Developing a Multi-Institutional PACS Archive and Designing Processes to Manage the Shift from a Film to a Digital-Based Archive

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The Quality Assurance Review Center (QARC) works to improve the standards of care in treating cancer by improving the quality of clinical trials medicine. QARC operates as a data management and review center providing quality assurance services for multiple external groups including cooperative groups and pharmaceutical companies. As the medical world migrates from analog film to digital files, QARC has developed an innovative and unique digital imaging management system to accommodate this trend. As QARC acquires electronic data from institutions across six continents, the system is continually developed to accommodate Digital Imaging and Communications in Medicine (DICOM) imaging originating from a wide variety of Picture Archival and Communications System (PACS) manufacturers, thus creating one of the largest and most diverse multi-institutional imaging archives in the cancer research community.

KEY WORDS: PACS, digital imaging and communications in medicine (DICOM), digital imaging, digital image management, workflow, archive, radiotherapy, quality assurance, clinical trial

BACKGROUND

For approximately 25 years, the Quality Assurance Review Center (QARC) has successfully managed data for thousands of protocol patients, using a well-established process relying primarily on a manual workflow, i.e., receiving, identifying, reviewing, and storing hard copy films. In recent years, as most institutions have migrated toward a filmless environment, QARC personnel have been developing an IT infrastructure and expertise accordingly. QARC is currently equipped to acquire and process case management data in multiple electronic formats. Electronic data submissions are sorted into two categories: (1)

Digital Imaging and Communications in Medicine (DICOM) imaging which refers to all diagnostic digital imaging that conforms to the DICOM standard¹ and (2) eMaterials, which encompasses all other types of electronic imaging including pictures, documents, slide show presentations, spreadsheets, movies, and Adobe PDF files. QARC also accepts DICOMRT and RTOG data exchange files² and stores them under eMaterials in the patient database. This paper, however, specifically focuses on the management of digital diagnostic DICOM imaging. The following sections trace the steps QARC has taken to successfully accommodate the influx of DICOM imaging.

In 2001, QARC began to accept studies submitted digitally, archiving its first 11 cases and storing the image files on one central server. The influx of digital imaging received at QARC has increased considerably over the past 6 years. In 2002, the QARC Picture Archival and Communications

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System (PACS) archive grew to store 42 cases in digital format, while in 2003, the total increased to 642. In 2004, a total of 3,867 cases were stored in the archive, and by the end of 2005, the imaging archive had accumulated 10,776 unique imaging studies. In July of 2006, the archive exceeded 15,000 DICOM studies, and as of July 2007, nearly 26,000 studies are stored in the QARC PACS.

The significant increase in the storage space required to archive these image files is shown in Fig. 1. In July of 2007, with a PACS containing over 6 million images, the QARC archive has exceeded 700 Gb. The studies housed in the PACS represent a variety of modalities and diseases acquired from over 850 different sites. As QARC interacts with investigators in six continents, the data arrives at QARC in many electronic formats, both with and without proprietary headers, often creating unique issues in opening and archiving data. This dramatic shift has created the need to find an accurate and user-friendly way to manage this new format, while maintaining the integrity of the data and ease of use for QARC staff and the physicians doing central reviews. To accomplish this in a manner which accommodates the heterogeneity of this data, QARC has developed a sophisticated image management system encompassing a complex patient database, DICOM image transfer software (called Dicommunicator) and a fully functional PACS archive.

METHODS

History

QARC is a research program within the University of Massachusetts Medical School providing radiotherapy quality assurance services, diagnostic imaging data management, and clinical research support for several National Cancer Institute (NCI)-sponsored cooperative groups and pharmaceutical companies. The NCI-supported cooperative groups are networks of physicians and hospitals that develop and conduct cancer clinical trials to evaluate new cancer treatments.³ QARC has been involved in industry clinical trials both within the context of the cooperative groups and directly as a resource for data management in selected clinical trials which require both imaging and radiation oncology treatment endpoints. These trials often involve targeted therapy requiring treatment response assessment and evaluation of advanced technology radiation therapy treatment objects for treatment execution.

