SESSION 3: Business and Medical-Legal Issues

An Overview of a Picture Archiving and Communications System Procurement

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The implementation and integration of a picture archiving and communications system (PACS) will be one of the most significant initiatives a healthcare enterprise will undertake. Developing processes that establish the needs of the users, support strategic initiatives, and address risk management is not trivial. The development of a plan that provides the PACS selection committees with a step-by-step roadmap to seek and procure the PACS best suited to their workflow is a valuable tool. This report is a high-level overview of steps to consider when establishing the process to procure PACS.

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CHOOSING AN APPROACH for the procurement of a picture archiving and communications system (PACS) best suited to the unique workflow within an enterprise can be a challenging responsibility. The objective of this report is to outline at a high level the significant steps in the procurement of PACS.

The implementation of PACS can be divided into the following stages, Dreaming, Planning, Collection, Investigation, and Negotiation. The benefits of establishing and following a step-by-step due-diligence process are better risk management and a high probability that desired outcomes will be achieved.

DREAMING STAGE

Begin dreaming about the purchase of a PACS by identifying the significant operational issues and the stakeholders, and by considering how the PACS will help resolve these problems. Issues that can be associated with enterprise risks, operational expenses, service delivery, and that impact many

stakeholders are more likely to gain Senior Administration attention and financial support. Be informed of the enterprise's other major strategic initiatives and consider how these initiatives will compete with or compliment the PACS initiative.

Answer the classic who, what, when, where, why, and how statements, outlined below, to assist in developing the dream.

Who Are the Stakeholders?

They are radiologists, clinicians, technologists, orthopods, surgeons, obstetricians, ward and clinic staff, senior administration, referring clinicians, and anyone reliant on diagnostic imaging (DI) images and reports in the community.

What Are the Problems to Be Resolved?

For example, DI projects a 12% examination volume increase, which cannot be accommodated within the space available, and the department cannot support any new volume growth because maximum efficiency has been reached.

Why Are You Suggesting PACS as the Solution?

Are there less expensive ways to resolve the issue?

When and Where Issues

Will implementation timing be critical to other enterprise initiatives? Is a modality-specific solution required or a full PACS solution linking multiple modalities and several sites?

How Can PACS Be Made One of Senior Administrations Strategic Initiatives?

Consider the alternative, remaining with film, and the long-term impact of this on the organization. PACS is a requirement in an electronic medical record (EMR) strategic initiative.

How Can PACS Be Tied to One of Senior Administrations' Strategic Initiatives If It Cannot Stand on Its Own?

For example, the hospital is planning to increase inpatient beds by 30%. Efficiencies gained from

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PACS and digital radiography (DR) will significantly increase productivity, thereby reducing the impact of new volumes.

How Will the PACS Be Paid for?

Can changes be made in operations, such as cost avoidance, productivity gains, or an increase in revenues that will result in both a business case and service benefits that Senior Administration will support?

PLANNING STAGE

Planning steps are relatively simple, yet often skipped. Historically, institutions that skip planning have created serious blocks on the path to implementation and have delivered less than desirable outcomes.

Creation of a Selection Committee

The role of a PACS Selection Committee (SC) is to develop a plan and drive the initiative. Composition of the SC is vital and should include champions and stakeholders from Senior Administration, radiologists, DI staff and Administration, Information Services (IS), and from the following departments: Emergency Room (ER), Surgery, Orthopedics, Intensive Care Unit (ICU), Obstetrical/Gynecology (OB/GYN), Referring Physicians, plus other specialty disciplines reliant on DI reports or images. The division of the SC into task specific subcommittees will allow the SC to deliver multiple tasks simultaneously.

Creation of Vision and Mission Statements

The first objective of the SC is to create Vision and Mission Statements. To do this, the SC uses the ideas from the dreaming stage and a list of primary needs identified by key stakeholders. An interview process can introduce stakeholders to PACS and then identify their needs. This is a valuable exercise for SC members.

A well-crafted Vision Statement establishes a direction the enterprise will move toward, adequately represents the needs of users, and supports enterprise-wide strategic initiatives such as the EMR. A mission statement demonstrates its value by providing the SC with high-level objectives that support the vision statement.

