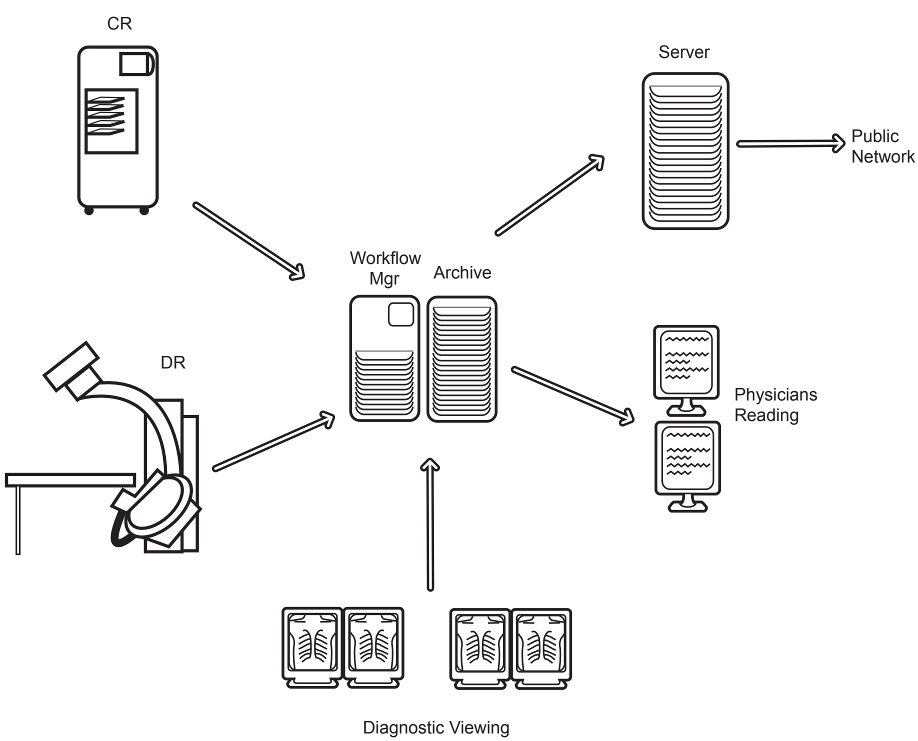
1 Introduction

1.1 PACS Introduction

A PACS system displays, archives and communicates medical digital images. It provides an electronic alternative to using conventional, analogue methods of acquiring and diagnosing medical images using film. Implementing PACS is non-trivial, and results in major changes in the organization because of its different technology and the expertise required using and managing it.

A Picture Archiving and Communication System (PACS) provides for the viewing, storing and retrieving, communication and managing of medical digital images and related information. The related information could be patient demographic information, contain diagnostic reports, or clinical history. The managing aspect facilitates the workflow of an imaging department such as organizing studies, presenting them in a consistent manner in the form of work lists, and keeping track of study status. In order to provide these features, a PACS system consists typically of an archive device, diagnostic viewing stations for radiologists and clinical review by physicians, server(s) to distribute the images via a public network and the required database and workflow management software. Digital X-ray modalities such as Computerized or Digital Radiography (CR/DR) are sometimes considered PACS components as well.



Implementing a PACS system is a major undertaking. The underlying technology is the representation of diagnostic images in electronic form, typically referred to as "softcopy" instead of hardcopy, i.e., on a film. The major difference between these technologies is that in the analogue world, a film was used not only to capture the image information, but also to communicate and archive it. Conversely, in the digital PACS world, the capture, communication, viewing, and archiving are all using digital data, and as many identical copies can be made available as needed. It is therefore possible to provide simultaneous immediate access to the images at any time and in any place. Shifting from using film to viewing images on a computer screen requires a total paradigm shift on the part of the user. Some of the work actually disappears, most notably the many functions related to managing and operating a film file-room. At the same time, other work functions are created, such as system administrators, application specialists, and those involved with the training on these new devices. The workflow changes totally. It is like applying "re-engineering" to a department and the entire organization.

A significant PACS implementation barrier is the cost of the system. Unfortunately, most of the savings are "soft" and not directly traceable back to the Radiology department itself. Particularly, when a PACS investment is competing with, for example, the acquisition of a new digital modality such as a CT or MR, which immediately generates new revenue upon installation, it is sometimes difficult to make a good business case.

