Application of Evidence-based Decision-making to Purchasing of an Imaging System

Matthew D. Mitchell, PhD; Craig A. Umscheid, MD, MSCE.
Center for Evidence-based Practice, University of Pennsylvania Health System, 3535 Market St., Philadelphia PA 19104, USA
www.uphs.upenn.edu/cep

SIGNIFICANCE OF THIS WORK:

Traditional EBM methods like systematic review of the research literature rarely address distinctions between different devices like imaging systems. Does this mean we must abandon evidence-based decision-making when doing technology assessment for hospitals? No!

SITUATION:

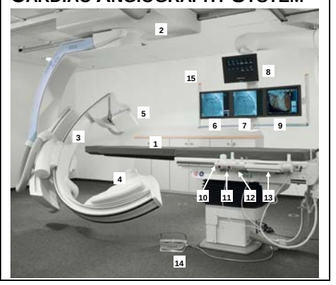
- **Penn Presbyterian Medical Center (PPMC) is the cardiovascular specialty hospital of the University of Pennsylvania Health System.**
- **The interventional cardiology suite at PPMC includes four catheterization laboratories, the oldest of which was installed in 1992 and upgraded in 2000.**
- **The purpose of this investigation was to use evidence-based practice techniques to select a new imaging system to replace the 1992 system.**

STEP 1: UNDERSTAND THE TECHNOLOGY

Why? To communicate effectively with clients and have more credibility in their eyes.

- TA organizations are largely made up of persons with expertise in epidemiology and research methods.
- We included a diagnostic imaging specialist in the team preparing this report.
- We acquired system brochures and other material from each of the manufacturers.
- We identified key technical specifications and learned how the different manufacturer's products differed from each other.

CARDIAC ANGIOGRAPHY SYSTEM



STEP 2: DEFINE THE ISSUE

Why? Because local factors like case mix and equipment compatibility could affect the relative importance of system attributes.

- We met with small groups of catheterization lab personnel, including the division director, the lab manager, the director of clinical engineering, and the cardiologists who use the facility.
- We learned about the history of the lab and its equipment and how procedures were scheduled and performed.
- We limited suppliers under consideration to ones that have previously supplied cardiac imaging labs to UPHS.

IMAGING EQUIPMENT AT AFFILIATED HOSPITALS

Hospital	Lab and when acquired	Image management (PACS)	Volume†
UPHS hospitals			
§PPMC	2 GE DLX, 1992 (upgraded 2000) GE, 2000 Siemens Axiom Artis dFC, 2005	GEMnet	3,632
HUP	Siemens Axiom Artis dTA, 2006 GE	McKesson	3,225
Pennsylvania	Philips Integros (analog), 1999 Siemens Axiom Artis , 2000	Siemens	1,240
Affiliated hospitals staffed by PPMC cardiologists			
Atlantic City	GE Innova, 2003	Medcon	
‡Burdette-Tomlin	Philips FD20, 2005	Philips Xcelera	
‡Nazareth	GE Innova 3100, 2005	GE Centricity	
‡Shore Memorial	GE Innova 2000, 2004	Medcon	
‡South Jersey Regional	Philips FD 10, 2004	Philips Xcelera	

†–Number of cardiac catheterization procedures in 2006
§–Staffed by PPMC cardiologists
‡–Diagnostic procedures only

STEP 3: IDENTIFY SYSTEM ATTRIBUTES

Why? This is the heart of the evidence-based decision process: to specify the questions that we will acquire evidence to answer.

- From the meetings, the manufacturers' specifications, and the literature, we compiled a preliminary list of system attributes.
- Attributes were grouped into categories, with 3 to 8 attributes in each category.

ATTRIBUTE CATEGORIES

- **User controls**
- **Patient handling**
- **Original image quality**
- **Review image quality**
- **X-ray specifications**
- **Interoperability and image management**
- **Quantitative analysis**
- **Patient and operator safety**
- **Familiarity**
- **Reliability and service**

STEP 4: REVIEW THE PUBLISHED LITERATURE

Why? Because other organizations may have already done much of the work.

