Best Practices Strategy for Dealing with non-DICOM Data objects in a PACS-Neutral Archive

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Message

In this paper, I am presenting an argument for a best practices strategy for dealing with non-DICOM Medical Image Data Objects in a PACS Neutral-Archive (PNA). In this context, the data objects I am referring to are diagnostic image objects that are produced through a clinical study process. The key message of this white paper is that managing the non-DICOM data objects in a Neutral Archive in their native format is not the best approach. A separate database full of non-DICOM data objects is effectively an alternative proprietary database for the Source system that cannot easily be shared with other systems. Non-DICOM objects complicate the viewing options. Furthermore they present an ugly data migration project sometime downstream that makes a DICOM migration look like a walk in the park. If the image producing device (PACS, modality, digital camera, etc.) cannot produce/output a DICOM-conformant image data object, the best practices alternative would be to convert the data object to a DICOM object. Converting non-DICOM image objects to DICOM objects is a relatively straightforward process that involves the use of a standardized information model, and results in an image object that can be represented in a standard database, which means the directory can easily be queried, so the image data can be retrieved, displayed and ported to other systems.

Preface

Diagnostic Image data objects fall into two distinct classes: DICOM and non-DICOM data objects. Most diagnostic imaging modalities and departmental PACS are DICOM-conformant, at least within the Radiology and Cardiology domains. That means that the interfaces between Image Sources, PACS and Archives are well established, and the protocols for query/retrieval (data exchange) are straightforward. In contrast, there are a number of issues associated with diagnostic imaging modalities and PACS that feature non-DICOM image data objects including: [1] costs and complexity associated with the interfaces that would be required to export or import non-DICOM data objects, [2] accessibility of the non-DICOM data (the ability of another system to query the non-DICOM Source and retrieve data from it), [3] portability (compatibility of the non-DICOM data with other systems).

Why is the nature of the image data object an issue with a PACS-Neutral Archive, when it is typically not an issue with a non-DICOM Source Modality or departmental PACS?

First of all, Imaging Modalities and departmental PACS that do not offer at least a DICOM option are probably not intended to share their image data with any other system. A digital Endoscopy camera might be expected to support hardcopy and possibly a digital data object that can be stored on a PC disk or a CD, but it obviously was not expected to forward its image data object to a DICOM-conformant PACS. A Dental department PACS might be expected to accept and manage JPEG image objects, but not be expected to share that image data with a Radiology PACS. Those Radiology and Cardiology PACS that were designed to ingest and manage scanned documents in JPEG or TIFF format (as opposed to managing the scanned documents as DICOM Secondary Capture objects in a new study series) typically are not expected to export those non-DICOM data objects to outside systems. On the other hand, a Neutral Archive is expected to exchange data between all existing PACS, display applications, even some imaging modalities in the current as well as future enterprise.

Secondly, it is possible that some Neutral Archive vendors are trying to offer reasons why they are important by arguing that there IS a storage problem for these non-DICOM objects. Don't get me wrong, non-DICOM data objects do present data management problems, but the challenges presented by a relatively small volume of non-DICOM images are far less than the challenges related to the management of the Tsunami of DICOM data objects.

Thirdly, data object classes will soon be important to achieving Meaningful Use.

The accessibility of all medical image data objects by the Electronic Medical Record (EMR) or the Electronic Health Record (EHR) Portal user is where this is heading. While it is a stretch to argue that image data is inferred in the Stage 1 core objective that requires demonstration of cross-provider patient medical data sharing, there is no doubt that medical image data sharing as well as portal access and display will certainly be addressed in Stage 2 objectives. In light of these forthcoming requirements to meet Meaningful Use, it is important to appreciate that the ease of Accessibility and Display are the keys to Meaningful Use of medial Images.

Healthcare organizations have been reasonably successful accessing, sharing and displaying the DICOM medical image data created in Radiology and Cardiology for years. The same cannot be said for the non-DICOM image data. Clearly those problems have to be solved in preparation for the Meaningful Use of all the patient's non-DICOM data objects that are created in the Healthcare Enterprise.

Preferred Methodology for Dealing with non-DICOM Data Objects in the PACS-Neutral Archive

Today the two most prevalent methodologies utilized by PACS-Neutral Archives for dealing with non-DICOM data objects are: [1] Convert the object to a DICOM object, or

[2] Preserve the object in its native format. A third option, which is most likely going to become the preferred option sometime in the future, is to utilize XDS or something like XDS (really a standardized mechanism to represent non-DICOM objects, including an information model, transport standard, and data sharing transactions) to manage the non-DICOM objects in their native format. You will see later in this paper why I believe that this third option is years away.

Key Attributes of the DICOM standard

There are a number of significant advantages to the DICOM standard, and it is important to recognize those advantages when considering how to deal with non-DICOM data objects.

