Taking Your Imaging Environment Totally Filmless and Fully Compliant

EXECUTIVE SUMMARY: GOING FILMLESS IS EASIER THAN IT LOOKS

As the medical world moves to Picture Archiving and Communication Systems, PACS, for filmless imaging, many facilities are wrestling with the issues of working in a hybrid environment, and then managing costs and compliance once they're fully converted to digital.

During the transition, radiologists don't want to work with analog films and digital images side-by-side, for productivity and interpretive reasons. And facility administrators don't like spending extra money and using even more space and staff to handle both digital images and film at the same time.

For facilities that have completed the move to PACS, new issues are emerging, such as exploding storage costs, compliance issues and disaster recovery requirements.

This white paper examines how strategically outsourcing key services can provide a cost-effective lifecycle approach to managing both the transition and the full PACS radiological environment. By taking advantage of outside expertise — and offloading many of the risks and costs of conversion and storage technology — facilities can achieve a filmless environment quickly. What's more, they can move forward with a full PACS implementation while controlling costs and ensuring compliance with HIPAA regulations.

By understanding the issues and costs involved in the PACS lifecycle, medical facilities can take their imaging environment totally filmless while minimizing costs and helping the institution achieve its true core objective, better patient care.

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ABOUT IRON MOUNTAIN INCORPORATED

Iron Mountain Incorporated (NYSE:IRM) helps organizations around the world reduce the costs and risks associated with information protection and storage. The company offers comprehensive records management and data protection solutions, along with the expertise and experience to address complex information challenges such as rising storage costs, litigation, regulatory compliance and disaster recovery. Founded in 1951, Iron Mountain is a trusted partner to more than 90,000 corporate clients throughout North America, Europe, Latin American and Asia Pacific. For more information, visit the company's Web site at www.ironmountain.com.

I. BACKGROUND: THE MOVE TO PACS

PACS is a revolution that is moving rapidly through the practice of medical imaging.

A 2005 Rand Corporation study found that "36 percent of acute hospitals were committed to adopting radiology PACS; 27.5 percent had already installed the system; and 8.5 percent had signed a contract to buy a system."[1] By most estimates, in 2007 roughly half the hospitals and major radiology centers in the United States were converted to PACS to some degree.

There are many powerful drivers behind this important shift to technology. One is that U.S. federal law requires that by 2014, medical providers must be using electronic records or risk losing reimbursement from Medicare and Medicaid.

Other drivers include the myriad of financial and performance pressures on radiology in particular and healthcare in general. According to the American Healthcare Radiology Administrators Foundation, radiology is feeling the affects of an aging workforce, reduced medical reimbursements, workflow inefficiencies, and the fact that institutions are increasingly dependent on revenue generated from imaging modalities.[2]

Also, like all specialties in healthcare, radiology is feeling the pinch from rising costs coupled with limited budgets.

Evidence shows that digital imaging reduces costs and improves efficiencies, because radiologists can more accurately review a greater number of patient studies when in digital format. Instead of viewing a printed image with a light box and magnifier, radiologists now have the capability to view images on specialized viewing monitors that offer far greater power and flexibility. With digitized images, a radiologist can zoom in on details, instantly call up and compare digitized historical studies, and perform many other manipulations.

PACS AT A GLANCE

In a Picture Archiving and Communications System (PACS), digitized images from various modalities — including CT, MRI, Ultrasound, X-ray and others — are saved, archived and retrieved for viewing in a standard format developed by the American College of Radiology and the National Equipment Manufacturers Association (NEMA). This image standard, known as Digital Imaging and Communications in Medicine, or DICOM, allows facilities to share images regardless of their PACS vendor.

Digitized images are typically combined with an indexing of patient demographic and exam information and stored on high availability servers, where they can be accessed through specialized viewing monitors for analysis and comparison with historical studies.

Workflow efficiencies are gained too. Facilities can move the files around easily, view from a remote location, and share them with multiple specialists at the same time. A typical experience is that of Gregg A. Alexander, MD, writing in *Orthopedic Imaging:*

"This new digital workflow has enabled us to accept a growing number of patients with our existing facilities and a smaller staff...Furthermore, we have found that electronic image capture and management save time for everyone involved in the health care delivery process — orthopedic specialists, technologists, staff, and patients."[3]

The real question is not *if* hospitals and clinics will move to an all digital imaging environment, but rather *when* and *how.* Once a facility decides to move forward, it must deal with two major stages. First, the transition itself which often involves providing care in a hybrid film-digital environment. And second, the post-implementation phase where ongoing costs, upgrades and disaster recovery issues come to the forefront.

