Implementation Aspects of Image Management, Archiving, and Communication Systems in Routine Clinical Use

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Implementation of a digital imaging network in routine clinical use is a difficult task. Not only the high technical requirements, but especially the complexity of the organization of the diagnostic information flow in a hospital makes commitment essential in PACS implementation. The application of project management with a dedicated project team is a good approach to establish this complex endeavor. The different phases of a project for implementation are initiative, definition, design, preparation, realization, and evaluation and are exemplified by what we learned from the Dutch PACS project.

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BY THE TIME a digital imaging network has been implemented in a hospital, many stages have already passed. The first and basic question is: "Is PACS useful, and will it be cost effective? PACS is still in its early stages, and many hospital directors and management teams are closely watching the developments in this rapidly expanding field but hesitating with regard to actual implementation.

The high technical requirements, and the complexity of the organization of diagnostic information flow in a hospital, especially when it is a large and diverse teaching hospital, account for the fact that implementation of routine PACS has succeeded only incidentally so far. Implementation in routine clinical use is not easy because of constant work pressure, heavy dependence on reliability, and the urge to be constant in quality and completeness.

Where are we now? Is it too early for PACS? No. We are beginning to see the first successful applications of PACS in clinical use. Implemen-

tation in health care goes beyond the capabilities of individual hospitals and industries at this time. Therefore, it is very stimulating that initially in the United States, Japan, and The Netherlands programs were defined by the respective governments to establish funding for PACS development and implementation. Other countries, such as Canada and Germany, often driven by a strong interest in technology assessment, followed.

In 1985 in The Netherlands, a collaborative effort was initiated to perform a pilot study of the development, implementation, and evaluation of a small-scale but complete PACS, and to realize an integration with the Hospital Information System (HIS).¹⁻³ The partners, Utrecht University Hospital (UUH), BAZIS Hospital Information Systems, and Philips Medical Systems, signed a contract for 3 years (July 1986 to July 1989). The manpower was financed by a grant from the Dutch Ministry of Health.

In the last few years, we succeeded in The Netherlands in successfully implementing a routinely used small-scale but complete PACS, coupled to the HIS.³ We went through many stages, pitfalls, discouragements, and successes. We learned a lot from our hands-on experience from this project, which proved to be extremely useful in defining the next stages in wider implementation and growth.

A very rewarding approach to implementing a system of this complexity is that of project management and a dedicated project team.⁴ A project has a well-defined goal; has a long duration; is complex expensive, and unique; and incorporates the following stages: initiative, definition, design, preparation, realization, evaluation, and follow-up phase.

This article provides an overview of the way in which to apply this approach to actual implementation and, exemplifying the different phases of project management, also provides a detailed account of what we learned from the Dutch PACS project and, if appropriate, information regarding suppliers.

WHAT IS THE PROBLEM?

To keep implementation manageable, it is very important that strict and well-funded choices are made from the very beginning. Each project starts

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with the first question: What problem are we going to solve?

Two major directions can be discriminated regarding the application area of PACS: (1) only digital modalities, and (2) full modality, including (digitized) films. Each addresses a different function and has different advantages and technical possibilities. Today, the first direction is clearly more feasible. Currently, the resolution of most commercially available monitors is $1K \times 1K$ or a little higher, and the intrinsic resolution of computed tomography (CT), magnetic resonance imaging (MRI), digital subtraction angiography (DSA), ultrasound, and nuclear medicine (NM) does not exceed 512^2 . Storage and transmission requirements are also less severe, and do not require extra investments in acquisition equipment other than special I/O. This is evident in most practical PACS applications so far. On the other hand, the advent of computed radiography and advanced laser digitizers make film-based PACS a possibility. ROC studies show that the resolution for reading for primary diagnosis must be at least $2K^2$ for most examinations.^{5,6} But what resolution is needed by the referring physician if he receives the images accompanied by the report?

In the Dutch example, we noted four major areas in which PACS could solve an identified problem and might be cost effective:

Digital Modality-Only PACS

With many modalities (ie, CT, MRI, angiography, ultrasound, mammography, and DSA) one must see the previous examination during acquisition as a guideline for performing the examination. This previous examination folder includes films and images from digital modalities. Our current regular practice in UUH is to have the old films available during the examination. For CT and MRI, some previous digital images are also viewed on the special viewing consoles, where some limited manipulation is also performed (eg, windowing, zooming, multiplanar reformatting). Fast reviewing in the examination room is essential, without burdening the technologist, equipment, or patient. A PACS that offers this function is fast and filmless and may also eliminate two other problems: the incompatible and expensive floppy disks, disk packs, tapes, or dedicated optical disks used for routine storage as well as for teaching files. This digital modality-

only PACS also makes teaching files cheaper, more accessible, and thus actually used.