- We searched the published literature for guidelines and standards applying to these devices.
- Clinical trials comparing different imaging systems from different manufacturers are rare in the peer-reviewed literature.
- The most recent standards from the American College of Cardiology were published in 2001. All systems being considered for purchase met those standards.
- We did find a evaluation of catheterization lab equipment published in 2005 and 2006 by the Device Evaluation Service of the UK National Health Service. The NHS evaluation also included a survey, in which users of each system were asked to subjectively rate aspects of the equipment such as ease of use and image quality.

NHS FINDINGS

Attribute	"X"	"Y"	"Z"
Respondents describing image quality as "very good." (attribute pertained to quality of images as seen in the lab)	Not included	7/10	1/11
Respondents describing overall ease of use as "very good."	Not included	1/10	8/11
Respondents describing overall reliability as "very good."	Not included	2/10	3/11
Respondents describing range of C-arm movement as "very good."	Not included	5/10	5/11

STEP 5: OBSERVE CATHETERIZATION PROCEDURES

Why? Many of the attributes relate to how real-life users interact with the device.

- We observed cardiologists perform catheterization procedures on labs from different manufacturers.
- We learned how ergonomic and other aspects of the imaging system affected the procedure.
- The cardiologists were quite helpful, and called our attention to aspects of the procedure that were helped or hindered by specific features of the imaging system.
- We made note of times when the cardiologist had to interrupt the procedure.
- We also observed the cardiologists review images after completion of the procedure.
- To measure ease of use, we counted the number of steps required to carry out frequently-used quantitative analyses like measurement of ejection fraction.

SAMPLE PROCEDURE OBSERVATION (EXCERPTS)

Introduction
A diagnostic catheterization performed by Dr. Untereker using the Philips equipment at Burdette-Tomlin Memorial Hospital (Cape May, NJ) was observed. This system is used for both interventional radiology and cardiac catheterization procedures, so it is equipped with a large image receptor. The size of the image receptor somewhat constrains the range of C-arm positions available for imaging the heart. The system PPMC purchases will be dedicated to cardiac work, so it can be equipped with a smaller receptor. The Philips system at Burdette was installed in December 2005, and is the company's current model.

Ergonomics
The general configuration of the Philips system is much like the GE and Siemens systems. It has two tableside control panels: one ("imaging module") for collimation and other x-ray functions, and the other ("geometry module") for moving the table and C-arm. These panels may be repositioned anywhere along the table edge, and may be removed to facilitate patient transfer. Staff comment that this feature is not often used during the procedure, but is frequently used before and after….
The geometry and imaging modules have shaped buttons and knobs for intuitive control. This makes adjusting beam collimation easier than on the Siemens equipment. While the correct buttons and knobs may be found by touch, Dr. Untereker does look at the controls while adjusting position…

Image quality and quantitative measurements
The image quality of the Philips system is good, according to Dr. Untereker, even when using a stock technic with no additional adjustments to image acquisition or display. In this particular case, calcifications in the patient's coronary arteries were clearly visible, even to a layman. Images displayed immediately when switching from run to run. A hand-held remote may be used in the examining room to control the display.
A separate Philips display system is available in the review room, but Dr. Untereker prefers to review images and prepare his report in the control room. While a dedicated control panel is available to select and display images, Dr. Untereker used the on-screen point and click interface for this purpose. His review took 8 minutes. …

Reliability and service
The lab director at Burdette is very pleased with the performance of the Philips system and the responsiveness of Philips technical support. She was particularly satisfied with the user support web site and with the prompt response to telephone calls.

STEP 6: INTERVIEW LAB MANAGERS

Why? Because they have important evidence about the performance of the system in the context of their institution.

- We spoke to the technical managers at each of the hospitals where we observed procedures.
- Interview topics included the service history of their imaging system, system reliability, and responsiveness of field service personnel.
- This allowed us to see whether problems experienced at PPMC were unique to an institution, characteristic of a specific device, or typical of all cardiac imaging systems.
- We also obtained the detailed service records of the imaging and PACS systems at PPMC. With this information, we could determine the degree to which problems experienced with those systems were related to the age of the system and could reasonably be expected to be resolved with purchase of a new system, regardless of manufacturer.

SAMPLE SERVICE HISTORY ENTRIES

Acom failures: The Acom workstation failed on multiple occasions. Various fixes included rebooting the system and removing a PC virus from it. The most frequent Acom-related problem was inability to transfer images to the Acom, which in most cases was the result of the Acom hard disk being full. Deleting files from the disk solved the problem. On other occasions, Siemens could not find any problem with the system diagnostics, and responded by reinstructing the PPMC staff about how to operate it.