A Sample Vision and Mission Statement

"Our PACS Vision. . ." To both enhance the delivery of patient care through the implementa-

tion of technology across the enterprise and to support regional Information Technology initiatives by sharing relevant patient information and images with key caregivers in a timely manner, thereby achieving the desired patient outcomes in less time and less cost.

To implement a technology that is cost-effective, meets or exceeds clinical needs, automates process, improves the workflow, and considers responsible resource management.

"Our Mission. . ." St. Elsewhere Hospital, the Diagnostic Imaging and Information Services departments, and the PACS Selection Committee support the following Mission Statement:

To achieve over the next xx months, as technology evolves, a well-managed cost-justified implementation of PACS that meets users' needs within the enterprise.

To integrate PACS with existing and future Information Systems thereby enabling the electronic distribution of relevant information and images to practical points of care.

To automate process using PACS to improve workflow that results in operational efficiencies, faster diagnosis which positively influences patient outcomes"

Scope of Project and Development of Strategic Plan

Establish the extent of the PACS implementation or scope as early as possible and try to maintain this scope. Project add-ons that result from new objectives or new programs are best left as complimentary implementation phases for new funding allotments. For example, one enterprise took the position that PACS will support all programs as of a specific date. All subsequent new programs were required to include in their planning the cost of viewing terminals, network, integration, and maintenance costs as part of their project plan. This measure allowed them to manage "project creep."

The Strategic Plan becomes the roadmap for the PACS initiative. The Strategic Plan can be leveraged to gain support for PACS from Senior Administration and stakeholders by creating demand with a plan that describes problems, defines needs, and proposes solutions.

Key elements in the Strategic Plan are:

- Objective and desired outcome
- Description of issues, definition of needs, proposed solution

- Scope of project
- Resources required—financial, human, and physical
- Roles and responsibilities of SC
- Due-diligence process including time lines
- Policies, procedures, and strategic guidelines
- Quality of implementation
- Strengths, Weaknesses, Opportunities, Threats (SWOT) relative to PACS
- Proposed configuration schematic

Internal Marketing of PACS

One important task often neglected due to the focus of the SC on PACS procurement is the creation of demand for PACS in medical disciplines dependent on DI reports and images. Executing the best seek and procurement process can be fruitless when system users do not understand or value benefits available to them and choose to criticize rather than support PACS. The human factor regulates the acceptance of technology and needs to be a process as well managed as the procurement process. Failure to do this has resulted in systems being removed or not utilized to potential, thus bypassing the benefits of technology. Plan specific events to raise awareness of the benefits of PACS throughout the enterprise.

COLLECTION STAGE

The collection stage documents the current environment and provides the baseline for change.

Required Skill Sets

To successfully complete the collection of data the SC requires the following skills: DI experience, computer hardware and network knowledge, and expertise with clinical, financial, and hospital systems. In situations where the SC is deficient, external resources, such as new employees or consultants, may be required.

Operational Review

A thorough understanding of the current operational environment's strengths and weakness is a requirement. An operational review must provide current and projected examination volumes, the costs per examination by modality, workflow strengths and weaknesses, and staffing levels. This information is then used in the development of a business case and for comparisons with projected PACS expenses. Understanding this information

will build credibility with Senior Administration and Finance and be of significant value when marketing PACS with key stakeholders. Being prepared to answer to the following questions will be valuable.

- What are the operating expenses with film including staff, supplies, and equipment service costs?
- What are the current exam volumes?
- Review all facility strategic reports: Will expansion or contraction of other programs impact DI?
- Are projected future volumes based on planned program growth or on historical volumes and patterns?
- What is the current demand to view films: over the counter, at clinics, external requests, etc?
- What are the critical response times: exam completion to being reported, being reported to being transcribed?
- What is the percentage of pull requests filled and unfilled in the film library? What is the percentage of lost films, etc?
- Is there sufficient floor space to expand exam rooms and to store film for the next 5 years?
- Given the competition within the community, are there strategic advantages for going filmless?

