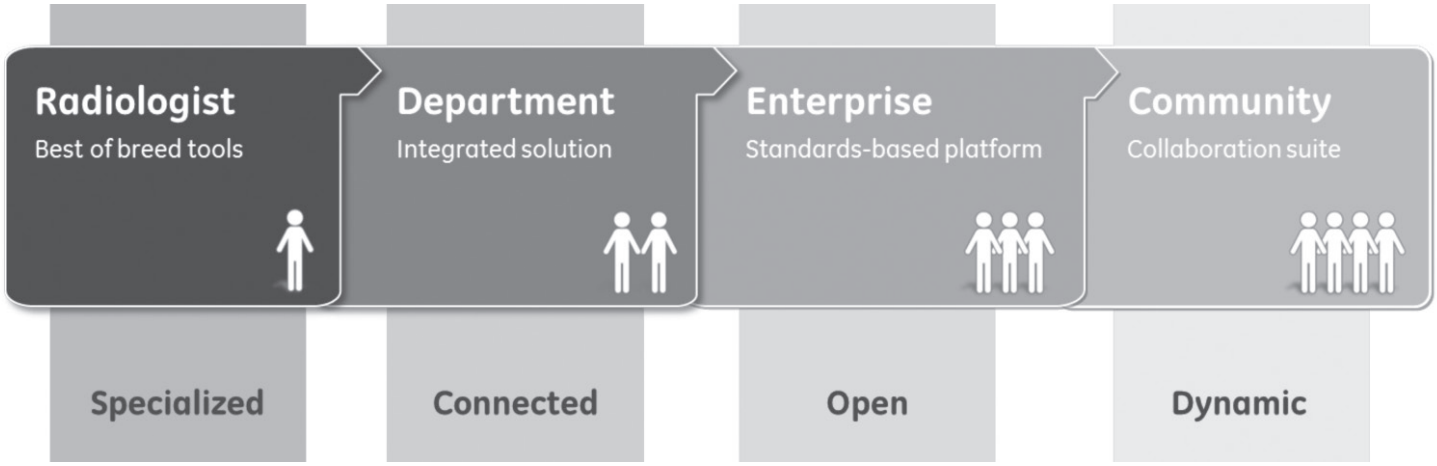
Over the past several years, imaging IT has experienced a transformational shift as the focus of technology development has moved from the user (study quality, reading efficiency) to the department (patient workflow, referring physician communications). The focus continues to broaden as IT vendors develop tools to address image management needs across the enterprise (multi-ology imaging, archiving capacity and strategy, image access at the point of care, and workload sharing, to name a few) and throughout the community (multi-disciplinary care teams, ACOs, integrated care organizations).

What image management components and services should your facility have in place to address this shift? Which image management approach will give you the robust capabilities to meet enterprise needs today and the flexibility to enable community-wide image sharing in the future? Given the wide range of technology options available, how can you configure a long-term sustainable image management and storage infrastructure that will deliver the desired performance and ROI?

The following framework has been developed by GE Healthcare to help you answer these and other questions. The Four-Layer VNA Model leverages other industry models to provide a flexible, scalable approach to image management that can be used as a template to evaluate the offerings of various HCIT vendors and determine how their technologies meet your requirements for:

- Interoperability
- Image accessibility
- Disaster recovery
- Upgradability
- Data security
- Ease of use

Unifying image storage and management at the enterprise level requires optimizing performance at each layer of the overall solution. The VNA solution has four layers to enable consolidation and sharing of imaging and other clinical documents: Storage & IT infrastructure, middleware, transport, and presentation.



**Storage infrastructure**
As imaging volumes continue to increase, so too must the capacity of the storage layer. At the same time, industry mandates for retention requirements in different areas of care are putting additional strain on storage resources. The rapid and continuous advances in storage technology mean that migration to newer, faster, and more robust hardware is inevitable.

When examining the evolution of storage media in medical imaging, it becomes clear that no standard format or architecture has remained the standard forever. From 14" optical disk jukeboxes ... to tape ... to today's MOD, DVD, SAN, and NAS solutions, the technology continues to evolve and the rate of evolution is increasing all the time.