Component failures: The majority of problems with lab #1 stemmed from mechanical or electrical failures of aging components. Mechanical failures reported in 2006 affected the C-arm rotation motor, the collimator collision sensor, and the table elevation handle. The C-arm motor problem was complicated when the replacement motor supplied by GE was found to be inoperable. Another motor was sent: this was the only service issue that was not resolved on the day of or day after a service call.
Component failures of an electrical nature included two failed switches (including the footswitch), an x-ray tube failure, and failure of three different circuit boards. Also, one system failure was caused by a circuit board that had become loose.

STEP 7: EVALUATE SYSTEMS BY ATTRIBUTE AND PREPARE REPORT

Why? To not only document the results of our analysis, but also to document methods.

- Once the attributes were rated and we had evaluated each aspect of the competing systems, we compiled a draft report containing our findings.
- System attributes were presented in table form.
- To help direct readers to areas where systems varied, we applied a light shading to table cells where one system's performance was somewhat inferior to the others, and a heavy shading to cells where one system's performance was markedly inferior.
- By documenting our methods as well as the results of the investigation, the executives were assured that the findings were based on sound evidence rather than the subjective preferences of the cardiologists.

Attributes of User Controls

Attribute	Importance	"X"	"Y"	"Z"
Control devices work in an intuitive manner	High	Yes	Yes	Yes
Control devices easy to distinguish from one another	High	Yes: size & shape	Yes: shape	No
Additional control devices	Low	Pistol grip control for C-arm and table	Second knob for table control	None
Zoom control	High	One step	One step	Multiple steps
Store and recall x-ray technics	Medium	Yes	Yes	Yes
Store and recall C-arm positions	Medium	7 positions	2 positions	3 positions
One-touch C-arm park	Low	No	Push and hold	Push and hold
Voice recognition (optional)	Low	No	No	Yes

Attributes of Familiarity

Attribute	Importance	"X"	"Y"	"Z"
Number of PPMC cardiologists presently using manufacturer's current imaging system	High	7/7	3/7	6/7
Number of PPMC cardiologists presently using manufacturer's current image management system	Medium	0/7	0/7	0/7

STEP 8: REVIEW REPORT AND RATINGS WITH USERS

Why? To prioritize system attributes as decision criteria, and to make sure the report is free from errors in our understanding of the attributes and their significance.

- After the draft tables were completed, we met with the PPMC cardiologists and lab managers.
- The committee went through each of the attribute lists and rated each attribute's importance as "high," "medium," or "low." These ratings were assigned in a blinded manner, before the committee members saw how each system performed on the respective attributes.
- Ratings were discussed by the participants until consensus was reached on each.
- The clinical experts also reviewed each of the tables so any errors or omissions could be corrected. This was necessary because we could not observe every clinician and see each system function in all kinds of clinical situations.

OUR FINDINGS IN THIS CASE:

- **Because the PPMC cardiologists perform procedures by themselves, without a fellow or resident assisting in the procedure, the ability to pan (shift views) from groin to heart was more important for this hospital than for other hospitals in our system.**
- **Some of the problems reported by the cardiologists and the lab managers stemmed from the fact that the cardiology PACS system at the hospital was obsolete and did not conform to current DICOM interoperability standards. Thus we recommended that a modern PACS be acquired too.**
- **The drawbacks of some of the systems could be mitigated by selecting different hardware options for the equipment purchased for PPMC than was selected for the other affiliated hospitals. For instance, with device "Z", specifying a ceiling-mounted C-arm instead of a floor-mounted C-arm would allow panning from groin to heart.**

CONCLUSIONS:

- **Principles of evidence-based medicine can be applied to decisions outside the usual practice of technology assessment.**
- **Criteria to inform the selection of a specific medical device vary from institution to institution.**
- **Evaluating devices in light of user preferences and under the specific characteristics where they will be used facilitates discovery of important differences that may affect decision-making.**
- **Including physicians and other device users in the technology assessment process not only builds support for the results of the assessment, but yields important insights into the attributes on which decisions should be based.**
- **Evidence-based practice centers can contribute to better purchasing decisions.**

Note: for purposes of this poster, manufacturer's names have been redacted from the attribute tables.