Analyze Workflow to Determine Special Needs

Consider the large DI clients such as the Fracture Clinic, OB/GYN Clinic, or the Chest Program. Identify each step in completing an examination for each stakeholder. Examine the process from patient registration to the pulling and forwarding of films for the next clinic visit. Identify each time someone reads, writes, or moves paper and film related to this examination. This will establish the unique workflow requirements within the enterprise. An intimate understanding of existing workflow patterns will significantly aid in the selection of a PACS system that will provide workflow that meets today's needs and has flexibility for reconfiguration in the future.

For example:

- Do the chest and abdomen of a chest/abdomen computed tomography (CT) scan need to be available to two different reporting radiol-

ogists? Exam splitting capability may be a PACS requirement.

- Does an ultrasonographer's handwritten impression sheet go with each exam to the reporting radiologist? Is it filed or thrown away when the exam is reported? Does the referring Obstetrician require a copy? Document scanning capability and matching with specific Digital Imaging and Communications in Medicine (DICOM) exams may be a PACS requirement.

A comprehensive understanding of the stakeholders' needs helps to develop questions for use in the Request for Information (RFI)/Request for Proposal (RFP) vendor evaluations of workflow.

Preliminary Business Case Development

A successful business case compares the cost of operations in a film environment with the projected costs in a PACS environment. Three prime areas need to be investigated: cost avoidance, productivity gains, and revenue-generation opportunities. The cost per examination is calculated with the supplies, staff, and service costs in both environments. At St. Joseph's Hospital there is a projected reduction in costs per examination with PACS. A payback on capital investment will occur over 7 years, with a projected increase in volume of 20% and an increase in technical staff efficiency of 18%.

The scope of the project and capital-financing plan will impact the business case outcome. Consider the following three payment methods: a capital purchase, an operating lease, and an Application Service Provider (ASP). The method of payment chosen affects the business plan significantly.

The business case is critical for Senior Administration approval to implement PACS.

Network Capacity Report

A detailed Network Capacity Report is necessary to determine the requirements and costs of interfacing PACS with existing applications on the current network. Key information found in this report would include the following:

- Make and versions of hospital information systems (HIS) or radiology information systems (RIS)
- Network architecture and topology

- Available bandwidth and bandwidth requirements
- Current enterprise security protocols
- Current remote access capacity and the required remote access capacity (web server and teleradiology)
- Projected network demand peaks

PACS Needs Requirements Report

A PACS Needs Requirement Report lists the PACS equipment by component and the integration requirements to meet a desired quality of implementation. Surveying the marketplace at this time will provide current trends and changes in technology that should be included, such as changes in archive long-term storage media. The report outlines the required storage, network, functionality, integration, and network performance requirements. The personnel with PACS experience should generate this detailed report. SC agreement and sign off on the system configuration will prevent future project creep. This report provides the requirements needed to write the RFI/RFP.

INVESTIGATION STAGE

The investigation stage of the PACS initiative begins with the formal RFI/RFP from the vendors.

Develop Scenarios for the Purpose of Evaluation

An approach to consider is to create questions for the RFI/RFP from data gathered in the collection stage workflow analysis. The development of scenario questions will help to evaluate the vendors' workflow solutions.

An example scenario question:

"The proposal shall indicate in detailed paragraph form how the following situations will be handled:

Example 1: A trauma patient arrives at the ER and has eight different examinations including a chest CT, chest portable, abdominal CT, abdominal ultrasound, left and right wrist and ankle, and lumbar spine. The HIS offers a single unique identification number for all examinations. The patient is scheduled to return 2 weeks later for a follow-up examination on the abdomen. How will the PACS archive prefetch only the relevant examination(s) (abdominal CT and abdominal ultrasound) and have them available for comparison with today's examination?"

Scenario questions educate evaluators as to how

technical specifications come together to create a workflow that can address many needs.

Request for Information

A well-crafted RFI can be a successful means to meeting the various needs listed below. RFIs are often considered optional but should be carefully considered as valuable tools to:

- Establish budgetary pricing on a configuration that reflects the enterprise's needs for use in the business case
- Provide a learning opportunity for the development of questions for the RFP along with knowledge of how vendors respond to various types of questions
- Allow the SC to learn how to evaluate proposals and refine their evaluation process prior to evaluating the RFP
- Provide a filtering process to establish a short list of vendors who will receive the RFP, thereby reducing the evaluation costs for both the hospital and vendors
- Provide the SC with the opportunity to increase their understanding of PACS and the offerings of vendors
- Establish which vendors are genuinely interested in your business through the evaluation of the quality, effort, and details in their responses

Business Case Version 2.0

With the budgetary costs and information gained from the RFI, the business case may require modifications and an alternative configuration in order to make PACS viable.