[1] DICOM provides a Standard File Format, which allows both metadata and image data to be represented in a consistent format. Note that permitted variances in how certain metadata is represented in the DICOM header have caused inter-system compatibility issues.

[2] DICOM provides a Standard Information Model (SIM). This is a formal set of required identifying information that must be associated with the image data object: Patient's Name and Medical Record Number, Study Accession Number, etc. The SIM also defines relationships between objects according to a standardized Patient-Study-Series-Object hierarchy. Without a formal SIM, there would be no uniform way to identify the data, query or retrieve the data, in effect creating a proprietary database. This is perhaps the most important advantage to the use of DICOM.

[3] DICOM provides a Standard Communications Protocol This is a formal method of interfacing modalities, workstations, and PACS; and communicating data between disparate systems with defined services for Storage, Query, Retrieval, Moving data between systems, etc.

[4] DICOM has lead to the development of established, well-defined, Uniform Image Viewers. Most established medical image viewers are designed to manage/display DICOM data objects. Today the majority of medical image data is Radiology and Cardiology image objects. Most if not all Radiology and Cardiology modalities and PACS are DICOM-conformant and the PACS feature DICOM Viewers. Most free-standing Medical Image Viewers that might be used as EMR/EHR Portal viewers are predominantly DICOM image data viewers.

[5] DICOM assures Data Portability (Mobility!). Most prevalent medical image users are Radiology and Cardiology PACS, and EMR/EHR Portal Viewers. All of these consumers are first and foremost DICOM-conformant, thus assuring data portability between them based on DICOM. While some Portal Viewers may be capable of displaying various non-DICOM data objects such as JPEG, MPEG, PDF, etc., many (if not most) of the existing PACS are not capable of displaying or managing these non-DICOM image objects. It will very likely take a long time for the installed base of PACS

systems (through replacement or upgrade) to support the display of non-DICOM image objects.

According to Mark Bronkalla, V.P. Radiology and Enterprise Solutions, Merge Healthcare:

> DICOM assures the long term Usability of the image data. Consumer image formats come and go. Long term support of file formats and image compression techniques is an issue. DICOM constrains the image pixel formats and compression techniques. Consider white light images (e.g. for dermatology) that may be captured with a consumer still camera resulting in image data that is stored in a raw format (for best image quality). Good luck finding a viewer for that 10 years later. Similarly even MPEG1 or TGA format viewing is getting harder to do for old files. (Targa boards were once common for scientific & medical image capture.) Motion video is another area where the underlying codec for a motion file such as an AVI may no longer be supported, such as the once popular Indeo Codec family.

The five attributes of DICOM listed above define a highly structured image data object, the kind of data object strongly recommended in the final Meaningful Use rules[1]

> Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focuses on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information. Stage 1 focuses heavily on establishing the functionalities in certified EHR technology that will allow for continuous quality improvement and ease of information exchange. By having these functionalities in certified EHR technology at the onset of the program and requiring that the EP, eligible hospital or CAH become familiar with them through the varying levels of engagement required by Stage 1, we believe we will create a strong foundation to build on in later years.
>
> Our goals for the Stage 2 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (such as blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging,

[1] DEPARTMENT OF HEALTH AND HUMAN SERVICES; Centers for Medicare & Medicaid Services; 42 CFR Parts 412, 413, 422, and 495; CMS-0033-F
RIN 0938-AP78; Medicare and Medicaid Programs; Electronic Health Record Incentive Program

nuclear medicine tests, pulmonary function tests, genetic tests, genomic tests and other such data needed to diagnose and treat disease).

Finally, we continue to anticipate redefining our objectives to include not only the capturing of data in electronic format but also the exchange (both transmission and receipt) of that data in increasingly structured formats.

The intent and policy goal for raising these thresholds and expectations is to ensure that meaningful use encourages patient-centric, interoperable health information exchange across provider organizations.

Another white paper[2] published by Embarcadero Technologies, Inc. offered a summary of the substantive MU objectives of Stage 1 in which one of the main objectives was to incorporate clinical lab-test results into EHR as structured data. It is highly unlikely that the Stage 2 rules would suggest treating medical images as unstructured data!

Key Attributes of the non-DICOM Object

Using the DICOM format as described above as an example of a structured data object, the non-DICOM image data objects typically encountered in medical imaging such as JPEG, MPEG, TIFF, PDF, BMP, WAV, etc. are standard consumer object formats, BUT they are not structured data objects. This is mostly due to the fact that they lack a standardized information model, or representation of metadata that consistently describes the data object and is also consistent with healthcare IT requirements.

So how do these typical non-DICOM data objects stack up to the rest of the DICOM attributes?