[1] "The State and Pattern of Health Information Technology Adoption," by Kateryna Fonkych, Roger Taylor, Rand Corporation, 2005

[2] American Healthcare Radiology Administrators Foundation Partnership Initiative Overview

[3] "Enhancing Productivity Digitally" by Gregg A. Alexander, MD, *Orthopedic Imaging,* March/April 2005

Understanding the choices available at each stage, and the costs and benefits associated with each, will help facilities make decisions that are right for them.

II. DEALING WITH HISTORICAL FILMS: WHAT ARE THE CHOICES?

Adopting PACS is clearly desirable as well as necessary. However, moving to digital storage and retrieval does not create a filmless environment overnight. Facilities must still decide what they will do with their historical film-based images. There are three basic strategies/approaches to addressing historical analog libraries.

1. Keep the status quo and accept a hybrid environment

In this approach, new images are stored and viewed digitally, but old studies remain in film format. This requires radiologists to work in a hybrid environment, often comparing physical film on a light box to digital images on a viewer.

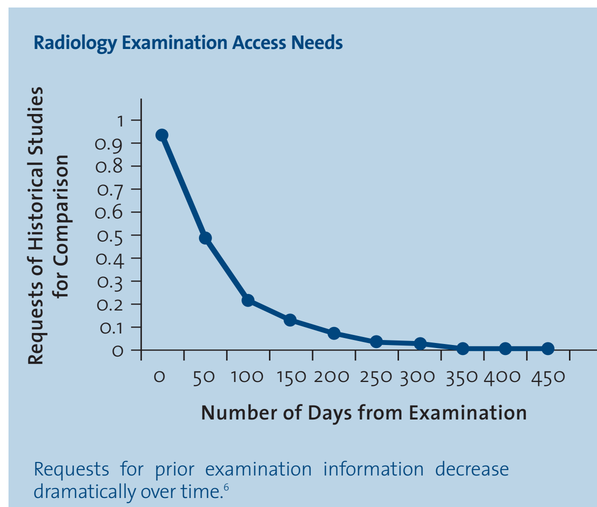
Few radiologists favor this approach. It slows down efficiency and impairs the radiologist's ability to compare studies with confidence. A SIIM (formerly SCAR) 2001 study found that presenting newly digitized analog films alongside PACS images increases productivity by up to 25%, versus comparing digital images with film studies in a hybrid environment.[4]

Bonnie Rush, president of Breast Imaging Specialists (BIS) and a leading authority on digital mammography and breast imaging, points out that viewing stations require moonlight conditions (about 3500 nits), while monitors need a nearly pitch-black room (about 180 nits), so separate reading rooms may be needed. (A nit is a unit of measurement of luminance, equal to one candela per square meter.) In her view, this increases the difficulty of comparing hybrid studies and introduces risks such as eye fatigue and difficult viewing angles that could lead to the missing of subtle findings.

2. Backfile conversion of entire film libraries

Another option is to invest in a comprehensive backfile conversion, in which all the historical studies are digitized at once, or as quickly as possible. This has the obvious benefit of creating a filmless environment, which radiologists welcome because of the improved viewing and access abilities, and administrators welcome because the floor space devoted to film can be quickly reclaimed and put to other, revenue-generating uses. However, the conversion process is disruptive and can take weeks if not months.

Further, for most hospitals and clinics, backfile scanning is prohibitively expensive. The average cost of digitizing film is $1-2 per image,[5] including the cost of the digitizing scanner, which can run from $30,000 to $60,000, plus staff training and time. Of course, once the process is complete, the facility has a costly digitizer that it no longer needs on its premises. A facility could choose to outsource the backfile conversion, but the overall cost is roughly the same once the outside fees are factored in. In addition, the digitized scans must be stored somewhere, either on premises or with a third party, and as discussed later in this paper, the cost of storing these large files can run into the tens of thousands of dollars.



Requests for prior examination information decrease dramatically over time.[6]

4 "Picture Archiving and Communications Systems: Strategic Considerations," VHA Inc., 2002

5 Mark Rempe, VP Health Information Services, Iron Mountain

6 "Solve the Enterprise Archive Puzzle," by Robert A. Cecil, PhD, www.imageeconomics.com, Jan. 2007

Perhaps even more compelling, research has shown that in most facilities, a large volume of historical studies will never be needed again. After two years the number of historical studies that are retrieved falls to below one percent. For most facilities, it makes little sense to pay the cost of converting films that will likely never be needed.