Full-Modality PACS

A radiology department services other wards and clinics, where all information regarding the patient (images, status, laboratory data) converges on the referring physician. Normally, in The Netherlands, only the wards receive the report. Folders are loaned only on special request. Clinicians attend consulting meetings held every day in the radiology department. Only the intensive care departments receive and keep the images and reports as long as the patient is there.

Making the images available in the ward in full modality (ie, all films, including all previous examinations and patient's history for the 10 years, helps in several respects: 24-hour daily availability, fast and complete access, knowledge of the context of the report, better communication between consultants, possible reduction of patient stay owing to faster availability of information and, possibly, better medical efficacy through more effective decisions. The clinical ward is where most cost savings may be achieved.⁸

Integration of HIS Data With Image Data

The two main reasons for effecting a HIS-PACS coupling are (1) proper image management (eg, achieving acceptable waiting times), and (2) user need for having all patient relevant diagnostic and therapeutic data available in the same workstation. Furthermore, effecting such integration is the most effective way to include pre-fetching of image data and to create elaborate teaching files that combine diagnostic and demographic keys.

Proliferation of Advanced Image Processing Techniques

The possibilities of digital imaging are emerging quickly. Three-dimensional display with real-time manipulation possibilities and high resolution may aid planning in operation theaters. Blood flow can be accurately measured in real time or by computing large sequences or tissue characterization. Because dedicated hardware/number crunchers are still expensive, an intelligent PACS can be built when using PACS to store and distribute the input and output image sequences, thus paving the way for wider application of these expensive diagnostic possibilities.

Clearly deciding which problem must be solved is essential. In the Dutch PACS project we focused on the last three points described above and plan to include the first approach in a second 3-year period. Implementation of PACS is complicated; it requires strong commitment and separate and dedicated management. Quite often a local research group, performing meritorious image processing, is believed to be the favorite starting point for PACS development. But much more is needed, as we show in our discussion of project management.

PROJECT MANAGEMENT

A project has a well-definable goal, beginning and end. It is a one-time operation, interdisciplinary, and is to be controlled from one point. It is complicated, and several parties make contributions. Other characteristics are that it is long-lasting, expensive, complicated, and unique. It is essential to the involved parties. The project is run by a project team, supervised by a project leader.

The course of the project must be divided into phases. Weekly meetings of the project team guarantee progress control and insure that all involved persons are informed. The profile of the project leader largely determines the character of the team. The project leader must have access to high levels of the department and hospital management. From the start, support of (top-level) management is essential. The project leader is responsible for staffing problems and the project's finances.

Special problems are encountered when the size of the collaborating organizations causes a certain level of bureaucracy. This is inevitable, and when these formal paths are accepted the correct way of following the other parties' procedures permits greater confidence and opens the way for more informal and therefore faster contacts.

Clear and complete contracts, in which the expectations of the partners are well defined, must be formulated. Your own professional lawyers must provide their expertise before final signing of such contracts.

In the Dutch PACS project, we have three major partners. UUH, a 900-bed teaching hospital with 3,500 employees, performs 110,000 radiological examinations yearly; and BAZIS HIS Foundation (based at Leiden), with HIS installed

in 40 Dutch hospitals, encompassing 18,500 acute beds, which is 30% of all hospital beds in The Netherlands (ie, 7,500 terminals installed for a striking complete function capability, including Radiology Information System (RIS) with 120 employees Philips, a well-known Netherlands-based multinational company with a large medical systems division, supplied the hardware in the Dutch PACS project.

Each party supplied a project leader to run the team locally. The organization is layered: The directors of the partners meet three times a year, together with the representatives of the Dutch Ministry of Health and the Dutch Radiological Society, which closely watches developments in (and supports) PACS. The project leaders meet once a month, to tune the activities of the different teams. Within each party, the support of other departments is necessary. Therefore, a steering committee meets once a month, consisting of the heads of the respective departments; eg, in the UUH consisting of the head of Radiology, the head of Internal Medicine, the head of Nuclear Medicine, the head of the Automation Department and the project leader. This seemingly bureaucratic organization creates many possibilities and keeps all parties informed and cooperating.