[1] File Format - The listed data objects themselves (JPEG, MPEG, TIFF, PDF, etc.) are examples of a standard consumer object file format, BUT each of the above listed objects has many variations and options, many of which are not widely supported. For example, MPEG 1,2,3,4 bear very little semblance to each other and are mutually incompatible. With minor exceptions, it can generally be assumed that these objects are not self-describing and that additional external metadata will be required to know how to index and retrieve these data objects.

[2] Information Model - The listed objects lack a Standard Information Model. The data format itself does not specify standard and required identifying information to be associated with the object, for example patient name and ID, study ID and study description; or the relationships between the objects, such as a multi-object image series or a multi-series imaging study.

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[2] How Meaningful Use Impacts Healthcare Data Management Professionals, What Healthcare Data Management Professionals Need to Know About Achieving HITECH Meaningful Use and Certification; Shahid N. Shah, CEO, Netspective; June 2010

[3] Communications/Interface Methodology - The objects lack an associated uniform Interface Methodology or Communications Protocol for querying and retrieving information based on metadata. Any of a number of transfer (interface) protocols might be used to exchange the data between systems (web services, FTP, CIFS, HL7, etc.) but there is no uniform interface methodology and communication protocol described for each of these object types.

[4] Uniform Image Viewer – The above listed object types lack a uniform viewing application - Flash can display a variety of static and dynamic non-DICOM objects (JPEG, PDF, etc.), but not all object formats. JPEG can be rendered in most standard web browsers, but without associated applications, the other object types may not be able to be displayed. In general, each file type requires a viewing application capable of displaying that format.

[5] Data Portability (Mobility!) - Depending on the object type, they may or may not be portable. The majority of medical image data consumers (PACS, Workstations, etc.) are based on DICOM, and they may not be able to ingest or display non-DICOM data objects. Even the few non-DICOM PACS and workstations may not be able to ingest or display the full range of non-DICOM data objects that are created by other disparate systems. Most importantly, without addressing both data and metadata in a consistent manner, data portability will always require custom development to insure compatibility between exporting and importing systems.

So it's clear from this perspective that the non-DICOM image data objects typically encountered in the Healthcare Organization are nothing like the structured medical image and image-related objects that are created / exchanged by DICOM-conformant systems.

Practical Options for handling non-DICOM Data Objects in a PACS-Neural Archive

As previously stated, the two most prevalent options today for handling non-DICOM data objects in a PACS-Neutral Archive are: [1] Convert to DICOM or [2] Preserve as a Native Object. Determining the most appropriate option, perhaps the best option, depends on a number of issues, which we will explore in the following paragraphs.

[1] Conversion to DICOM

We will discuss the Conversion to DICOM approach in the context of the five Attributes of the structured DICOM object, but the attributes will be slightly re-arranged to produce the following checklist that is a reflection of how the problem should be approached.

1) The Standard File Format
2) The Communications/Interface Methodology
3) The Standard Information Model
4) Established and Uniform Image Viewer
5) Portability

Before we explore the various issues and decisions related to choosing the right DICOM Conversion process, it is necessary to understand that there are two (2) options for DICOM conversion.

DICOM Conversion Options

Converting an unstructured (non-DICOM) data object to a structured data object can be accomplished by adding the structured aspects of DICOM to the non-DICOM data object. The two methodologies for this DICOM conversion process are presented below. It is important to appreciate the similarities and dissimilarities of these two processes.

DICOM Wrapping – Wrapping creates a DICOM Header containing the expected metadata elements required in a standard DICOM Header and places it in front of the object's pixel data, effectively creating a new file. The pixel data itself is converted to a format that is normalized for DICOM, such as JPEG. The original object header is discarded. Wrapping effectively converts the original data object to a DICOM SOP Class that most closely approximates the original object. For example a TIFF image could be converted to a Secondary Capture DICOM object. A DICOM Viewer can then easily display this DICOM Secondary Capture object.

DICOM Encapsulation – Similar to Wrapping, a standardized DICOM header is created, the pixel data is converted to a format that is normalized for DICOM (normally a DICOM Secondary Capture object, probably JPEG represented pixel data), but then the complete original data object itself is encapsulated in a set of DICOM tags (normally private tags since no standard for this exists). As a result of this encapsulation, the original object format is maintained within these private tags. A DICOM viewer would then access the object as it normally would access a "wrapped" object (reference the above SC example), and ignore the private tags describing the original object.

The real benefit here is that the application that "encapsulated" the object could be instructed to retrieve the encapsulated object and access the private tags to decode and restore the original data object in its entirety as it was preserved in the DICOM object when the encapsulation occurred. The only potential limitation to a full restoration of the original data object would be if an application at some point stripped or modified the private tags that contained the original data object. In that case, the encapsulation application may not be able to reconstitute the original object. An example of potentially useful non-DICOM header information is that which may be stored in the EXIF data for still image cameras.