QARC's mission is to improve the standards of care in the management of cancer by improving the quality of clinical trials medicine. In support of the radiation therapy and diagnostic imaging programs within the cooperative groups, QARC provides an extensive array of services. These include protocol development, credentialing institutional performance, protocol case management (data acquisition, management, archiving, and

Fig 1. Growth of digital data archives from July 2005 through July 2007 measured in gigabytes.

sharing), radiology and radiation therapy case review, institutional performance reporting, research, and publications.

Since 1980, QARC has been continuously funded by the NCI Cancer Therapy Evaluation Program to acquire data and films for review and archival.⁴ QARC currently houses images and data on more than 40,000 patients (July 2007) treated on clinical trials since 1975. QARC houses images which are often no longer present at the home institution. The patient database at QARC is aligned to all of the cooperative groups served by QARC; therefore, outcome assessment is facile once permission is obtained from each of the groups for data evaluation. QARC currently serves as the quality assurance vehicle for the Children's Oncology Group (COG), the Pediatric Brain Tumor Consortium (PBTC), Cancer and Leukemia Group B (CALGB), Eastern Cooperative Oncology Group (ECOG), Southwest Oncology Group (SWOG), and the American College of Surgeons Oncology Group (ACOSOG). Across these groups, QARC manages over 300 clinical trials. QARC has excellent working relationships with each of the data and statistical centers and administrative leaders of these cooperative groups and has established a network with their associated diagnostic imaging and radiation oncology investigators.

Digital Imaging Management System

QARC has created a digital imaging management system through the integration of three key components. The first is QARC's patient database, which is a relational core application that is central to all of QARC's daily operations. This database currently houses data for over 40,000 patients (July 2007) and has evolved into a robust multi-institutional PACS environment. The second component is the Dicomcommunicator software, a program which is used at institutions around the world to facilitate the submission of DICOM imaging to QARC. QARC installs, configures, and supports this software at remote institutions. This application has been fully integrated into the patient database and further developed at QARC to be used as a tool to import DICOM imaging into the imaging archive. It also serves as a DICOM image viewer featuring advanced image manipulation tools. This viewer is built using the DicomObjects

toolkit provided by Dr. David Harvey, Medical Connections, Wales, UK.⁵ In 2006, the Dicomcommunicator software was further extended onto a web platform to facilitate the export of patient imaging from the QARC PACS to a secure QARC web server where physicians at remote sites can easily retrieve and review it. The final component of QARC's digital image management system is the network infrastructure, which includes an array of four 1.8 Terabyte servers that house QARC's digital archive of over 6 million DICOM image files.

Patient Database

QARC's patient database is a 21-CFR part 11 (Title 21 Code of Federal Regulations⁶) compliant relational system that is central to all of QARC's daily operations. This system currently houses approximately 30 years of QARC data. This database is used throughout all departments of QARC to monitor cooperative groups, institutions, contacts, protocols, correspondence, imaging, benchmarks, patient data, and reports. The user interface assists users in monitoring patients as they progress through the clinical trials process by generating alerts, correspondence, reports, data import/export utilities, audit trails, and by insuring the integrity of all data and digital imaging. The database also features an integrated QARC Knowledge Base (QKB) utility. This is an indexed help facility and library tailored for QARC staff. The database is under constant evolution and process improvement. Solid procedures are in place to assure the security and integrity of the data, including multiple auditing mechanisms, regular backups of the database and associated files, disaster recovery plans, and strict adherence to a change management process.

All submitted digital diagnostic imaging is stored in the QARC PACS archive and linked to the corresponding patient record in the database. This database is a large and rich archive containing images and specific details of target volumes. It is used to score institutional performance, which is later reported to the cooperative group performance committees. Analysis of data stored at QARC has provided investigators with information for presentations and publications. As the database continues to mature, QARC anticipates more investigators will be using data at QARC for various research endeavors.

Dicomunicator—Data Acquisition

Dicomunicator, a software program which helps to facilitate the DICOM image management process, is fully integrated with the QARC patient database. Dicomunicator was initially written by Dr. Keith S. White of Primary Children's Medical Center (Salt Lake City, Utah) and is used at institutions around the world to facilitate the submission of DICOM imaging to QARC. Dicomunicator was donated by Dr. White for use in the clinical trials process in 2000 and has since been managed and developed at QARC. QARC installs Dicomunicator at investigator institutions and integrates the software with the PACS system to provide a platform for seamless data exchange and image transfer. The software allows remote site Clinical Research Associate (CRA) staff to retrieve and forward de-identified and encrypted image objects to QARC.