In some cases, the implementation of PACS is encouraged, or strongly favored, by national reimbursement policies or federal initiatives. For example, a country such as South Korea, struggling with a weak currency and a national payment deficit, favors examinations using PACS versus expensive film, which is typically paid for in hard foreign currency. The number of PACS installations there exceeds installations in many other countries of the world. Other national initiatives in some of the Scandinavian countries also resulted in very rapid PACS roll-outs in the majority of hospitals.

PACS systems are not only challenging from a personnel perspective, because of the changes in work habits, workflow, and the learning of new skill sets, but also from a technical viewpoint because the used technology is very much state-of-the-art and cutting edge. Digital acquisition using Computerized and Digital Radiography uses detectors that are just barely matching the resolution characteristics of the film-screen combinations, display technology can only barely match the quality of the images on the film, high speed networks are just fast enough to meet the demands of making the images available at any place in real-time, and affordable storage technologies are only recently available to meet the demands of the huge digital data generation. Therefore, users have to take into account that these components are sometimes more on the "bleeding edge" than the "leading edge." This impacts availability, serviceability and reliability of some of the components. In addition, it is unfortunate but having very specific requirements, especially for acquisition and viewing, rules out the use of several commodity products such as used in the consumer industry.

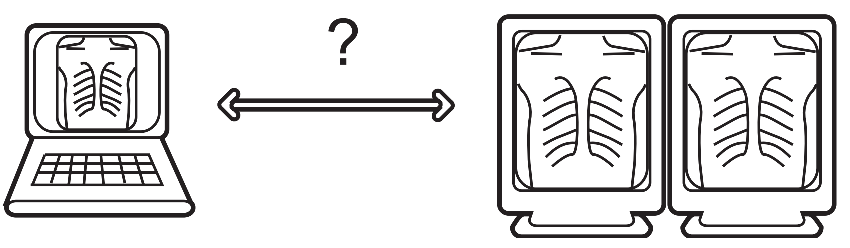
Change can be frightening to people, and the implementation of this new technology is no exception. However, early experiences have shown that PACS technology is more efficient, more effective, and generates long-term cost savings. Other areas are converting from analogue to digital technologies as well. For example, 2003 marks the first year that the sales of digital photo cameras for consumers exceeded analogue, film-based camera sales world-wide. PACS is no exception. It follows the general trend to replace analogue with digital technologies. The question for each institution is not whether or not to jump on the PACS band wagon, but rather when to do it.

1.2 PACS Through the Years

PACS through the years definitely has been a "lessons learned" experience. This chapter describes some of the history and evolution of these systems as well as early experiences.

The first large-scale PACS installation was in 1982 at the University of Kansas, Kansas City. As is typical with early experiments, people learned more about how NOT to do it. The experiences from this installation taught that PACS requires abundant data exchange, and that an Ethernet connection is not necessarily the best method to do this (remember the fastest connection at that time was 10 MBit/sec, and routers and bridges were not really commonplace).

Display technology has also come a long way. Initially, there were only 1k by 1k monitors, and there was a big question as to whether the resolution was going to be sufficient. It is interesting to note that this discussion is still very valid, not because higher resolution monitors are unavailable, but because there is a definite price trade-off. Is it OK for referring physicians to use their high quality PC monitor, or should they use a medical grade monitor with a special video board? It is not only a question of using the appropriate hardware, but also using the correct display look-up tables to provide a consistent presentation.



Economically speaking, it is also interesting to see that over the years, the question as to whether PACS is cost-justifiable has not been easier to answer. The early work at the Hospital of the University of Pennsylvania, as well as at Washington University in Seattle, provided some early numbers and a framework to use, however, a clear "savings-model" is still difficult to formulate. The challenge is that one cannot just look at how much is saved by eliminating film, but that the true savings lie more in the increases in efficiency. Productivity studies by the VA in Baltimore in the early nineties have helped in this regard. However, one has to realize that, as Dr. Eliot Siegel from the VA in Baltimore strongly advocates, one has to re-engineer a department and its workflow to make use of the advantages of this new technology to really realize the benefits. As you can imagine, the early PACS only replaced their film-based operation with a softcopy environment without emphasizing re-engineering.

