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# **Report of the Joint Working Group on Telemammography/Teleradiology and Information Management**

**March 15–17, 1999  
Washington, D.C.**

*Sponsored by  
U.S. Public Health Service's Office on Women's Health  
National Cancer Institute  
American College of Radiology*

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## Acronyms

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ACR	American College of Radiology
AMLCD	active matrix liquid crystal display
ATM	asynchronous transfer mode
BIRADS	Breast Imaging Reporting and Data System
CAD	computer-aided diagnosis
CRT	cathode ray tube
DICOM	Digital Imaging and Communications in Medicine
DLT	digital linear tape
FDA	U.S. Food and Drug Administration
FFDM	full-field digital mammography
GSR	gigabit switch router
HIPAA	Health Insurance Portability and Accountability Act of 1996
IHE	Integrating the Healthcare Enterprise
IP	Internet protocol
ISDN	integrated services data network
MIR	Mallinckrodt Institute of Radiology
MRI	magnetic resonance imaging
MRS	magnetic resonance spectroscopy
MZMC	Mt. Zion Medical Center
NEMA	National Electrical Manufacturers Association
NCI	National Cancer Institute
NGI	next generation Internet
ODL	optical disk library
PACS	picture archiving and communications systems
PET	positron emission tomography
PHS OWH	U.S. Public Health Service's Office on Women's Health
QALY	quality-adjusted life years
RAID	redundant array of inexpensive disks
ROC	receiver operator characteristics
UCSF	University of California at San Francisco
WAN	wide-area network

## Planning Committee

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The U.S. Public Health Service's Office on Women's Health and the National Cancer Institute gratefully acknowledge the members of the planning committee, who devoted time and effort to the development of the conference agenda.

<b>Chairs:</b>	Faina Shtern, M.D. Daniel L. Winfield, M.S.	PHS Office on Women's Health Research Triangle Institute
<b>Members:</b>	Steven T. Drew Sam Dwyer, Ph.D. Melvyn Greberman, M.D. Steve Horii, M.D. H.K. (Bernie) Huang, D.Sc., F.R.C.R. Ronald B. Schilling, Ph.D. John Silva, M.D. Daniel Sullivan, M.D.	Radiological Society of North America University of Virginia U.S. Food and Drug Administration University of Pennsylvania University of California at San Francisco PrimeX General Imaging Corporation Defense Advanced Research Projects Agency National Cancer Institute

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### **Session 1: Clinical and Technical Overview**

<i>Session Leaders:</i>	Carl J. D'Orsi, M.D., F.A.C.R. Edward A. Sickles, M.D., F.A.C.R.	University of Massachusetts, Memorial Health Care University of California at San Francisco
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### **Session 2: Operational Experience in Teleradiology**

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<i>Panelist:</i>	Curtis P. Langlotz, M.D., Ph.D.	eDict Systems, Inc.

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<i>Speakers:</i>	Fred M. Behlen, Ph.D. David Forslund, Ph.D. Janice C. Honeyman, Ph.D. R. Gilbert Jost, M.D.	University of Chicago Los Alamos National Laboratory University of Florida Mallinckrodt Institute of Radiology
<i>Panelists:</i>	W. Edward Hammond, Ph.D. Charles E. Kahn, Jr., M.D.	Duke University Medical Center Medical College of Wisconsin