Wrapping vs Encapsulation - The DICOM Wrapping process is similar to DICOM Encapsulation in that a DICOM header is built using the metadata components of a Standard Information Model provided by an Order or a Schedule or a manual submission of such data by a technologist or lab technician. Wrapping differs from Encapsulating in that the original data object is converted to a valid DICOM object type and its original header is discarded, making it nearly impossible to return the object to its originating Source in the original format.

Note that there a number of DICOM supported "encapsulated" data types like PDF, MPEG, etc., but the description presented above is referring to DICOM encapsulated proprietary data types.

Bearing in mind the two options for DICOM Conversion, let's use the five point checklist to guide us through the decisions required to choose the right DICOM Conversion process.

1) The Standard File Format

Selecting the most appropriate Standard File Format for the converted object is highly dependent upon the Source device that created the non-DICOM image data object.

If the Source device is Archive Compatible, that is to say it is [1] capable of sending/transferring image data to an external archive, [2] capable of remembering that it has transferred the data to the external archive, [3] capable of then purging from its own data database the data that has been transferred to the external archive, and then [4] retrieving the data from the external archive as needed; the DICOM Encapsulation methodology would be the best conversion methodology. Encapsulation preserves the original native data object and its private metadata tags, making it possible for the encapsulation application to return the native data object to the originating Source, should that be desirable/necessary.

If the Source device is *not* Archive Compatible, the primary issue is whether the Source device would ever expect the data object to be returned.

Return not needed…Some Source devices like Digital Cameras, EKG units, etc. are not designed to archive data. They simply produce data for export. This type of Source device would not expect that data to be returned. In most cases where the Source device is designed for data export, the DICOM Wrapping methodology would be the best conversion methodology. Wrapping converts the original native data object into a suitable DICOM Object, and discards its private metadata tags. Wrapping makes it possible to ingest and display the converted (now DICOM) object without concern for having to return the native data object to the originating Source.

Return needed…If the Source device will require the data object to be returned, once again the DICOM Encapsulation methodology would be required.

2) The Communications/Interface Methodology

The next issue that needs to be resolved is the Communications/Interface Protocol. Selecting the most appropriate Communications/Interface methodology is also highly dependent upon the Source device that created the non-DICOM image data object. Does the Source device already support an interface that is compatible with the Neutral Archive? How easy will it be to modify the Source device to accommodate an interface that is compatible with the Neutral Archive? Will the vendor of the Source device be

cooperative in installing and supporting this interface? Is the proposed interface affordable? Is the proposed interface easy to support/maintain? How much data will the interface be expected to process (what is the expected throughput)?

• Manual interface – Perhaps the easiest interface methodology for low volume data transfers is the manual interface. The user at the Source manually transfers the image data to a removable memory medium: a memory stick, CD, etc. The portable memory device is then manually inserted by a user into a suitable device/port on a PC that serves as a data ingestion station for the PNA. This interface methodology might be acceptable for small data volumes, but probably not be acceptable for large and frequent data transfers.

Another example of a manual interface is the conventional "Print-to-PACS" application, which is a dedicated DICOM wrapping / encapsulating service application. A "Print to PACS" driver or a more advanced "Print to PACS" interface application paired with a GUI that supports file selection and the wrapping / encapsulation application ideally can run on the image generating system with no interference with the original application.

Brian J. Cavanaugh, President of PACSGEAR, states:

> Adding PDFs, JPEGs, and other clinical documentation to DICOM studies provides better input at the point of care. Today, virtually anything can be wrapped or encapsulated and added as a DICOM object to the patient's record. With the addition of DICOM Modality Worklist and HL7, it is easy to match these objects to the appropriate study in PACS or EHR.

• Basic Digital interfaces that are manually executed – FTP files transfers, CIFS file share dropping, HL7, etc. In this case, the Source device and the PNA data ingestion station are connected by the most efficient digital interface technology they both support. Most likely the user executes the data transfers manually.

• Basic Digital interfaces that are automatically executed - FTP files transfers, CIFS file share dropping, HL7, etc. This scenario would apply to a Source device that was Archive Compatible. The Source device and the PNA are connected by the most efficient digital interface technology they both support. The Source application most likely initiates the outbound data transfer as a form of data "archiving" application. The data could be returned from PNA to the Source by either the PNA (a pre-fetch and auto-route function) or through a query-retrieve function executed by the Source.

Mark Bronkalla, V.P. Radiology and Enterprise Solutions, Merge Healthcare, states:

> The biggest issue with the Basic Digital Interfaces (such as FTP, CIFS, etc) and the automation of the Digital Interface is the question of 'how is the DICOM metadata selected for attachment?' Remember that part of the problem with non-DICOM file formats is the lack of identifying data for the patient and study within the data object itself.