Central responsibility to the Dutch Government was through BAZIS because of the nationwide involvement in health care. The scale of the 3-year Dutch project was 5 full time equivalent (fte) at UUH and 5 fte at BAZIS, with funding of \$750,000 per year. A second 3-year phase that will incorporate the four abovementioned implementation areas on a manageable scale is currently being planned. In UUH and the Utrecht University, a separate project on three-dimensional computer vision research (scale: \$ 6 milj. in 4 years) has been initiated and approved.

A project is divided into several sequential phases, which are discussed in detail. As the project leader of the clinical evaluation in UUH, I focus in the examples mainly on the activities in UUH.

Initial Phase

A complex endeavor such as PACS implementation begins with the creation of belief, ie, showing management its feasibility. As an example, in 1985 I took the technical director of UUH with me to visit the annual meeting of the RSNA in Chicago, where he could see for him-

self the rapidly growing developments in the PACS field; together with the head of the UUH Radiology Department, we visited the fancy three-dimensional Graphics Laboratory of the University of North Carolina Computer Science Department in Chapel Hill, NC (Professor S. Pizer). This finally led to approval for construction of a specially ergonomically designed "digital reading room," costing about \$100,000.

Documentation of the plans must be good. We organized a national symposium with the Dutch Radiological Society as well as the Delft Technical University. We made study tours, both to the United States and Japan,⁷ and visited several good conferences, notably the SPIE Medical Imaging conferences at Newport Beach and the outstanding Nato ASI meeting in Braunlage 1985.⁸

Funding is necessary, as long as PACS is in a phase in which cost effectiveness has yet still to be proved, and the character of the implementation is a learning project. The different partners may have very different goals. The Dutch PACS project was set up with the following goals: for the Ministry of Health, to find implications on both a hospital scale and a national scale of the introduction of PACS, in terms of costs, efficiency, and efficacy of health care; for UUH, the implementation of a routinely usable PACS for the clinic (15 beds in internal medicine, 20 beds in cardiology and cardiosurgery) and to study effects on organization, efficiency, efficacy, and cost^{1,9}; for BAZIS, to integrate PACS with RIS/HIS¹⁴ and to perform research on image quality evaluation, computer simulation,¹⁵ and technology assessment²⁴; and for Philips, to evaluate the PACS equipment in all its aspects.²¹

Definition Phase

Definition of the project is the most important phase. The complexity of the organization of PACS requires thorough information analysis, which means knowing exactly what the logistics are for the study. As an example, in UUH we chose the departments of internal medicine, intensive care cardiology, and intensive care cardiosurgery. For a period of 3 months, we timed and counted by hand all images involved for each department, encompassing the complete patient history. We learned how many images per examination per patient were made, discussed at consulting meetings, and loaned to other departments. We achieved insight into peak load

production timing. We were surprised to find that only 15 beds required a large buffer capacity of 800 to 2,000 images if the full folder were digitized and stored. With a mean hospital stay time per patient of 12 days, we needed to store 2,000 images a month in this initial phase, when no previous digital data were in the system. We finally decided to have at least the last 3 years of patient history available on the ward.

Flow between the radiology department and requesting departments can be studied from RIS data.¹² We used the matrix, formed by 160 types of examination (eg, thorax, CT head, IVP) and 67 requesting parties (wards, intensive care units, general practitioners) to determine the required storage capacity for each party by calculating for each cell in the matrix the requested area of plain film. From discussions with our chief technologists, we knew the number and size of film sheets required.

The required quality and speed must be defined. To determine the image quality after scanning by digitizer for the radiology department and the clinical ward, we designed a number of ROC studies.^{5,6,13} We stated that for legal reasons no data compression should be used for primary diagnosis. Regarding speed, we stated the psychological limit of 2 seconds for image retrieval at the user's end. Prefetching is a difficult but necessary element. It is the only way to reach the required speed and it is the reason that the current method of handling film manually works. We are currently setting up procedures to introduce all scheduled information in PACS.