Beyond the physical speed and capacity of the storage solutions under consideration, vendors are offering more and more sophistication at the storage level. For example, de-duplication (replacing duplicate blocks of data on a storage medium with placeholders) can increase capacity by 20, 40, or even 60 percent. Mirroring (maintaining a dynamic copy of all data) provides essential recovery capabilities in the event of a disaster. Many of these features and functionalities, previously exclusive to Tier-1 storage providers, are now available as part of a data management software solution – giving buyers greater options in storage hardware choices.[6] However, customers need to fully understand the limitations and problems of these technologies in the healthcare space when applied to medical images and documents. This may offset the potential benefit of reduced storage capacity and spending requirements. Issues include:

- **Loss of image quality** — Compression of medical images has been an area of major debate for many years. Even today for diagnostic purposes, care providers depend on lossless images. For reference purposes, the images can be lossy compressed, but there is no agreement on the acceptable limit for lossy compression. Moreover, de-duplication algorithms, like block de-duplication, used by storage suppliers may not be designed for image data, which is considered difficult to de-duplicate. It is recommended that customers control the level of compression for different data types through middleware technologies.
- **Reduced flexibility** — Performing de-duplication and mirroring at the hardware layer can limit your ability to change storage vendors and technology in the future.
- **Increase in capacity requirements** — Storage features and functions may double or quadruple your storage requirements if the middleware layer is already managing multiple copies of your data.

In addition to storage technology, vendors are offering storage-as-a-service, leveraging the "cloud." Some vendors tout cloud storage as the ultimate hassle-free way to solve storage problems indefinitely and suggest that it is more cost-effective than storing image data locally. But the reality is the cloud is simply a managed service, and that could mean relying on a third party to facilitate your disaster recovery/business continuity. A recent article from InformationWeek showed most enterprise-class companies — 87 percent, according to their survey — are not embracing cloud-based storage solutions, even for the most basic data archiving purposes.[7] For healthcare providers, concerns over cloud-based storage include data security, speed of data access, and data ownership.[8] In addition, large healthcare organizations may not reap the cost benefits of cloud-based storage as readily as smaller providers.

**RECOMMENDATION:** Customers should give most importance to the flexibility to move from one platform to another with minimal effort to achieve the highest performance and lowest cost per unit of storage. Having this flexibility provides options for incorporating the latest advances in storage technology as they become available, not only to accommodate increasing storage requirements, but also to meet green-data-center initiatives with regard to saving energy on power and cooling. This also demands neutrality of VNA middleware to the underlying storage fabric and the storage vendors, helping customers upgrade storage infrastructure seamlessly. Given the unique requirements and complexities of imaging data, it is important to manage the image-information life cycle based on clinical content and not on file-system attributes. Therefore capabilities like information life-cycle management are best managed at the VNA middleware level.

**Middleware**
VNA middleware is essential for unifying clinical imaging applications. While there is no industry-standard definition for VNA functionality, a VNA solution acts as a bridge between the storage layer and the presentation layer of the technology, consolidating data from several different data sources and providing access to that information, to be presented through a web-enabled interface to care providers. In this capacity the middleware layer is expected to act not just as a repository but also as a true source of metadata associated with each document and image to link them and help present relevant information to care providers.

At the most basic level, the middleware should integrate and unify disparate storage solutions so the organization is not hostage to a single storage vendor. Importantly, the middleware should support different industry standards to ensure interoperability with disparate departmental systems while preserving multiple native formats from the various modalities and devices. DICOM is the industry standard for images and most VNA middleware is expected to support it, but with the wide range of structured and unstructured information (such as JPEG, MPEG, PDF, WAV, etc.) that emanates from different care areas, support for interchange standards goes beyond DICOM.

XDS (Cross-enterprise Document Sharing) is one such standard that has emerged to provide interoperability to consolidate non-DICOM information natively in a vendor-neutral way. Sharing information using IHE-XDS has two significant advantages:

- **Greater efficiency for the end user** – XDS provides a common wrapper or metadata definition, much like DICOM, that functions as a standard format to identify the contents of the file, such as the originating institution, source information, and patient information.

