

An Effective Strategy for Streamlining Implementation of Digital Mammography

INTRODUCTION

Offering a range of benefits over traditional screen-capture techniques, sites implementing digital mammography are growing. However, converting to a digital environment is a complex transition and presents new challenges for workflow and data management. For many facilities, the entry price of equipment and of archiving large digital mammography files can be significant barriers to conversion.

Shared experiences from early adopters and published papers indicate that two areas of concern can readily be addressed; the comparison of softcopy images with analog films during the transition and the costs associated with managing the long-term archiving of digital data. The result of the transition to digital with these two barriers addressed can be beneficial to the imaging center and the patient. This paper discusses some of these benefits and conversion issues.

STATE OF MAMMOGRAPHY IMAGING

Of the 33.5 million mammographic studies completed each year, approximately 70 percent of those are obtained for screening purposes. At this time, the vast majority are acquired on analog imaging equipment.

Most experts agree that digital mammography offers a host of advantages over traditional screen-capture exams from both a patient care and practice management standpoint. Beginning with higher throughput resulting from workflow enhancements in both the exam rooms and radiologist review. In addition, a digital environment provides:

- Superior image quality due to the ability to enhance image contrast and density
- Enhanced visualization of image detail through image magnification and manipulation
- Elimination of hardcopy fileroom space and management of hard copy archives
- Ability to have multimodality diagnostic quality workstations with integrated CAD.

At a multi-modality workstation, the ability to review ultrasound, MR images as well as mammograms on the diagnostic quality monitor.

As of mid-year 2006, more than 10% of the 10,000 breast cancer-screening facilities approved by the U.S. Food and Drug Administration had purchased full field digital mammography (FFDM) devices.(1)

But the opportunity for digital imaging in mammography is changing because of two factors:

- As early as October 2006, the findings of a highly anticipated national study are expected to show the efficacy of digital mammography over standard X-rays. The study, conducted by the American College of Radiology Imaging Network, will be presented at a medical imaging conference on Sept. 16. The results could raise the profile of digital breast-cancer screening and boost demand for digital medical-imaging equipment.
- With the recent FDA approval of the first of several in a pipeline of computerized radiography (CR) devices for digital mammography, the adoption is expected grow even more quickly because of lower conversion costs.

Lastly, in addition to new CR devices is the coming of Tomosynthesis, an investigational technique shows great promise in reducing “call-backs” for ambiguous results created by screening mammograms. (2)

(1) Forbes, September 2006, Danit Lidor

(2) Health Imaging & IT, April 2006, Cheryl Hall Harris, RN - A report at the 2005 RSNA meeting revealed that about 12 percent of screening patients require additional imaging studies. However, investigators at the Dartmouth Hitchcock Medical Center in Lebanon, N.H., reported that of a cohort of 98 women with questionable results on FFDM (full field digital mammography) 49 would have been given a definitive diagnosis on the first try with tomosynthesis.

STORAGE DEMANDS OF DIGITAL MAMMOGRAPHY

Digital mammography techniques described above impose greater demands on an archiving system with implications for how these systems should be designed, managed and implemented.

The demands include:

- **Larger file size**

Individual image files may be up to 25 MB in size based on the FFDM manufacture, compared to typical X-ray files which range from 5 to 8 MB. Moreover exams may have as many as 10 views when considering imaging dense breasts with implants.

- **Need for ready access to prior exams**

Mammography reading protocols call for comparison of current images to all prior exams. In order not to impede workflow, the archive must have the capacity onsite to accommodate this requirement and ensure that data is local to the reading workstation.

- **Strict government regulations**

Digital mammography images are subject to a range of regulatory standards including the Mammography Quality Standards Act (MQSA) and the Healthcare Information Portability Act (HIPAA), both with implications for how files are archived.

Under MSQA, mammography files must be stored losslessly, meaning that they retain their full fidelity in contrast and spatial resolution. Moreover, the length of time to store mammography images exceeds the life of the technology used to store them.

HIPAA regulations dictate that health care facilities must be extremely careful to document steps taken to meet security and data integrity capabilities of the storage solution. In the digital domain this is higher than in the analog film as the expectation is to have a data disaster recovery method in place in the event of an audit.

Even facilities that have been storing images electronically for other modalities find that the addition of digital mammography calls for a major expansion of an existing archive or a completely new archiving system.

IMPLICATIONS ON STORAGE SYSTEMS

The above factors elevate both the costs and complexities of implementing digital mammography storage. Even facilities that have been storing images electronically for other modalities find that the addition of digital mammography calls for a major expansion of an existing archive or a completely new archiving system.