Coupling to HIS/RIS is essential.¹⁴ A special team at BAZIS specified the first stage: an American College of Radiology/National Electrical Manufacturers Association (ACR/NEMA) one-way coupling. They worked together with Philips and the UUH many times to achieve correct definition of events: What is an examination, a discharge of the patient? Which data base is the master; which one is the slave? We chose a downloading of all patient RIS data (patient data, order data, reports) as soon as the RIS detected an event, such as admission of the patient or request for an examination. Most important is the consistency of data in both coupled data bases. Sometimes a patient is registered twice on two UUH registration numbers; this can be corrected later. A patient may marry and take her husband's name. Mistakes are made by reception

clerks. Another point of concern is that storage of data on optical disk is read-only and cannot be modified.

A fruitful way to obtain the required definition in all its aspects is to organize a brainstorming session for an entire afternoon away from the workplace. We found this to be extremely effective, inviting the persons involved daily—the chief technologist, a radiologist, a co-worker in the archive, a HIS specialist, and the PACS team. This bottom-up approach, including the employees who do the actual work, is a necessary prerequisite in addition to the top-down project management. The definition phase may be concluded by a detailed request to bid, which can be provided to several industrial and other partners, if such is the chosen path.

Design Phase

At this time, film-based PACS can only be implemented in parallel with the original films. The responsibility to patient care prohibits rejection of plain film. Design requires very intensive interaction between partners in meetings and correspondence. Computer simulation is a very useful tool to model the configuration and the projected performance. For this purpose, BAZIS developed a sophisticated computer model^{15,16} in which the hierarchy and size of storage buffers, with the given speed of transmission lines, could render the histograms of response times at the workstation or other area given a statistical (eg, Poisson) distribution of arrival times of examinations and request. Data for input were acquired in UUH in a detailed study of the current imaging procedures.¹²

For the design of ROC studies, BAZIS developed a personal computer (PC) based shell program around ROC software to facilitate the setup and portability of these studies.¹³

The environment must be designed professionally to increase radiologists' acceptance of this new way of working. We designed a dedicated "digital reading room," with help from the Delft Technical University Department of Industrial Design.¹ We paid special attention to light, heat, and sound conditions. Separate cable conduits, for power and signals circuit the room. The room thus built was located in the middle of the radiology department, making cabling distances as short as possible. Next to this room, we designed and built a special computer room for the noisy

PACS and CT/MR/DSA viewing station supporting hardware, where radiologists never had to come. PACS equipment needs space, and it is essential to devote proper space for it. The UUH moves in July 1989 to a newly built modern facility on the university campus. We allotted enough space for the next years of PACS and digital radiography development. Again a digital reading room has been planned, now as part of the large central reading room, separated by a half-movable wall, incorporating the three-dimensional workstation and PC-based teleradiology stations as well. A special ISDN phone connection facilitates the latter. Cable conduits are in every corridor, and air conditioning is adapted to the computer needs. Because of the importance of undisturbed routine handling of patient care, PACS in the new UUH is scheduled to be developed and used in first instance in the special "graphics laboratory," next to the radiology department. As soon as parts have proven reliable, the viewing stations are moved to the digital reading room.

The design of the user interface posed many problems, particularly because of the limited possibilities of the hardware and of the supplier in providing necessary modifications. Finally, we designed and implemented a four-layer access to image data: selection of ward, patient, examination, and image.⁶ To determine what radiologists expected, the Technical University Delft Department of Industrial Design designed an Atari/GEM-based real-time user interface simulation based on a desktop metaphor and use of icons, which was evaluated by radiologists.¹⁸ BAZIS designed a model for studying and extrapolating the costs of PACS from hospital based to a national scale.^{19,24}

Preparation Phase

Every party involved in the project must be well informed. The weekly meetings of our project team served that goal. As project leader, I met with the archive clerks once every 2 months to inform them about the project. On one hand, they were anxious about the possibility of losing their jobs; on the other hand, they were very interested in this new development. They also envisioned eventual new opportunities for developments in their own job and wanted to be prepared. Having this development in their own department also caused them to feel pride. To

obtain the ongoing support of less involved persons, we rewarded the radiologists who participated in the ROC experiments with coauthorship in publications.

We found that the diagnostic quality of $1K^2$ display of scanned nondigital examinations is not sufficient for primary diagnosis but is sufficient for clinical use. This was a severe disappointment, and the project was adapted. We went back to primary reading from film. The focus of the IMAC study was on clinical efficiency and efficacy. In the next phase, $2K^2$ screens will be evaluated.