That brings us to one of the big “drivers” in this technology: network standardization. In the early 80’s, there was no one single standard. TCP/IP was just one of the several options available. The government was pushing for the OSI standard, and major manufacturers, notably GM, were trying to enforce broadband instead of Ethernet standards. As a matter of fact, the first PACS by Philips used broadband technology. There were also “ad-hoc” developments using inventive solutions in the 80’s, such as the one at Michigan State University, whereby images from three CT scanners were sent to the University diagnostic center for reading leasing bandwidth from the commercial CATV cable system; a predecessor to cable modems! The early versions of DICOM, called ACR-NEMA, only specified a dedicated point-to-point connection, leaving it up to the manufacturer to exchange the data via their network of choice. It took about ten years for the network standard to emerge, something we take for granted now. Today, everyone uses the TCP/IP as the basis for network communication, making it easy for new developments at the physical level such as gigabit/sec Ethernet to be deployed.

In addition, what made this technology affordable was the implementation of communication standards, especially HL7 in the IT domain and DICOM in the imaging domain. Both were initiated in the late 80’s and enjoyed widespread support in the early 90’s. In particular, early demonstrations at the Radiological Society of North America (RSNA) of the DICOM standard brought awareness to the user community. Subsequently, the open-source DICOM toolkit, developed by the research lab of the Mallinckrodt Institute of Radiology in St. Louis, gave a big push to the DICOM standard implementation. As of today, PACS and DICOM/HL7 go hand-in-hand having an inter-dependent relationship.

The focus for PACS has truly shifted. It began as a means to eliminate film archiving, i.e., the focus was on the “A” in PACS. Teleradiology definitely addresses the “C” in the PACS, whereby images are sent to another location, such as from a remote clinic to a main hospital or to a doctor’s home during the night. Improvements in image communication have always been a major driving force in PACS development. This was the main reason that the US Department of Defense (DOD) became involved, and why they sponsored early PACS projects at Georgetown and the University of Washington. They are responsible for running a large amount of medical facilities, ranging from South Korea to Germany, as well as covering the many bases in the US, ranging from Alaska and Hawaii to Nevada. At some facilities, either a civilian radiologist would review images periodically, or they shipped the films to one of their main facilities. The navy was particularly interested in improved communication, because of the importance of determining whether an injured sailor needed to be picked up from a vessel by a helicopter, posing risks and high costs. The vision of a single "virtual" radiology department by the DOD, spanning all services and locations, has really helped to propel the PACS development.

More and more, the "S" or "system" aspect in PACS has become critical. A PACS system cannot be implemented through merely connecting a series of boxes; it must be integrated, and able to support a changing workflow environment. The integration aspect has been emphasized by the recent Integrating the Healthcare Environment (IHE) initiatives. Going beyond integration in radiology, the US Department of Veterans Affairs (VA), which has more than 150 hospitals, has also been a major source for innovation. They have one of the best integrated electronic patient record systems. That is what continued innovation and vision of PACS will ultimately bring us: a truly integrated electronic folder, accessible by multiple physicians, across institutions, and ideally also by the patients themselves.

Both the US Department of Defense and Veterans Administration are good examples of how a top-down directive and vision can make a major difference in implementing a new technology. It is somewhat surprising that major hospital corporations, some of which have more than 100 hospitals, have not pursued the same ideas with the same vengeance as the US government.

PACS has been instrumental over the past 20 plus years to facilitate the exchange and integration of imaging into mainstream healthcare. However, there is still a long way to go. As a matter of fact, the majority of the US hospitals still do not have a PACS. However, given its many benefits, it can only be a matter of time.

1.3 Lessons Learned

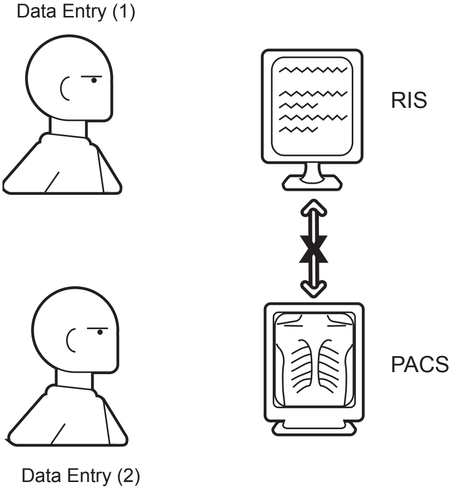
The issues relating to Image Management, patient demographic consistency, lack of checks and balances, image quality issues and resolution of workstations, the evolution of CR/DR and archive media volatility, migration to software-only solutions and support staff issues are among the most important lessons learned.