Dicomunicator is compliant with the DICOM standard which defines guidelines for query, retrieval, storage, printing, viewing, and transfer of electronic images. The Dicomunicator software ideally resides on a PC that has access to both the PACS system network and the Internet and will allow the institution CRA to query or push imaging from the PACS to a local PC where she or he can select specific studies to send to QARC. The studies may then be sent by burning the images to a CD or via e-mail. The e-mail option is beneficial because it provides virtually real time submission of patient studies, which can be critical

when questions of patient eligibility for a clinical trial are a factor. The e-mail mechanism also allows the software to circumvent issues that arise with various firewalls when trying to use other forms of file transfer. User training is also straightforward, as e-mail is a technology that most computer users are familiar with.

A major advantage of the Dicomunicator software is that it scrubs demographic data (patient information) from the images (specifically Patient Name (H10,H10) and Patient ID (H10,H20) attributes) using methods provided by the DicomObjects Toolkit and replaces them with the cooperative group, protocol and patient registration number. It encrypts the images before sending them over the Internet as e-mail attachments. (This is a secure encryption algorithm that encrypts the entire image file.) Dicomunicator can compress the images and has the capability to determine how many images it can reliably send as attachments per e-mail message (e.g., can be configured not to exceed 2 Mb per e-mail). Dicomunicator relays the e-mails off of the institution's SMTP server to QARC. (QARC has no size limitation for received e-mail messages.) In addition, Dicomunicator maintains an audit history of submitted imaging that helps the CRA keep track of which studies have been sent to QARC. Figure 2 is an illustration of the software interface.

In July of 2006, the Dicomunicator project completed its pilot phase with 25 institutions fully licensed and operational. Dicomunicator can directly interface and query/retrieve DICOM stud-

Fig 2. Dicomunicator software user interface.

ies from eight different PACS vendors: Agfa, Fuji, GE, Integrad Web by Dynamic Imaging, Kodak, Philips, Siemens, Stentor. As the Dicommunicator project has progressed, QARC has focused on methods of process improvement including: expanding the list of supported PACS manufacturers to accommodate variations in the interpretation of the DICOM standard, streamlining the software's interface to increase ease of use in the clinical trials process, improving the remote installation process utilizing internet conferencing tools, and increasing awareness of the availability of the software through documentation on the QARC website and through presentations at cooperative group meetings.

Dicommunicator—Data Importing

Dicommunicator is a critical component of managing digital DICOM data at QARC. All DICOM imaging is imported into the QARC PACS, matched to the appropriate patient, and resolved to the patient's diagnostic record where it can be launched and viewed by a physician. The software is used to import DICOM studies into the database and match them to the appropriate patient record. During the import process, certain DICOM header attribute values are stored in the database tables allowing these fields to be easily queryable. The stored values are: Study Date (H8,H20), Study Description (H8,H1030), Modality (H8,H60), Patient's Name (H10,H10), Accession Number (H8,H50), Patient ID (H10,H20), Patient's Birth Date (H10,H30), Patient's Sex (H10,H40), Patient's Age (H10,H1010). When images generated from remote Dicommunicator sites arrive at the QARC server, they are extracted from the e-mails using the same Dicommunicator software and stored in the QARC imaging archive. Dicommunicator also has the ability to import imaging submitted on CD in DICOM format. As most institutions prefer to forward image objects to QARC through CD, it is critical that QARC's image management software is able to provide this type of flexibility. CDs contain data representing many electronic formats, both with and without proprietary headers; this often creates unique issues in opening and archiving data. Dicommunicator has been developed to accommodate DICOM image files originating from a wide variety of imaging vendors.

A QARC CRA reviews each submitted CD and determines which of the studies are needed for diagnostic imaging central review endpoints. This step, involving human intervention, is critical in the image processing workflow, as it may take a number of requests to get the correct data submitted to QARC. CRAs are also able to address proprietary files or identify image quality issues before the data is integrated into the QARC PACS. The CRA updates the patient's diagnostic inventory in the patient database and completes an automated form which establishes a worklist. (See Fig. 3.) Documentation coordinators then extract each study as indicated on the worklist and import it into the patient database using Dicommunicator. During the import process, documentation coordinators assign Cooperative Group, Protocol and Patient Case Number values to each study according to the information provided by the treating institution. Images are stored in a folder structure and organized according to the following hierarchy: (1) Cooperative Group, Protocol, Patient Case Number, (2) Study UID, (3) Series UID and (4) image files, as depicted in Fig. 4.