• Web Services. In some sense this would fall into the previous category - Basic Digital interface that is automatically executed. The difference would be that a web service would have to be described and created that both the Source vendor and the PNA vendor would agree to support. Discussion around the actions supported by the web service (store, query, retrieve), then of course the information model (which we explore in the next section), would have to be held, so both vendors could agree on those issues. In the end, this would result in an ability for the Source to transmit data over an agreed web service, in an agreed format, with an agreed information model. A web services interface could also be used to exchange DICOM objects, in some sense WADO provides this already but only for the retrieval of the DICOM objects. It is important to note here that DICOM does have a working group set up to define Web Services for DICOM. This working group is attempting to define storage, query, and retrieval mechanisms for DICOM objects over standardized (meaning they are globally agreed) web services.

Important note: In order for encapsulated data objects to be returned from PNA to Source, the interface would have to be able to access the application that "encapsulated" the object and that application would have to retrieve the encapsulated object and access the private tags to decode and restore the original data object in its entirety as it was preserved in the DICOM object when the encapsulation occurred.

3) The Standard Information Model

The next issue to be resolved is how to build the DICOM Header, so the data object can be associated with a Standard Information Model. The Source department/user will have to be willing to adopt a new workflow, one that will require creating an Order or a Schedule using an existing HIS, RIS, etc., or manually entering the required patient/study ID.

Some PNA vendors (i.e. Agfa , DeJarnette, and Merge) have created simple web-based administrative tools/stations that are patterned after order entry applications. These tools facilitate collecting the information required to build a solid DICOM Header (Patient Name, DOB, Sex, etc.) and they can facilitate creation of a study accession number. Whatever methodology is chosen for creating the header, the main point here is to use the Standard Information Model defined by the DICOM standard. Using any Information Model other than DICOM will effectively create a proprietary database that will most likely not be compatible with other systems, because they will create interoperability issues within the DICOM space.

4) The Established and Uniform Image Viewer

The next issue is to determine the best way to display the new data object. If the data is a Wrapped object, any DICOM viewer can easily display the object. If the data is an Encapsulated object, the DICOM version of the object can be displayed by any DICOM viewer. However, the recovery and display of the original data will require the original application, or an application that understands the content type that is essentially

encapsulated. The workflow in this case also becomes modified in that the data will need to be retrieved back to the encapsulation source, which will essentially "de-encapsulate" it, bringing back the original object which can be opened/viewed in the application that created it, or another compatible viewing application. This is the key point to the strategy of encapsulation and de-encapsulation of data types outside those specified by the DICOM standard.

5) Portability (Mobility)

The last issue should be the key issue…Mobility or the Portability of the data to other systems. One of the key arguments for the PACS-Neutral Archive is its ability to exchange data between disparate systems over a lengthy period of time (years). This ability to assure long-term data exchange supports the promise of no more data migrations. This also implies that the underlying data formats used within the archive be stable and not need to be migrated over time as consumer standards fall from favor and lack compatibility with newer PC operating systems.

Since DICOM is by far the most prevalent standard for managing structured medical image data in today's medical imaging devices, it makes sense that it would be the most logical choice for managing non-DICOM medical image data.

Mark Bronkalla, Vice President Radiology and Enterprise Solutions for Merge Healthcare, states:

> One of the most significant challenges is supporting the continued usability of the stored objects over very long periods of time. Clinical IT people typically think in terms of 5-7 years for basic adult study retention, but really this timeframe must be expanded to think of the pediatric studies, oncology studies, and others not yet mandated by the government, that have extremely long retention and usability requirements. Having file formats and compression techniques that are supported over not just 5 but more like 20-30 years and longer is a significant challenge and risk. We have seen many file formats and compression techniques come and go. It is in our best interest to convert from 'consumer' formats to medical industry standards at the earliest possible step to ensure long term usability.

We will review the role of Cross-Enterprise Document Sharing (XDS), another standards-based specification for managing the sharing of documents between any healthcare enterprise, later in this paper. While XDS may facilitate the sharing of both DICOM and DICOM-based data objects, XDS in and of itself cannot assure the correct display of the DICOM data objects by a XDS-enabled Document Consumer, which will probably (for some time to come) be an EHR viewer or a departmental PACS-based viewing application.

Perhaps I should explain this last statement.

By definition, an XDS Imaging Document Consumer must be able to both retrieve and display DICOM objects. However, the XDS application itself does not include a tag re-mapping or morphing functionality. DICOM image data submitted to the XDS repository by disparate PACS could easily contain those DICOM Header idiosyncrasies that are known to interfere with the proper display of the images by another PACS (Viewer). XDS does not resolve the PACS-to-PACS DICOM header idiosyncrasies.