***Note:*** *XDS is not a storage format like DICOM (part-10 files) which means that the actual document or image is stored in its native format (JPEG, PDF, MPEG, etc). It only provides an exchange standard to transport documents, store them, and index them with the right metadata information.*

- **Ability to standardize on a viewer** – With XDS the enterprise can use an interoperable, vendor-agnostic viewer to access and display non-DICOM and DICOM content.

XDS was developed by IHE (Integrating the Healthcare Enterprise), an organization focused on interoperability standards, to facilitate the exchange of clinical documents between healthcare institutions. IHE-XDS does not just provide the transport mechanism to share the clinical documents/images in the native format, but goes beyond to provide a standard mechanism to communicate and store associated metadata. IHE-XDS defines the registry as a new actor, which, as part of the middleware, stores and indexes this metadata and provides crucial information to the viewer for proper display and linking of DICOM and non-DICOM information. To compare it with the DICOM world, the proper display of images is managed through setup of hanging protocols that are derived from the metadata associated with the image. Without IHE-XDS, this metadata information will need to be exchanged using proprietary mechanisms.

The middleware layer also needs to have software components (either as a functional element of a larger solution or as a standalone application) that manage other critical aspects of an enterprise solution, such as:

- **User accounts** — Controlling who has access to the image and data.
- **Security policies** — Defining rights and privileges (e.g., who can read, who can edit) for all user types and all data types within the system.
- **Master patient index (MPI) functionality** — Maintaining a unique identifier for each registered patient that eliminates duplication of data and ensures a complete longitudinal record is available. This is required only if the enterprise has several different patient data sources.
- **Image lifecycle management (ILM)** — Establishing and executing rules for image retention based on clinical metadata that follow federal, state, facility, and departmental guidelines to maximize storage utilization.
- **Conversion services and tools** — Interfacing non-standard edge systems to the central repository in a standards way; imaging to DICOM and non-imaging clinical documents to XDS.
- **Shadowing** — Maintaining point-in-time copies of data.

In addition, middleware solutions must be able to respond to requests or "triggers" from external systems such as departmental PACS or the EMR. Typical requests can include:

- Responding to pre-fetch commands (DICOM)
- Routing exams based on scheduled events.
- Accepting messages to synchronize patient information (HL7).
- Returning a WADO (Web Access to DICOM Objects) object to the viewer.

**RECOMMENDATION:** The VNA middleware is the linchpin to create the full solution. It integrates and unifies disparate storage solutions while supporting multiple native formats from the various modalities. The most important aspect of any middleware solution is that it supports cross-functional standards (such as DICOM, IHE-XDS, and HL-7) so that the layers above and below can communicate seamlessly and no information is lost or omitted along the way. IHE-XDS support has to be mandatory for any middleware as it provides the standard mechanism to exchange non-DICOM data in native format and a registry to manage the metadata effectively.

**Transport**

The transport layer enables the exchange of data between the middleware and the presentation layer. This area is governed by a range of protocol standards, each with its own set of advantages and limitations.

- **DICOM** is the predominant medical imaging standard that enables the integration of modality hardware with the network infrastructure by providing protocols for handling, storing, printing, and transmitting medical imaging information. DICOM's network communication standards include specific calls/commands such as Query and Move.
- **HTTP (Hypertext Transfer Protocol)** is the underlying communication protocol for the web, and it is integral to several protocols used in medical imaging, such as WADO.
- **MINT (Medical Imaging Network Transport)** was developed to supplement DICOM and address some perceived limitations by utilizing HTTP as a transport mechanism with XML providing the encoding. However, the standard has not been officially adopted by the DICOM standards committee.
- **SOAP (Simple Object Access Protocol)** is a basic messaging framework that utilizes an XML-based protocol for information exchange in a distributed environment. SOAP supports different styles of information exchange, including Remote Procedure Call style (RPC) and message-oriented exchange.
- **RAD-69** is a secure synchronous transaction developed by IHE to transfer DICOM data over web services.
- **XDS** allows the integration of multiple types of data (JPEG, MPEG, PDF, WAV, etc.) into medical imaging management systems.