Once the DICOM image files are imported into the PACS, a QARC CRA verifies the imported imaging and resolves each study to the corresponding event and study on the patient's electronic diagnostic record in the QARC database. Each study is uniquely linked to the event and study on the patient record by the StudyUID attribute associated with the images. Patient records are linked to image files within the patient database as shown in the schematic labeled Fig. 5. The QARC CRA sets up a template for each study, which indicates which studies are expected at what clinical trial time point. These become the events, so that imaging studies in the QARC PACS are catalogued with the study relevant time points (e.g., post-two cycles of chemotherapy, at treatment completion, post-second surgery, at relapse, etc.)

This system creates one comprehensive database where a physician can easily query for a patient, launch and view a specific study with a few simple mouse clicks. Figure 6 depicts a view of a patient's diagnostic record in the database, and Fig. 7 illustrates the viewer that launches the patient imaging directly from the diagnostic record. The entire workflow process for receiving, identifying, logging, and importing digital imaging has evolved to become completely digital and is

Fig 3. DICOM image import administrator.

managed through a database utility called the “Dicommunicator Import Form Administrator,” which allows a user to quickly and easily track the status of any patient’s imaging.

Dicommunicator—Data Exporting

Through continued collaboration with Dr. White, QARC extended the original Dicommunicator application onto a web platform to create a tool used for remote web-based review of objects stored within the imaging archive. QARC calls this latest version Dicommunicator.net, which was developed within the Microsoft .NET framework as its name suggests. QARC built utilities, which allow internal CRA staff to export imaging from the QARC PACS to a secure web server where study radiologists at remote sites can retrieve and review it. This export utility de-identifies each image by removing the Patient ID (H10,H20), Patient Name (H10,H10), Institution Name (H8,H80), Patient DOB (H10,H30), and Referring Physician Name (H8,H90) attributes using methods provided by the DicomObjects Toolkit. As QARC participates in cooperative group studies,

which require real time response review of intended radiation therapy treatment strategy, this vehicle permits study investigators to remain actively involved in the daily management of their study. Thus, investigators have full access to data and images of patients on their studies. The Dicommunicator.net application utilizes the same DICOM viewer and image manipulation tools as the Dicommunicator applications installed at QARC and at remote sites (See Fig. 8).

RESULTS

As evidenced by the implementation of a fully functional PACS environment, the trend from film to digital submission has caused a shift in the workload from the institution to QARC, contributing to a need for a larger IT staff and the addition of student interns to help import the imaging from CDs into the PACS archive. In addition to advanced IT expertise and support, this new paradigm has created a need for an increase in IT skill set of all QARC staff. The QARC IT Department works to ensure that this is a smooth

Fig 4. DICOM image archive storage hierarchy.

Fig 5. Schematic of patient database relationships.

transition by writing QARC Knowledge Base (QKB) articles and storing them in a queryable database utility and through providing regular training workshops.

Rapid technological changes in both imaging and radiation therapy have created both opportunity and challenge for QARC. Incorporating emerging technologies and treatment strategies into protocols, evaluating an institution's ability to use new technologies, and developing data collection and review processes have required constant review of internal workflows and innovations at QARC. As cancer treatment protocols have become more complex with image-guided RT and multiple endpoints, QARC has adapted to support these new requirements. Image acquisition for therapy target definition and diagnostic imaging endpoints such as staging, eligibility, and

response require capturing both anatomical and metabolic images. QARC is constantly refining its ability to receive, review, and archive digital data from multiple electronic media.

These technological advancements have helped investigators to fulfill the requirements of protocol performance. The extra time required to manually copy and ship films to QARC has been eliminated, expediting the time to data completion, and thus, allowing more rapid case review and feedback to the investigators and sponsors. The expense associated with copying and shipping these films has also been eliminated, resulting in cost savings for the institution. Historically, a computed tomography (CT) study containing ten films might cost approximately \$200 to copy and an additional \$20 in courier costs to ship to QARC. Most institutions install the Dicomunicator software

Fig 6. Example patient diagnostic record as displayed in patient database.