Perhaps the biggest XDS constraint is probably the costs associated with [1] sources becoming XDS compliant (by means of adapters or vendor developed software), [2] the costs associated with the use of an MPI, and [3] the costs associated with the deployment of XDS image document consumers (EMR/PACS/Specialized). These are costs that most Healthcare Organizations aren't ready for today. Right behind that is the desire to view the images within the PACS as part of the overall viewing / reading workflows without the need to launch another external XDS client / viewer. How long will it take for the installed base of PACS to be upgraded in order to become XDS-conformant Image Document Consumers?

One could make the argument that conversion of non-DICOM data objects to DICOM is the reality of today, so "Why fix it, if it ain't broken?" Nevertheless a thorough review of the Preservation approach is a worthy exercise.

[2] Preservation of the (non-DICOM) Native data object

We will discuss the preservation of the (non-DICOM) Native data object approach in the same context of the five Attributes of the structured DICOM object. Once again, the attributes will be slightly re-arranged to produce the following checklist that is a reflection of how the problem should be approached.

1) The Standard File Format
2) The Communications/Interface Methodology
3) The Standard Information Model
4) Established and Uniform Image Viewer
5) Portability

1) The Standard File Format

Many of the non-DICOM image data formats encountered in medical imaging (JPEG, MPEG, TIFF, PDF, WAV, etc) are considered standard consumer data object formats, so there is no objection to the file format per se. However the many variants and long term viability of the format and their variants is an issue for long term usability and compatibility. The more immediate problems that are encountered when the PNA stores data in these standard object formats become obvious as we recall the other Attributes of the structured DICOM object.

2) The Communications/Interface Methodology

The first significant issue that needs to be resolved in the Native Object preservation approach is the Communications Protocol. Once again, the appropriate Communications/Interface methodology (between Source and Neutral Archive) is highly dependent upon the Source device, and of course, if attempting to enable data sharing, any data consumer devices. The same questions that we reviewed in the Communications/Interface Methodology section for DICOM conversion methodology apply here. Does the Source device already support an interface that is compatible with the Neutral Archive? How easy will it be to modify the Source device to accommodate an interface that is compatible with the Neutral Archive? Will the vendor of the Source device be cooperative? Is the proposed interface affordable? Is the proposed interface easy to support/maintain? How much data will the interface be expected to manage?

If the goal is to enable data sharing, there is an additional question: Will the chosen communication protocol be supported by all of the other data consumers or will other interfaces need to be considered as outlined in the above questions? This problem gets "N" difficult as more consumers are added.

The same types of digital interfaces considered for the transfer of non-DICOM data to the DICOM-Wrapping and Encapsulation applications/appliances would be candidates for transferring the non-DICOM data in the native format between the Source and the PNA.

- Manual interface based on a memory stick, CD, etc.
- Basic Digital interfaces that are manually executed: FTP, CIFS, HL7, etc.
- Basic Digital interfaces that are automatically executed - FTP, CIFS, HL7, etc.
- Web Services (a type of programmatic API) assuming the Source device can be configured to support a web services interface.

I think one could view all of the above interface types as Custom, because there is no standard for this type of communication and the proposed content-type. Therefore getting other vendors to support any of these custom interface types would be difficult.

Note that simple file transport methodologies such as CIFS or NFS do not easily allow metadata to be associated with the image data object, so these interface methodologies would probably not be useful for transferring non-DICOM data from Source to PNA, unless the Information Model is to be applied once the data has been ingested by the PNA, or possibly another file/object is subsequently transmitted to the PNA (i.e. XML) that describes the object. The point being that the data interface methodology alone is not the solution.

Then there is the issue of exchanging non-DICOM data objects between the Neutral Archive and other consumers of the image data throughout the enterprise such as Portal Viewers and departmental PACS. Manual interfaces and manually executed digital interfaces will probably not be successful simply because they would be inefficient. NFS and CIFS interfaces have the metadata limitations. HL7 and web services interfaces are

possibilities, assuming that these data consumers would be able to support what has to be considered custom interface methodologies.

One of the significant problems with managing Native non-DICOM data objects is that this approach may ultimately involve the development, deployment and long-term support of multiple communication interfaces between Sources, the PNA and the Consumers of that image data. I would think that this level of complexity and cost would be difficult to justify.

3) The Standard Information Model

The next issue is associating the non-DICOM data object with a Standard Information Model. Whether this process involves creating an Order or a Schedule using an existing HIS, RIS, etc., or manually entering the required patient/study ID, the very definition of a structured data object requires association of the image data object with the appropriate metadata. This metadata association could either be executed in an external "interface device" or internally, once the data has been ingested by the PNA. However, using any Information Model other than DICOM will effectively create a proprietary database that will most likely not be compatible with other systems, thus significantly impacting the Portability of the data.