In particular, to accommodate FFDM studies, an archiving implementation demands:

- **Significant scalability**
Predicting storage needs long-term is difficult for any imaging facility across all modalities. Again, in mammography, large image size and regulations that call for lengthy storage time increase this difficulty exponentially. Therefore, an archive needs significant built-in scalability to accommodate future storage needs.
- **Budget for archive implementation and maintenance**
Capital costs of storage media and software are only a small portion of the expenses of a digital archive. Other costs include upgrades of both hardware and software as technologies advance and storage needs expand, as well as facilities maintenance and management.

- **State-of-the-art image communications technologies**

Today, many imaging departments and freestanding centers outsource some of their reading. Many practices operate in multiple locations. Additionally, exams may be read by consulting radiologists for specialized diagnoses and second opinions. All these situations call for remote communications of current and prior images, which must be addressed with potentially high-bandwidth networks.

OPTIONS FOR BREAST ARCHIVING SOLUTIONS

The unique storage demands of digital mammography create specific criteria when considering digital mammography storage any facility including:

- **Capacity to address access to prior exams**
Every patient has varying history of prior studies. Access time required to transmit an image from an archive to the workstation. Data management tools exist to allow sites to consider whether or not all studies must be stored onsite or whether a combination of onsite/offsite provides protection and access in a balanced way.

Generally a balanced configuration of onsite/offsite provides the HIPAA protection sites need with access images are pre-fetched, that is transmitted to a workstation in advance to eliminate waiting and provides the capacity required for long term storage without onsite space constraints.

- **Cost-effective pricing model**

The mammography exam sizes coupled with the need for exams to be recalled frequently and retention often exceeding the life of the storage technology, archiving price structure is a key consideration. Ideally to manage costs, sites should consider how to create a one fee for the life of the study, regardless of file size and how often the image is recalled. Otherwise, archive storage costs can mount rapidly.

- **Standards-based archive**

The sharing of medical data, especially in women's health drives the need to have data stored in a format that can be easily interpreted by multiple applications. In some cases single institutions may have multiple vendor reading stations. Using guidelines from IHE and format standards like DICOM will assure the compliance in multi-user environments.

- **Quality customer support**

Again, because of the need for ongoing access to prior exams, responsive customer support is particularly important for an outsourced archive, If a problem prevents ready access to these exams, workflow suffers far more than for other modalities making customer support even more crucial.

BENEFITS OF OURSOURCING ARCHIVING

Outsourcing FFDM storage to the right provider can be an extremely successful cost and operational strategy for managing the complex demands of digital storage, especially with mammography.

Outsourcing FFDM storage to an appropriate provider can offer a host of benefits including:

- **Minimization of expense for managing the archive**

A consistent major advantage of outsourced archiving is the ability to shift the large expense of archiving media from a capital purchase to an operating expense. This includes the staffing, the equipment and the space.

Archive service providers offer a range of payment structures, but generally eliminate any upfront capital expenses. By eliminating archiving capital expenses, outsourcing storage may enable facilities not otherwise able to fund a digital conversion to do so.

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- **Built-in scalability**

With an archiving service provider, scalability is built-in. Naturally, unlike an in-house archive, a large commercial storage provider can accommodate unanticipated escalation of storage needs. Conversely, if storage needs are less than anticipated with an outsourced archive, a site need not carry the costs of unnecessary archiving hardware that eventually will become obsolete.

- **Elimination of the expenses of archive implementation, management and maintenance**

A managed archive provider assumes full responsibility for any necessary onsite hardware installation as well as the administration and maintenance of your archive. This eliminates the need for IT staffing, checking for data integrity and other system maintenance. A trusted service provider should have full mirrored archives in two geographically separate locations, not only protecting your data in the event of an emergency but also assuring business continuity.

As a result, archiving costs are more predictable and controlled than with an in-house archive. Moreover, the archive management may be more thorough and streamlined than when implemented in-house because it is maintained by IT archiving experts.

- **Minimization of multi-format image storage**

For many facilities, outsourcing archiving also offers opportunities to minimize the disruptions created by maintaining both hard and soft-copy storage for prior exams.

Sites using film capture that also use CAD or that wish to scan in existing films in advance of a digital conversion can take advantage of an outsourced archive to streamline operations once they convert.

InSiteOne represents an example of an outsource solution provider with over 6 years experience in providing managed archive services. InSiteOne offers a cost effective pricing structure for FFDM storage service. This service offers redundant back up in multiple locations as well as advanced image pre-fetching and communications technologies. Like all of InSiteOne's managed services, the FFDM archiving service charges one set fee for the life of the study regardless of file size and allows unlimited access to all images.

CONCLUSION

In conclusion, FFDM files place a specific and challenging set of demands on an archiving system. For many facilities, these demands can be met most cost-effectively and efficiently by an outsourced managed archiving provider. Sites wishing to outsource FFDM storage should examine a full range of considerations and select such a provider carefully.

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