What have we learned from the 20 plus years since the introduction of PACS? We can only thank the early adopters for their willingness to be at the "bleeding" edge to benefit the next wave of implementers. And we truly had to learn a lot; one of the reasons that this technology initially did not take off as fast as some people would have expected or hoped to see.

Key Lessons Learned:

Image Management is Critical: The first implementers were really excited when they could send images from ICU or ER to the main radiology department, and easily access all the images from any digital modality on a viewing station. However, image management was lacking. For example, physicians were often in the dark as to whether a study was complete or if additional images had yet to be received or transferred. It was also difficult to verify whether a transfer was complete from a remote location. Questions such as "how many images should I have," "did I receive everything," and "where are my images" could not be easily answered. This situation necessitated the creation of a new set of image management services, either proprietary or as standard DICOM services.

Patient Demographics are Unreliable When Re-Entered: Correct data entry of initial patient information is critical to successful patient identification. If a technologist has to re-enter patient demographic information, the chance for typing errors is roughly 20-30 percent. Therefore, if a patient has multiple studies as part of a visit, they might not be linked at the image archive due to mismatching patient demographics.



In addition, key identifiers such as an Accession Number, if entered incorrectly, might even match a patient order with the wrong patient. This showed that Modality Worklists, generated by communicating with a Radiology Information System (RIS) are essential. One hospital in New York ultimately replaced all modalities that were unable to download modality work lists after installing a PACS system; some of which were only a year old. They found that maintaining correct patient demographics necessitated a two-to-three person dedicated staff to support the

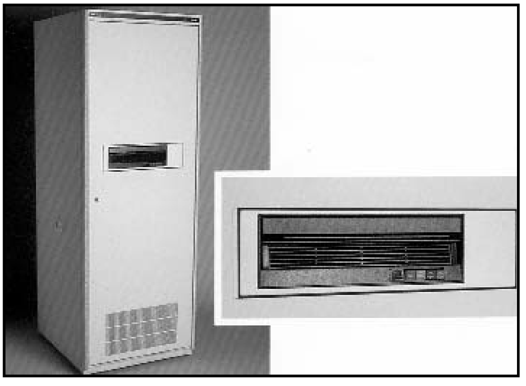
PACS system. This led to people proclaiming that "installing a PACS before a RIS" does not make sense. The RIS provides consistent and exclusive data entry of the patient information.

More Automation Requires Additional Checks and Balances: When using a Modality Worklist at a modality which provides the capability to select a patient from a list, it was found that technologists would select the incorrect patient information 20 percent of the time. The result was that, for example, Mrs. Jones' images would end up being identified as Mrs. Peterson's. One should note that mislabeling is even worse than not labeling at all; unlabeled images typically end up in a special area at the PACS image archive, while mislabeled images might remain unnoticed. Another frequent scenario is when a technologist forgets to "close" a study, and adds the images from the next study in the first patient folder. Lessons learned from these errors were for the modality manufacturers to develop a more efficient user interface to eliminate the incidence of errors. However, humans make mistakes, especially when they are in a stressful environment such as the ER or OR. Therefore, in addition, the capability to reverse these incorrect selections in an easy manner is critical. Early PACS required a service call, system administration privileges, or even worse, someone to change each image individually instead of fixing a complete study or series. Imagine, having to manually change the demographics for a 350-image CT study image by image!

Image Quality is a Challenge: A radiologist viewing an image at one of the early PACS systems discovered that he could not see the same pathology as he did six months ago when he made his diagnosis. Upon investigation by the PACS support people, they confirmed that the monitor was indeed not performing as expected; calibration was needed. The problem was, calibration to what baseline? There was none. This caused the DICOM committee to specify a new part of the standard specifying the Grayscale Standard Display Function (GSDF). It subsequently prompted vendors to devise a method to calibrate the monitors and apply the measured calibration values when images are displayed. Image quality is still somewhat of an issue because it is often subjective, i.e., what looks great for one physician, might not be good enough for another physician. Objective measurements and test images, both using test patterns as well as clinical images showing pathology, were needed. Here is where the American Association for Physicists in Medicine (AAPM) stepped in and developed a set of test images and procedures.