The transport mechanism has to be based on an SOA (Service-Oriented Architecture) to decouple the presentation layer (viewer) from the middleware layer so that different presentation layers can query or interact with the same middleware layer. This flexibility allows the organization to select a presentation layer from one vendor and a middleware layer from another. IHE-XDS provides that capability in the healthcare domain.

**XDS in a nutshell**

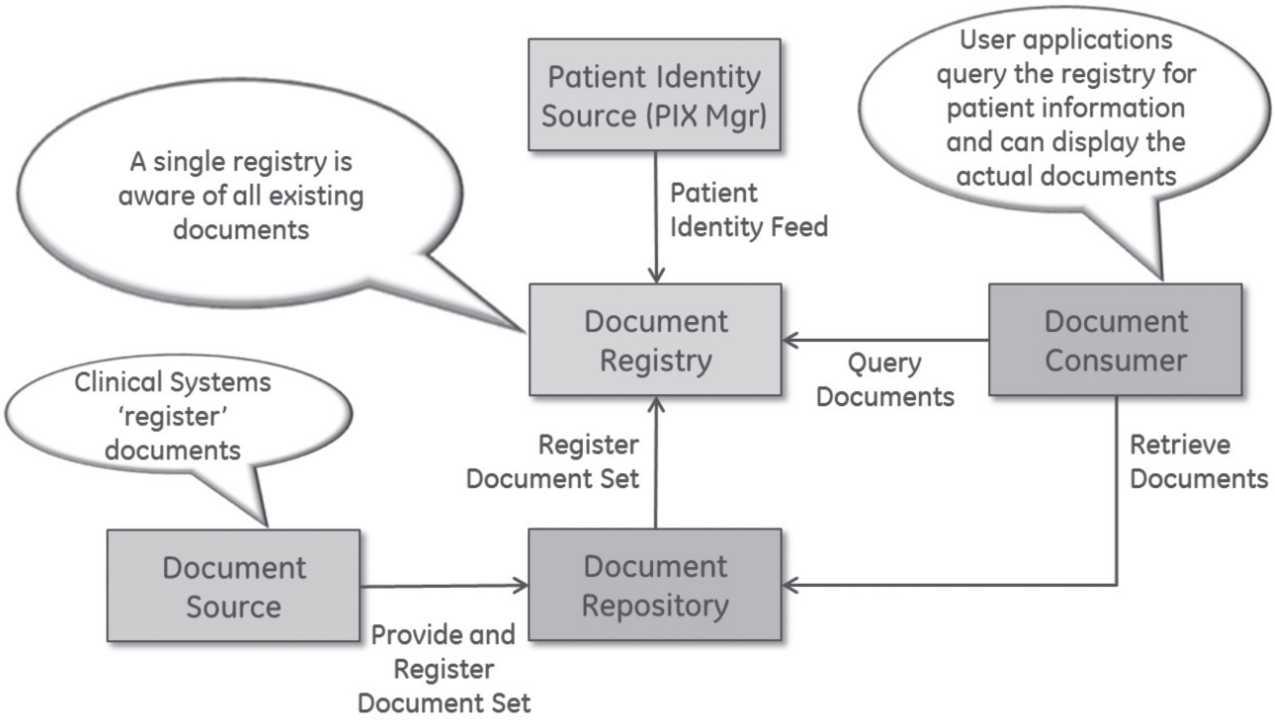
In the XDS environment, an XDS Document Source places a document along with a set of standardized metadata that describes the document in an XDS Document Repository. The repository registers the document in a central XDS Document Registry. In this way the registry builds a central index of an open longitudinal patient record consisting of standardized metadata. This represents the central index of the VNA middleware.

An XDS Document Consumer queries the document registry for relevant patient information and then retrieves the relevant documents from the document repository where they are stored.

XDS Document Source, Document Consumer, Document Repository, and Document Registry are defined as independent IHE actors which allow different clinical IT systems from multiple vendors to be integrated into the standards-based open VNA middleware platform to facilitate access to health information. Through XDS-I, an extension of XDS to imaging data, DICOM studies are also being indexed in the XDS Document Registry. With XDS-I the DICOM studies continue to be stored in a DICOM archive and only a reference document, a so-called DICOM manifest, is stored in the XDS Document Repository. With XDS and XDS-I the XDS Document Registry becomes a longitudinal patient record for both DICOM and non-DICOM imaging and non-imaging healthcare information.