3. Convert on demand

A third option that is being adopted by many facilities is a "go forward" approach by converting on demand, or "as you go." Rather than converting all film in the image library, a facility only converts historical studies as they are needed for specific cases and treatments.

This approach has several obvious benefits, most notably lower overall conversion costs, because there is no need to pay for digitizing every file. Additionally, converting on demand means paying as you go, which allows a facility to spread the cost of conversion over a greater time period as each conversion is linked to a specific case under treatment over time.

While converting on demand makes sense both economically and from a patient care perspective, there are still issues to consider if the process is undertaken in-house.

For one, a facility must maintain its film library, in addition to pulling historical films and digitizing on demand, which means more space, instead of less space, will be used for a few years until the film libraries are retired to archiving. The scanner itself, as noted above, costs between $30,000 and $60,000, and it requires both space and specially trained staff who are trained to use it.

All of these approaches offer advantages, but also involve trade-offs that may not be acceptable to many institutions. The next section discusses a solution that is gaining in popularity: Outsource imaging on demand, which achieves the benefits of digital without most of the drawbacks.

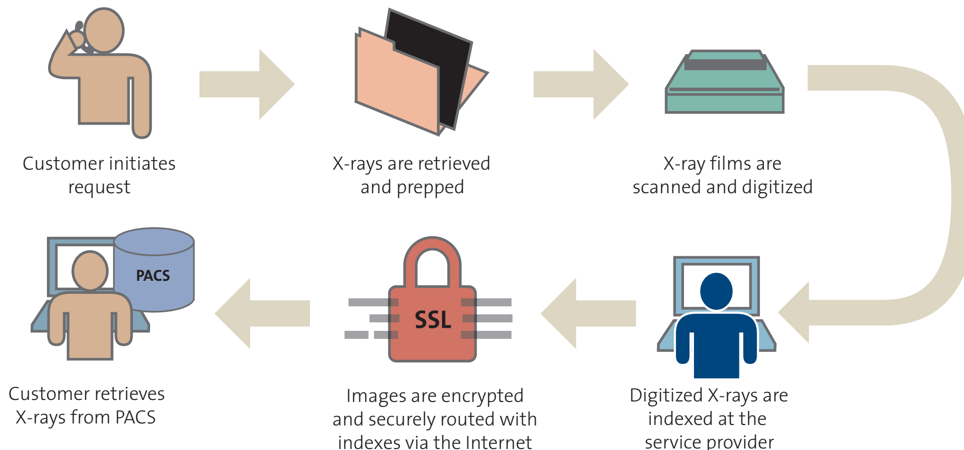
THE SPECIAL CONCERNS OF DIGITIZING MAMMOGRAMS

While not allowed for final interpretation, digitized images of previously obtained mammograms may be used for comparative purposes if the interpreting physician deems acceptable. If digitized images are used for comparison purposes, the FDA recommends only digitizers approved or cleared by the FDA's Office of Device Evaluation for such purposes be used. In addition, the FDA recommends that phantom and clinical images produced by such digitization pass all applicable quality control tests and be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.

(Source: The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9)

III. AN OUTSOURCE APPROACH TO IMAGING ON DEMAND

Many healthcare facilities are using an outsource approach to imaging on demand, in order to gain the benefits without the costs or other drawbacks. This approach allows facilities to instantly free up space, while providing radiologists with all the advantages of a filmless viewing environment.



Typical workflow for outsource imaging on demand. Film libraries are stored off-site with a vendor, who then digitizes and transmits the images as needed by the hospital or clinic.

How outsource imaging on demand works

In an outsource imaging on demand approach, film libraries are relocated to a vendor's site. Then, as needed and requested by the hospital or clinic, the vendor digitizes the analog films and sends the converted images to the facility.

The radiology film is digitized and formatted as a DICOM image that can be read and archived by a PACS, regardless of the vendor. Once scanned, DICOM images can be indexed and identified according to each facility's preferences. Indexes can include various information such as Accession number, Terminal Digit (TD) number, Master Patient Index (MPI) number, name, social security number, etc.