Fig 7. Dicommunicator viewer and image manipulation tools launched directly from the patient database.

on an existing PC, and therefore, only need to purchase a license at a one-time cost of \$215 per installation. Under this generalized scenario, the Dicommunicator investment is roughly equal to the cost of one CT submission; therefore, subsequent submissions can be made at virtually no additional cost. In addition to the decrease in time to data completion and reduction in cost, QARC's centralized digital imaging management system provides a rich archive of complete uniform diagnostic imaging data sets, which are available for investigational research.

DISCUSSION

QARC strives to accommodate data submitted in multiple formats (including both digital and analog) so that a wide variety of institutions are able to participate in the clinical trials research. Currently, an increasing percentage of submitted materials are in digital format, and QARC expects to eventually receive all patient data submissions in this format. There are advantages to submitting digital diagnostic imaging rather than analog films that have most likely contributed to this trend. As

Fig 8. Dicommunicator.net software—user interface.

mentioned previously, sending studies in digital format is much cheaper and faster for the institution than copying film. Also, QARC receives complete studies without missing slices and with all of the windows (e.g., lung, bone, soft tissue), therefore, eliminating the need for follow-up requests for missing images and expediting the review process. Advantages to importing CDs into QARC's PACS archive include the accessibility of the imaging to the users and the convenience of having all patient imaging in one central database that can be launched directly from the patient record.

QARC personnel have developed the infrastructure and expertise to acquire and process case management data in multiple electronic formats through institutional performance credentialing, eligibility review, and timely acquisition for interventional review of study patients. QARC shares its strength in electronic data transfer with other quality assurance centers to promote uniformity and standardization in data transfer for images and radiation therapy objects. QARC collaborates with the partners of the clinical trial enterprise to be an important resource in quality assurance, promoting quality improvement strategies, and elevating the standards of care provided to patients treated for malignancies.

However, the evolution of this system has not been without challenges. As QARC archives data from institutions around the world, image submissions originate from a variety of different systems and vendors, each enlisting their own interpretation of DICOM. QARC IT staff continually develop the Dicomunicator software to accommodate this diverse data, using the DICOM standard as the guideline for acceptability. Another frequent issue involves institutional CRA staff, putting all existing studies for any given patient onto a CD (often with unclear or no labeling) and submitting it to QARC. Some institutions put studies for multiple different patients on one disc. Sorting and archiving this digital data can be time consuming and cumbersome for QARC CRA staff. In the past, when films had to be manually copied, more care was taken by the institutional CRA to send only the required studies. Now with the ease and low cost of copying studies onto CDs or sending them electronically, much of this work has shifted from CRAs at remote institutions to QARC personnel.

QARC's experiences with developing its digital imaging management system is a microcosm for larger industry trends and challenges related to digital image communication, standardization, and storage. The wide variety of PACS manufacturers in the field, coupled with the many different interpretations of the DICOM standard, creates an environment where it is difficult to transmit patient data across partnering institutions. QARC has devised a system that is able to import and standardize a diverse pool of imaging, as well as de-identify, encrypt, and share this imaging with treating physicians.

As the industry trend toward a filmless environment continues to progress, many hospitals are investing large amounts of money into implementing PACS tools to manage their patient data. This complex internal initiative is further complicated when institutions employing differing PACS vendors attempt to share patient data. As the DICOM standard matures and PACS manufacturers build more sophisticated systems, this type of data transfer may improve; however, this is somewhat dependent on collaboration among PACS vendors to design interoperable systems.

Some institutions may find that it is more cost-effective to build internal applications which help standardize, de-identify, and encrypt patient data for easy import, review, and export as QARC has done. Internal development will also give each institution greater control over how data is acquired, stored, and manipulated. As technology improves and hardware becomes less expensive, it is likely that the industry will move toward methods of image transfer over the Internet (rather than via CDs/DVDs and other media). QARC's Dicomunicator.net web tool allows treating physicians to retrieve and view patient data in a secure environment and is QARC's first attempt at leveraging the Internet for secure image transfer.

CONCLUSION

The Quality Assurance Review Center has evolved its IT infrastructure to create an environment that successfully manages digital DICOM imaging. Advancements include developing sophisticated software, evolving a comprehensive

patient database into a robust multi-institutional PACS, and increasing the IT skillsets of all QARC staff.

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