The Information Model is essentially the "glue" between other applications for Query (how do I find it) and Sharing (how do I associate it) with other objects for the patient. In my opinion, the Information Model is the MOST IMPORTANT challenge in dealing with non-DICOM objects, and one of the reasons XDS, or XDS-*like* is attractive. I think we will come to find anything other than DICOM, or XDS-based information models to be VERY proprietary, and that these proprietary models will require the most migration/change in the future for a customer. And that means cost ($$$$$).

4) The Established and Uniform Image Viewer

The next issue is to determine the best way to display the non-DICOM data object. Whether the data Consumer is a Portal Viewer or a department PACS, that means an interface must exist between the Portal or PACS and the Information Model so the non-DICOM data object can be identified and retrieved. Assuming such an interface is in place, the core issue is how the Portal or PACS will display the non-DICOM native object.

Some DICOM viewers can display JPEG or PDF objects by invoking the appropriate mime-type viewer. Some Portals and departmental PACS viewing stations would have to have an instance of the appropriate viewer already installed (Adobe Acrobat, Microsoft Word, etc). If the native data object can only be viewed with the custom viewer created for the original data object's Source device, the issue now becomes whether this custom viewer is compatible with the Portal or the departmental PACS application and its associated hardware platform, and what the integration and support of that viewer will cost. Further, what is the feasibility of integrating and effectively deploying a

custom/special viewer for each unique new data type? Serious consideration should be given to the decision to burden a Portal or a departmental PACS viewing station with multiple viewing applications. In addition to cost, multiple viewing applications is not the ideal situation for the users, and this particular approach may not be supportive of Meaningful Use.

5) Portability/Mobility!

The last issue is once again the key issue…Portability of the non-DICOM Native data to other systems in the enterprise. The nature of the Communications/Interface Methodology and the Information Model may effectively render the non-DICOM Native data object proprietary…unusable by anything other than what is effectively the proprietary extension of the Neutral Archive and its custom viewer and the original Source device. The non-DICOM data object may not be portable to any of the many other systems in the enterprise that are more likely to be DICOM-conformant and not particularly suited to non-DICOM interfaces and viewers.

Cross-Enterprise Document Sharing (XDS)

Other than DICOM, the only other standard methodology for exchanging and managing medical documents (data objects) is XDS and its image-specific subset XDS-I. That is due to the inclusion of an information model, query, retrieve, and storage protocols fully defined by XDS/XDS-I. Unfortunately, this technology is not widely in use today. The XDS/XDS-I standard will accept a wide range of standard image object types including DICOM and the many other object formats used in medicine: JPEG, MPEG, TIFF, PDF, WAV, etc. The advantages of the XDS/XDS-I standard include two important features: [1] the institution of a Standard Information Model fed by an enterprise Master Patient Index (eMPI), and [2] the use of an interface communication protocol based on web services.

Source devices, Neutral Archives, and Consumers of image data can exchange both DICOM and non-DICOM Native data objects, if each is configured with XDS/XDS-I technology. That's the problem. Many Source devices and potential data Consumers do not currently support XDS/XDS-I. While the addition of an internal or external XDS module is a relatively inexpensive ($10-15K USD) proposition for compatible Source and Consumer devices, my experience to date suggests that adding the XDS/eMPI technology to Neutral Archive can add as much as 30% to the baseline cost of the PNA. I've even seen it TRIPLE the cost of the PNA deployment in those country/region wide deployments outside the United States. The $10M Neutral Archive system jumps to a $30M system when the XDS technology is added to the configuration, with the most expensive component of the XDS technology package being the MPI module.

Wayne T. DeJarnette, Ph.D. President, DeJarnette Research Systems, Inc. confirms this observation:

> While XDS/XDS-I adds some cost, it is not the cost of XDS/XDS-I which drives this, it is not the registry required for XDS/XDS-I, it is the outrageous and unsustainable prices being asked for EMPI itself.

XDS/XDS-I guarantees a suitable identification and communication capability between devices, for both the DICOM and non-DICOM data objects. Nevertheless, once the non-DICOM native objects are successfully transferred to the XDS Image Document Consumer (device), viewing the non-DICOM object will most likely require the appropriate mime-type viewer or a custom viewer. And viewing the DICOM objects is still somewhat complicated by the PACS-specific idiosyncrasies buried in the DICOM header tags.

Assuming all Sources and Consumers in the enterprise are configured with XDS/XDS-I, the image data is portable to the extent that it can be identified and exchanged between devices, but there is no guarantee that the Document Consumer can use/display the DICOM data object. Portability is one thing, but Compatibility is another.