<b>Session 4:</b>	<b>Emerging Technologies and Concepts</b>	
<i>Session Leaders:</i>	H. K. (Bernie) Huang, D.Sc., F.R.C.R. Ronald B. Schilling, Ph.D.	University of California at San Francisco PrimeX General Imaging Corporation
<i>Speakers:</i>	Michael J. Ackerman, Ph.D. Stephen G. Batsell, Ph.D. Barbara G. Beckerman, M.B.A. H.K. (Bernie) Huang, D.Sc., F.R.C.R. John Huffman, Ph.D. Alan H. Rowberg, M.D. Ronald B. Schilling, Ph.D. Capt. Paul Tibbits, M.D.	National Library of Medicine Oak Ridge National Library Lockheed Martin Energy Systems, Inc. University of California at San Francisco Stentor, Inc. Rowberg and Associates, Inc. PrimeX General Imaging Corporation Office of the Secretary of Defense (Health Affairs)
<i>Panelists:</i>	Maj. Greg T. Mogel, M.D. Capt. Jerry A. Thomas, M.S.C., U.S.N.	U.S. Army Medical Research and Materiel Command Uniformed Services University of the Health Sciences
	<b><i>Industry Panel: Roadblocks to Practical Implementation</i></b>	
<i>Moderators:</i>	Melvyn Greberman, M.D., F.A.C.P.M. Faina Shtern, M.D.	U.S. Food and Drug Administration U.S. Public Health Service's Office on Women's Health
<i>Panelists:</i>	Hartwig Blume, Ph.D. John D. Cox, Ph.D. Glenn S. Fields, M.S.S.M. Jean-Pierre Georges, Ph.D. Morgan W. Nields, M.B.A.	Phillips Medical Systems, Inc. PrimeX General Imaging Corporation General Electric Corporate Research and Development dpiX, Inc. Fischer Imaging Corporation
<b>Session 5:</b>	<b>Implementation Issues</b>	
<i>Session Leaders:</i>	W. Dean Bidgood, Jr., M.D., M.S. Edward V. Staab, Jr., M.D.	University of Oklahoma Health Sciences Center National Cancer Institute
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<b>Session 6:</b>	<b>Clinical Evaluation: Current Status and Challenges</b>	
<i>Session Leaders:</i>	Joseph Gitlin, D.P.H. Curtis P. Langlotz, M.D., Ph.D.	Johns Hopkins Medical Institutions eDict Systems, Inc.
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## Introduction

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In March 1996, the U.S. Public Health Service's Office on Women's Health (PHS OWH) established a Federal Multi-Agency Consortium for Imaging and Other Technologies to Improve Women's Health. This consortium facilitates technology transfer from laboratories to patients. The membership of the consortium includes, but is not limited to, the National Cancer Institute (NCI), Food and Drug Administration (FDA), Health Care Financing Administration, Central Intelligence Agency, Department of Defense, Department of Energy, and National Aeronautics and Space Administration. The activities of this consortium have been critical for sharing expertise, resources, and technologies by multiple government agencies for the advancement of novel breast imaging for early diagnosis of cancer, such as digital mammography, magnetic resonance imaging (MRI) and spectroscopy (MRS), ultrasound, nuclear medicine, and positron emission tomography (PET), as well as related image display, analysis, transmission, and storage and minimally invasive biopsy and treatment.

The consortium sponsored a public conference entitled "Technology Transfer Workshop on Breast Cancer Detection, Diagnosis, and Treatment" convened on May 1-2, 1997.<sup>1</sup> During this meeting, consortium members developed recommendations for the scientific and technologic projects critical for advancement of novel breast imaging.

Subsequently, PHS OWH and NCI jointly sponsored the establishment of several working groups to define further the research agenda in the areas of breast imaging examined by the May 1997 conference. These groups focused on specific recommendations for research priorities and technology development and transfer opportunities across multiple areas of breast imaging:

- Nonionizing imaging (e.g., ultrasound, MRI, optical imaging) for the development and testing of novel modalities free of ionizing radiation
- Functional imaging (e.g., PET, MRI and MRS, and optical imaging and spectroscopy) for the achievement of comprehensive in vivo cellular and ultimately molecular biologic tissue characterization
- Image processing, computer-aided diagnosis (CAD), and three-dimensional digital display for

enhanced lesion visualization and radiologic image interpretation

- Telemammography, teleradiology, and related information management
- Digital X-ray mammography, with an emphasis on digital display technologies and workstation design for image interpretation
- Image-guided diagnosis and treatment for potential replacement of open surgery with minimally invasive and/or noninvasive interventions
- Methodological issues for diagnostic and screening trials for imaging technologies, with specific focus on the development of computer models for analysis of patient outcomes and cost-effectiveness.

This report summarizes the results of the Conference of the Joint PHS OWH/NCI Working Group on Telemammography/Teleradiology and Information Management. Seventy-four international scientific leaders, representing clinical practice, academic research, government agencies and laboratories, and medical imaging system manufacturers, attended the meeting held March 15-17, 1999, in Washington, D.C. This paper describes the group's findings and recommendations.