Realization Phase

During installation of the equipment and the subsequent period, there may be many breakdowns and failures. It took us months and much equipment replacement to achieve sufficient reliability. During this phase, the direct, frequent, and committed support of the industrial partner is crucial. Especially in this phase the half-time presence of an industry engineer on site is a necessary prerequisite. The composition of the project team is the most important aspect at this time. Documentation regarding use and service of the system must be complete.

The old application forms for our target patients were replaced by green forms to indicate to the technologists that the films should be brought to the laser-scanner for immediate scanning. Scanning films for clinical use proved to be a heavy workload, and we hired a special "digitizer." On the average, 80 images a day had to be scanned or to be found if not brought by the technologist. One must pay attention to public relations in this phase. When we had the digital reading room opened by the technical director of UUH, we invited the Dutch national newspapers and TV. All presidents of the partners gave a short presentation, and we were presented on the 8 o'clock TV news. At the EuroPACS 1988 conference, held in April in Utrecht and Leiden, BAZIS demonstrated in the UUH the world's first working HIS-PACS coupling. BAZIS produced an instructive videotape explaining this coupling, and UUH produced a video describing the setup of the clinical evaluation of PACS.²⁰ Recently, when the successful, reliable, routine clinical operation was started for the wards, a large Dutch newspaper published a review article in its scientific pages.

Evaluation Phase

In the evaluation phase, a few well-stated research questions about what has to be evaluated and for whom must be defined to streamline the endless variations possible. For clinical evaluation, we formulated a clear document describing four evaluation areas: the technical area and those of efficiency in terms of time and workload, efficiency in terms of costs, and efficacy of diagnostic procedures.⁹

Technically, we evaluated a video scanner against a laser scanner, both digitizing a $1K \times 1K^{21}$; we chose the laser scanner. To evaluate efficiency, we compared the timing of the conventional flow of images to the target wards with PACS.²² We followed 1,000 patient examinations by introducing special forms in the application folder. We discovered that 25% of old examinations are (legitimately, owing to several locations of archiving) loaned or cannot easily be located at the moment necessitated by the new examination. PACS substantially improved the speed of handling. This was great news. PACS can indeed be used 24 hours a day; there are no longer any lost or missing folders and communication between the different medical specialists is improved.

Efficacy is difficult to measure. We determine the average stay of patients in the hospital, the number of treatment procedures, and assess the role of the improved communication on the ward. In this stage, it is not clear whether we will be able to obtain firm data on this aspect.

In terms of costs, we found that PACS becomes cost effective mainly due to a reduction of hospital stay time. We calculated²¹ that although equipment investments are tenfold and personnel costs about equal, the reduction by 1 day of every third patient's hospital stay will compensate the cost of the PACS investment at this stage. BAZIS performed a technology assessment evaluation on a multihospital scale.²⁴

Follow-up Phase

Maintaining the system in routine operation requires backup for manpower and equipment. The procedures must be stable and in accordance with protocol. The clinicians at the target wards at UUH have found the services so beneficial that returning to old methods is frustrating. Satisfaction in the clinic creates responsibility. To manage updates, the system operator must attend

training sessions in the companies' development laboratory at times to learn about new releases. Most hospitals have a special hospital automation support group which is in charge of HIS and its functioning and which is the logical group to supervise PACS operation and maintenance.

SYSTEM GROWTH

To connect more departments, one must go through the above phases again to adapt the PACS system optimally to local organization and procedures. The system, not the user, must be adaptive. One must insure that the expansion is feasible and can be manned and that the new procedures are parallel with the routine flow until the users are fully satisfied and the system is reliable.

PACS eventually stimulates other procedures, eg, instant reading to prevent the images from being distributed before they are read. Eventually, PACS will have not only a basic storage and distributive function but will become intelligent. The advent of computer vision techniques, recognition based on neural networks, and interactive three-dimensional display will result in highly sophisticated viewing stations. Gateways between PACS and research groups working in these fields are fertile means both to stimulate clinical acceptance of these techniques and to fo-

cus development on actual practical problems.²⁰ The next planned phase of the Dutch PACS project is the final merging of these developments.

CONCLUSIONS

Our main conclusion is that PACS requires commitment. Its complexity and scale justify dedicated project management. Implementation requires firm making of choices and allocation of a substantial amount of money, manpower, and management support. PACS works for clinical wards, speeds up the process, and may become cost effective in a reasonable time. The hands-on experience gathered in the successful Dutch PACS project substantiates these conclusions.

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