Similar to how DICOM became the standard for modality interoperability, XDS is rapidly becoming the standard for all other types of clinical content that come from the multiple -ologies in the medical imaging space. The VNA solutions need to be able to manage data in these standardized formats for maximum flexibility in bringing meaning to the information. Radiology productivity has improved 70% over the past 10 years due to the adoption of image IT and standards such as DICOM.[9] Enterprise and community productivity could achieve similar results through the adoption of standards like XDS and interoperable systems.

**RECOMMENDATION:** IHE-XDS is based on service-oriented architecture (SOA) and was developed keeping in mind the unique requirements of the healthcare domain. It is based on IT standards like web services and HTTP, thus enabling broader acceptability. IHE-XDS enables clinical data to be transported in the native format with relevant metadata for the presentation layer. IHE-XDS support has to be crucial while selecting a VNA solution.



**Presentation**

The presentation layer is the "viewer" that finally delivers the clinical images and associated data to the physician. Functionality at this level should include seamless integration with the EMR and the ability to display all DICOM and non-DICOM information in a single view to ensure non-traditional sources of imaging come online. This means adherence to the DICOM and IHE-XDS standards as consumers of information.

It may also provide the ability to support the distinct management/viewing requirements of each area of care (e.g., radiology, cardiology, pathology, etc.). For example, in radiology, it might mean providing tools to perform measurements on images while still being able to review other clinical images and documents. Achieving that level of workflow integration requires a vendor with deep domain knowledge and first-hand familiarity with departmental workflow requirements. If a solution doesn't fit well with established department practices and patterns, user adoption will be slow and productivity can suffer.

Another crucial requirement here is "anywhere, anytime" access; thus the presentation layer also needs to be flexible enough to accommodate the wide range of different operating systems and browser versions found in end-user environments. In addition, for ease of deployment, the viewer should be a "zero-footprint" installation with no administrative rights required, and no reliance on third-party plug-ins such as ActiveX.

**RECOMMENDATION:** As the most visible element of your image management solution, the presentation layer can make or break the success of your implementation. The viewer should enable a seamless experience for the end-user clinician and be easy to learn and use. A well-designed presentation layer accommodates different departmental workflow patterns rather than forcing your clinicians to work in unaccustomed—and unwelcome--ways. Standards compliance (DICOM and IHE-XDS) with "zero-footprint" is important to foster wider adoptability across the enterprise.