XDS/XDS-I alone does not eliminate future data migrations of the DICOM data, where the migration process is required to modify the metadata in the DICOM header in order to assure compatibility.

Shannon Werb, CTO & COO for Acuo Technologies, states:

> XDS, or something XDS-*like*, is the most viable mechanism for management of non-DICOM data objects in the future. XDS essentially solves the non-DICOM data management problem through standardized web services for store/query/retrieve along with a standardized information model that is integrated through the patient record, including imaging. Until XDS, or XDS-*like*, is better adopted, the short term reality is that most customers choose DICOM conversion. One of the key benefits I can see for the continued use of this short term solution is that the data can be easily referenced within an XDS environment that wouldn't require data migration of a proprietary data store of non-DICOM objects created through another mechanism.

Wayne T. DeJarnette, Ph.D. President, DeJarnette Research Systems, Inc. states:

> I agree that long term this (XDS) is the solution. I also agree that this (XDS) will not be seen widely in the near future, although installations are being done which make use of it. This market is always slow to adopt, and in this economic environment, very few are willing to spend dollars to develop this capability.

Summary

The DICOM standard, representing a Standard Information Model and a Communications protocol, as well as a standard data format, fulfills all five of the attributes desirable in a structured data format. Most importantly, DICOM is a standard

that is widely supported in most Image Sources and data Consumers common to the Healthcare Enterprise. XDS/XDS-I is an up and coming standard that facilitates identifying and exchanging both DICOM and non-DICOM data objects within and across enterprises. But even in a XDS/XDS-I environment, DICOM greatly simplifies viewing and Portability between largely DICOM-conformant Sources and departmental PACS.

I believe that I have made a solid argument in this paper for DICOM conversion of non-DICOM data objects, regardless whether the environment is pure DICOM or a blend of DICOM and XDS/XDS-I. The DICOM conversion of the non-DICOM data object satisfies four of the five key attributes of the structured data object: Standard File Format, Standard Information Model, Established and Uniform Image Viewer, and Portability. The fifth attribute, Communications/Interface Methodology, can be satisfied with web services or manual or automated digital interfaces, whether the Source device is Archive Compatible or not.

Wayne T. DeJarnette, Ph.D. President, DeJarnette Research Systems, Inc. states:

> The industry will be more successful with this approach (conversion of non-DICOM data to DICOM data), placing the burden of conforming to a well accepted, widely adopted standard on the backs of the offending "modality manufacturers".

The argument in support of managing non-DICOM data objects in their Native format in the Neutral Archive is weaker. This approach adds additional interfaces to the Sources, Archive and data Consumer devices. But the greatest argument against managing the Native data objects in the Archive is the likelihood that that approach will introduce a proprietary Information Model to the image data, rendering the data usable by only that Archive and custom viewers. Data Portability will not be assured, and Data Migrations to another Archive will most likely be a future requirement.

Chris Magyar, Chief Technical Architect, IMPAX Data Center, Agfa HealthCare, states:

> The primary objective of a PACS-Neutral Archive is to promote the efficient sharing of standards-based imaging information between users of existing and future standards-based imaging applications. Ideally, non-DICOM image objects should be transformed into valid DICOM data types at the time of acquisition making sure that these objects are described with accurate patient demographics and procedure information. This is the only way to ensure that this imaging data will be accessible to any user of a standards-based imaging application – and not just users of the source application or proprietary image viewers.

Additional information on the PACS-Neutral Archive, including deployment strategies, and the role that PNA technology will likely play in achieving Meaningful Use can be found in my weblog located at http://www.graycons.com.

About the author…

Michael J. Gray

Mr. Michael Gray is the principal of Gray Consulting, a consulting practice established in 1991 to develop a number of consulting services designed to assist Health Systems and Radiology Practice Groups. Gray Consulting has provided consulting services related to PACS and Enterprise Archiving to over 75 Organizations.

Mr. Gray's areas of expertise are Market Analysis, Technology Analysis, Strategic Planning, Needs Assessment, Workflow Analysis and Re-design, Business Case Modeling, Vendor Analysis/Selection, and Technical Contract Negotiation. Mr. Gray's unique perspective has proven invaluable to Radiology and Information System administrators planning the introduction of new Image Management technologies into their imaging departments and hospitals. Mr. Gray routinely publishes articles on his Weblog (http://www.graycons.com) on subjects such as workflow design, business case modeling, system deployment strategies, expansion or replacement of data Storage Solutions, development of Data Migration strategies from old to new PACS, and the latest market concepts including PACS-Neutral Enterprise Archiving.

Mr. Gray has a BS in Biology and Chemistry from Washington University, St. Louis; has been awarded three US patents; and has an extensive bibliography in medical image display and electronic information management systems.

Mr. Gray and his family reside in Novato, California.