Images are typically encrypted and sent directly into a hospital's PACS over a secure connection using a Virtual Private Network (VPN). Once received by the hospital's PACS, the image can be registered with the hospital's Radiology Information System (RIS) and then accessed by radiologists for analysis and comparison with other digital studies stored in the facility's PACS.

The hospital or clinic must consider the communication bandwidth available between the vendor and the facility, because that will affect access time and how far in advance a study needs to be ordered. For example, a typical chest X-ray is a 40 MB file and can be transmitted to a provider across a T1 line in minutes, and across an OC3 line in just a few seconds. For a slow connection, the biggest factor in timing could be the transmission; for a high-speed connection, the most important factor could be the time it takes to pull the film and digitize it.

Of course, while high-speed lines enhance productivity they also cost more, so the facility must weigh the trade-off between bandwidth and cost.

Advantages of outsourcing on demand

By outsourcing the conversion on an "as you go" basis, hospitals and clinics gain several benefits.

Not least is the immediate conversion to a filmless environment, which, as discussed above, is preferred by most radiologists. Instead of comparing soft and hard copy studies and moving from light box to monitor, radiologists can always compare digital-to-digital, with all the attendant benefits of image manipulation, greater productivity, reduced patient waiting and improved patient care.

The entire facility also benefits, through improved overall efficiency and workflow productivity in the institution.

In addition, facilities are able to move as much of their film library off-premises, as desired. This not only frees up immediate floor space for other uses, it also shifts the film storage from a premium real estate location — the medical facility — to the vendor's lower cost storage location.

At the same time, the medical facility avoids having to invest in expensive digitizing equipment. The burden of buying and maintaining the scanning technology is shifted to the vendor, who is better positioned to keep that technology up to date and who can amortize the cost over multiple customers. The medical facility pays only for the scans that are needed, a service that typically includes preparation, scanner costs and direct labor costs in the range of \$2 to \$10 per study, depending upon the modality.

"Due to efficiency gains in our processes, we were able to save six full time employees and satisfy the hospital's radiologists"

Chief Information Officer
PinnacleHealth

Of all the available options, outsourcing imaging on demand offers the lowest cost of ownership for most institutions. The hospital or clinic benefits from:

- a filmless environment for comparing studies
- the vendor's expertise, technology, and lower-cost storage space
- elimination of capital expenditures on conversion equipment
- immediately recoverable floor space due to film libraries stored off-site
- reduced staffing requirements
- cost-effective "pay as you go" approach

IV: AFTER THE CONVERSION: CONTROLLING COSTS AND ENSURING COMPLIANCE

Institutions that have moved to PACS have discovered that once the conversion to digital is finished, the challenge is not over. On-going costs and compliance issues emerge over time for the PACS-enabled facility, often creating a new set of challenges and budget pressures.

The high cost of digital storage

Diagnostic-quality images are captured using extremely high resolution modalities resulting in very large electronic files. Digital images are considered a legal record — and therefore cannot be altered in any way. Furthermore, while compression technology exists that can reduce the size of electronic files, compression is only minimal (currently only 2:1).

A large hospital can create 3-4 petabytes of data in a year (a petabyte equals one million megabytes or 10^{15} bytes). Storing such large volumes of data requires special storage environments that are significantly more complex and costly than storage of other electronic records. In addition, image size and resolution are increasing as technology advances. More images are being captured too, as more and more illnesses are being diagnosed with digital images across an increasing range of clinical specialties, including radiology, cardiology, mammography, and pathology.

Because of these factors, it is estimated that diagnostic image storage needs will double every three years, with long-term storage and retention requirements ranging from a minimum of five years to the life of the patient.

Digital storage is not cheap, either. The first terabyte (trillion bytes) of storage media alone can cost $20,000 — excluding management overhead, space, cooling and power, etc., and each additional terabyte may run to $8,000. While storage media prices typically go down over time, image size and digital modalities continue to increase. It's typical for a facility to face additional major storage purchases within the first year of their PACS operation.

To control these costs, PACS-enabled facilities can lower costs by improving storage architectures. For example, Hierarchical Storage Management (HSM) allows the most recent images to be stored in short-term, high-performance spinning disk, while moving older images into lower cost medium and long-term tiers for archiving.

In addition to storage costs, there are other "hidden" costs as well, such as "personnel costs for system and network maintenance and administration, along with support costs for software, hardware, and the network" which can cause the actual cost of a PACS to be twice as much as the original acquisition price.[7]

Technology obsolescence

The more a facility invests in on-site technology, the more it risks paying for obsolete equipment. This has been true historically, and with technology advancing at an ever-faster pace, it will certainly be true in the future.