Senior Administration Decision to Purchase

Present the Strategic Plan, Business Case, and reference documents created in previous stages to obtain the approval to proceed to the RFP.

The role of Senior Administration is to:

- Ensure the initiative remains in line with the PACS Vision Statement
- Ensure the PACS initiative supports the EMR initiative
- Ensure PACS remains as a key institutional initiative
- Challenge the validity of business case assumptions and implementation plans
- Grant permission to proceed to RFP

Agreeing to proceeding to RFP commits Senior Administration to fund the PACS initiative once a vendor of choice (VOC) has been selected.

Request for Proposal

A well-crafted RFP becomes the basis for the purchase agreement. The RFP can be a refinement of the RFI. An RFP requests the information required to make an informed decision. It also provides an accurate method for evaluating many proposal responses in a minimum of time. Specific objectives defined in the Strategic Plan should serve as the basis for evaluation criteria in the RFP. Vendor's responses can also be used to develop a detailed Acceptance Test Plan (ATP).

Evaluation of Proposals

Evaluation criteria need to be developed and agreed upon prior to the release of the RFP. The criteria must emphasize the primary objectives from the Strategic Plan. Methodologies and processes for the numerical evaluation of different vendors' systems, based on measurable specifications and subjective inputs, are available. Managing this step is by no means trivial. Different vendor response styles and personal preferences or interpretations of information make it difficult to ensure that all vendors are fairly evaluated.

Decision to Purchase

Once a VOC is established, a final presentation is made to Senior Administration requesting permission to negotiate and purchase. This requires a final revision of the business case that uses actual pricing from the RFP. Once approved, the negotiating team begins negotiations with final objectives related to operating and capital costs.

NEGOTIATION STAGE

The negotiation stage is critical to the long-term success of the project. Negotiations will determine the purchase price, as well as other critical ownership details.

A well-planned negotiating strategy will include the following:

Technical Review

A technical review of the final configuration should confirm all PACS components, functionality, integration requirements, and the resulting workflow. When the RFP is used as the technical

specification for functionality and performance, reference to the RFP must be included in the final agreement. Ensure that the vendor updates the RFP responses with current deliverable specifications prior to the negotiations.

Financial Negotiations

Understand the enterprise expectations prior to starting the negotiations.

Operating Costs

- Annual Service Plan options
- Upgrade path options
- Financing terms and conditions: purchase versus lease versus ASP

Configuration Details

- Network upgrades
- Type and quantity of workstations
- Furniture requirements
- Computed radiography (CR) versus digital radiography (DR) options
- Archive options
- Special software packages: cardiac, orthopedic, etc

Other Critical Details

- Penalty clauses
- Delivery, installation, and implementation timelines
- Acceptance Test Plan (ATP)
- Application and System Administration training
- Current and future interface and integration costs
- Performance guarantees

Legal Agreement

Smaller PACS implementations require less supporting documentation. The scope of the project determines if a purchase order (PO) or contract finalizes the agreement. Once the terms of an agreement are established, a legal review by attorneys with experience in high -technology system purchase agreements is recommended. At the very least, the enterprise should arrange for their own attorney(s) to review terms and conditions prior to the signoff. Definitions of terms, penalties (or the lack of), dispute resolution mechanisms, contract termination, ATP, and software licensing agreements are examples of issues for review by the enterprise's lawyers. Depending on legal availability, allow 1 to 4 weeks for the legal review and subsequent negotiations.

Upon signature on an agreement or issuance of a PO, it is important to celebrate the completion of a well-executed procurement process and the start of the implementation phase.

CONCLUSION

This report outlines a number of key steps in the different stages for PACS procurement. Critical success factors include the identification of stakeholder's issues, relating issues to enterprise strategic initiatives, and creating a business case with benefits for all stakeholders. Understanding the current environment's workflow and integration issues allows for the creation of an RFP that will assist evaluators in the selection of the best PACS solution.