CR and DR are as Good as Film: Computerized and Digital Radiography (CR/DR) are now common. However, it took at least ten years to convince many non-believers that this technology produces images that are at least equivalent to films. Orthopedic specialists, who sometimes look at very small hair-line fractures, and the mammography readers, looking at small dots representing a millimeter micro-calcification in a breast image, were the most difficult to persuade to use digital technology. Embracing the technology by more than just a single vendor (FUJI) in the early 90's also helped convince many users. If one would compare digital acquisition technology to film from a purely theoretical perspective, looking at resolving resolution and efficiency of capturing energy, the film-screen combination technology, which has been refined for almost a century, is still superior. However, the fact that softcopy images can be reprocessed, manipulated, and are readily available without the chance of losing them, outweighs the somewhat better specifications of a film-based system. If nothing else, digital technology has proven to be "good enough" to resolve all common pathology that a physician looks for.

Archiving Technology has Proven to be Volatile:



Early 12" Optical disk archive with two GByte (1 GByte each side) capacity

We know that computers become outdated within a few months; however, we need to be able to retrieve images stored in an electronic archive for five to seven years, sometimes longer. The problem is that any physical archiving technology that was readily available seven years ago, supported by operating systems and manufacturers for service and support, is definitely obsolete today. I have a 12-inch optical disk in my office as a reminder on how quickly technology becomes obsolete.

There have been some bad experiences. One manufacturer had to give all their customers an archive replacement alternative when they decided not to support a certain type of long-term storage device (which happened to be a 14-inch optical patter jukebox). Another manufacturer went out of business, leaving a major hospital in Chicago with millions of images stored on an unsupported device and media. Not only have there been many iterations of optical drives and standards, there has been an even larger number of tape technologies come and gone. There now seems to be a trend towards storing everything on-line in a RAID or network appliance, making storage less dependent on archiving hardware technology. Using an Application Service Provider (ASP) is also a good choice, leaving it up to an outsourcing company to deal with obsolescence.

Hardware has Become a Commodity: One of the first PACS viewing stations developed had a customized user keyboard/control panel. A lot of time was spent with focus groups, prototyping and user group meetings to ensure that all the controls necessary for image selection, correct window width/levels, and other image manipulations were easy to use. These proprietary, custom made controls became slowly replaced with standard Graphical User Interfaces using drop-down menus or keyboard function keys. The same applies for the dedicated image processing boards (even though there are still a few vendors that offer these), and communication boards which are becoming main-stream commodity products. The only component that is specific for imaging applications is the video board because supporting 5 MPixel graphics is not something that is common in any other application area.

It is often not very efficient to ship hardware back and forth. Imagine a European PACS vendor who purchases a US-manufactured computer system, which is shipped from the US, staged in their manufacturing facility, and then shipped back to the US for installation in a US institution. An alternative is drop-shipping the hardware directly from the manufacturer to an institution and installing the software on-site, or depending on the customer to purchase the computer system. Some hospitals, such as those with government contracts, can purchase computer hardware cheaper than many PACS vendors can provide. A good alternative is for them to buy the additional video boards and monitor hardware direct and purchase “software-only” PACS.

A Dedicated Support Staff is Needed: A PACS system requires a dedicated support staff. The function and responsibility of the various people involved varies depending on how much the existing IT department, biomedical engineering, and technicians take upon themselves. It is not uncommon for one of the radiologists to function as a “champion,” and take on the support or training role. In any event, the PACS administrator emerged as a new profession, because it was found that a system without one or more dedicated persons was ultimately doomed to fail. A PACS is still rather complex and requires hand-holding, checking, and several dedicated maintenance tasks.

Over the past 20 or so years, many lessons were learned, thanks to the early adopters and pioneers in this area. These lessons are the foundation on which new standards have been defined and additional features and improvements are provided by the PACS vendors as part of their systems. These improvements facilitate, finally, widespread implementation.