According to an article in *ImagingEconomics,* "It is not uncommon to replace PACS hardware every 4 to 5 years and to upgrade software each year."[8]

[7] "The New PACS Puzzle: Cost and Technology Change, " by Michael J. Cannavo, *ImagingEconomics*, July 2005

[8] IBID

Disaster recovery

An important question is, how do disaster recovery (DR) plans and HIPAA requirements relate to PACS installations?

HIPAA's Security Rule Act is written to be "technology neutral," leaving room for each covered entity to choose the technology best suited to its needs. The act spells out three requirements of a facility:

- You must conduct a formal analysis of risks to data
- You must produce a DR plan that covers backup, storage and recovery
- You must identify and reasonably address the identified risks

A facility must have a backup copy stored at an off-site location, and the facility is responsible for ensuring that the data is protected and secure during storage and any transportation.

Unfortunately, what this means in practice is anything but simple and clear-cut. A recent article in *TechRepublic* noted that "The HIPAA regulations regarding the security of digitally stored information are complex and difficult to navigate at best."[9]

What is clear is that facilities moving to PACS must be prepared to reevaluate their disaster recovery plans, and likely revise their practices to ensure compliance.

Outsourcing PACS archiving and disaster recovery

Because of cost and compliance issues, many facilities find it cost-effective to outsource some portion of their PACS operation and their disaster recovery planning to a third-party vendor.

An outsourced archiving program linked to a disaster recovery plan allows a facility to solve two problems at once while often gaining cost benefits. For example, the same facility that stores the archived images can also cost-effectively make the copies and vault them in secure, protected storage for disaster recovery.

By outsourcing PACS storage and disaster recovery, the medical facility offloads the burden of buying, maintaining, operating, and upgrading technology.

The more that is outsourced, the more that the technology burden is shifted to the third-party vendor. As discussed above, ongoing technology and obsolescence costs can be significant, if absorbed by the medical provider. The third-party storage vendors, on the other hand, specialize in this type of technology management and are able to spread the cost over much greater volumes of data received from multiple clients. By outsourcing PACS storage and disaster recovery, the medical facility offloads the burden of buying, maintaining, operating, and upgrading technology.

How much of the image storage should be outsourced? That depends on the specific needs of the facility, the bandwidth between your vendor and the facility, and other considerations. Most facilities will prefer to have the newest images stored on-site for the fastest possible access. However, if you have a high-bandwidth connection (such as OC3 and faster) between your facility and the vendor, you can consider storing even current studies off-site. A vendor that specializes in this area can assist with developing the most cost-effective storage architecture and network design, matching your storage needs and bandwidth to provide the right balance between cost and performance.

Finally, an outside vendor can provide special expertise in creating a best-practice storage solution that meets or exceeds HIPAA mandates, and provides disaster recovery capabilities that minimize the costs and time to recover from system failure or catastrophic disaster.

9 "HIPAA Compliance and Disaster Recovery" *Tech Republic,* Feb. 13, 2006

V. CONCLUSION

The move to PACS is extremely beneficial, but there are many choices along the way. Hospitals and clinics need to understand the options and the trade-offs associated with each choice.

During the transition to PACS, most facilities will want to avoid a hybrid environment that forces radiologists to compare primary digital studies to prior film studies. Experience shows that digital-to-digital comparisons are not only faster, but are less prone to mistakes and thus result in better patient care. Since digitizing all historical films is costly, most facilities prefer an on demand approach where films are digitized as needed. When on demand digitizing is handled by a third-party vendor, facilities minimize capital costs, free up floor space, simplify staffing requirements, and achieve a filmless imaging environment for comparing studies.

Once the move to PACS is complete, medical facilities face the continuing costs of maintaining, upgrading and replacing storage technology, while meeting new and complex HIPAA compliance issues. For these reasons, many facilities find it cost-effective to outsource disaster recovery and some portion of their operations to a third-party, long-term storage and disaster recovery specialist who can advise on the best storage solution and a disaster recovery plan that meets or exceeds HIPAA requirements.

By understanding the issues and costs involved in the PACS lifecycle, medical facilities can make decisions that minimize the costs, maximize the benefits, and help the institution achieve its true core objective, better patient care.

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