**IN THE FINAL ANALYSIS**

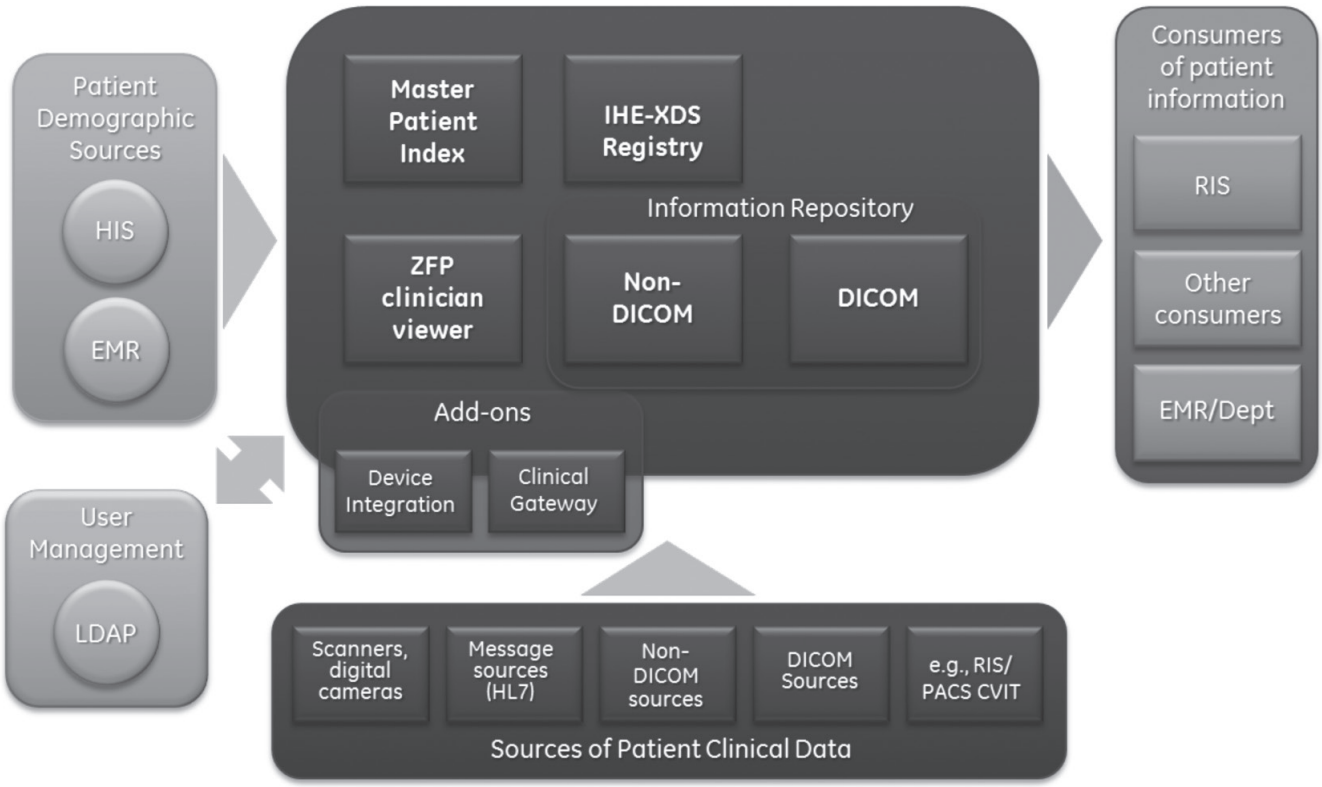
The vendor-neutral archiving (VNA) solution is more than just a repository; it is the crucial platform for consolidating and sharing imaging and other clinical data efficiently. When deciding on a VNA, the solution needs to be looked at more holistically, keeping in mind enterprise-wide consolidation and sharing of imaging (DICOM) as well as other clinical documents (non-DICOM data). The figure below provides a holistic view of such a solution.

In an era of evolving standards, advancing technology, and skyrocketing clinical imaging volumes, the single most important aspect of choosing an enterprise solution for image management is flexibility.

- Flexibility of connecting all kinds of devices and systems.
- Flexibility of accessing information anywhere, anytime
- Flexibility to scale effectively with facilities' growing needs
- Flexibility to meet departmental needs

And flexibility of choosing the right vendors at each level in the technology stack for maximum performance, lowest cost, and greatest ROI.

This flexibility comes from the adoption of industry standards such as DICOM, HL-7, and IHE-XDS, along with IT standards such as HTTPS, web services, and XML, and from vendors with extensive experience in complex installations—complex in both the sheer size of the installation and the number of vendors involved—who understand the intricacies of interoperability in a multi-vendor enterprise environment.



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GE Healthcare provides transformational medical technologies and services that are shaping a new age of patient care. Our broad expertise in medical imaging and information technologies, medical diagnostics, patient monitoring systems, drug discovery, biopharmaceutical manufacturing technologies, performance improvement and performance solutions services helps our customers to deliver better care to more people around the world at a lower cost. In addition, we partner with healthcare leaders, striving to leverage the global policy change necessary to implement a successful shift to sustainable healthcare systems.

Our "healthymagination" vision for the future invites the world to join us on our journey as we continuously develop innovations focused on reducing costs, increasing access, and improving quality around the world. Headquartered in the United Kingdom, GE Healthcare is a unit of General Electric Company (NYSE: GE). Worldwide, GE Healthcare employees are committed to serving healthcare professionals and their patients in more than 100 countries. For more information about GE Healthcare, visit our website at www.gehealthcare.com.

GE Healthcare IT
540 West Northwest Highway
Barrington, IL 60010
USA

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imagination at work



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