### ***Goals of the Joint PHS OWH/NCI Working Group***

The working group defined telemammography as "transmission of mammograms for display at a site remote to that used for image acquisition." The group had three primary goals:

- 1) To review the state of the art in telemammography and teleradiology, including current and future clinical applications and technical challenges.
- 2) To outline a research agenda, including short- and long-term priorities in technology development, basic research, and clinical testing.
- 3) To identify technical limitations and develop problem statement(s) seeking new or emerging technologies.

To achieve these goals, the meeting opened with two keynote addresses:

- Role of Teleradiology in the Integrated Health Care Delivery System, presented by Alan F. Dowling of Ernst & Young, LLP
- Intelligence Technologies for Digital Image Display, Processing and Transmission, presented by Darryl N. Garrett of the National Imagery and Mapping Agency.

In his keynote speech, Mr. Dowling outlined several components for any telemedicine, information, and other related technologies (see Table 1). The keynote presentations were followed by a series of sessions, as summarized below.

**Session 1: Overview of Telemammography** addressed the health care need, realistic clinical scenarios, and technical requirements for telemammography and teleradiology.

**Session 2: Operational Experience in Teleradiology** included reviews of the current practice and future plans for clinical teleradiology systems at major academic and government centers, including fiber-optic technologies.

**Session 3: Information Management** examined state-of-the-art technologies and their potential integration of digital radiology.

**Session 4: Emerging Technologies and Concepts** addressed recent innovations and research opportunities. This session included an industry panel that examined roadblocks to practical implementation of digital radiology and telemedicine.

**Session 5: Implementation Issues** highlighted the importance of widely accepted technical standardization, patient confidentiality and data security, and a medico-legal strategy for long-term success of teleradiology.

**Session 6: Clinical Evaluation** addressed the needs and challenges in demonstrating the cost-effectiveness of telemammography and teleradiology.

**Working Session:** Working group members met to formulate consensus reports describing the current state of the art and recommendations for future priorities in technology development and related research.

**Summary Session:** The consensus reports were presented during the summary session. The reports addressed (1) the current state of the art and

**Table 1: Strategic and Tactical Benefits of Telemedicine Technologies**

<b>Structure</b>	Transform unstructured processes into routine transactions
<b>Task support</b>	Propagate and support organizationwide best processes
<b>Geography</b>	Make processes independent of geography
<b>Disintermediation</b>	Connect two parties without the "middle man"
<b>Parallelism</b>	Change sequence of tasks to allow parallel action
<b>Automation</b>	Reduce or replace human labor processes
<b>Dematerialization</b>	Replace physical objects with electronic information
<b>Tracking and control</b>	Track and control tasks, status, inputs, outputs, and outcome
<b>Analysis</b>	Bring complex analytical methods to bear on process
<b>Knowledge management</b>	Improve process by capturing and disseminating knowledge
<b>Strategy</b>	Enable provision of services dependent on the technology

Source: A.F. Dowling, Presentation to the Working Group on Telemammography/Teleradiology and Information Management: March 15, 1999, Washington, D.C.

fundamental clinical/technical roadblocks, (2) technical parameters required to meet current and future clinical needs, and (3) future priorities in technology development and related basic and clinical research.

Subsequent to the working group meeting, its leaders developed written summary reports with input from session participants. These summary reports have been integrated into this article with editorial input from the working group chairs and sponsors.

## Session 1: Overview of Telemammography

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The transmission of mammograms for display at a remote site (i.e., telemammography) promises to facilitate a variety of new approaches to image interpretation. Using telemammography, imaging practices that operate at more than one site will be able to monitor and interpret all of their mammograms (including diagnostic examinations) in a single location, or at least in a small number of centralized locations. This centralization permits all or almost all examinations to be interpreted by those physicians in a group practice who have the greatest expertise in mammographic interpretation. Because more experienced interpreters produce more accurate results, telemammography represents an important advance over standard procedure. Another important application for telemammography is to facilitate second-opinion interpretation, by making off-site, world-class mammography expertise accessible in real time to community-practice physicians. Telemammography also can increase access to examination for a variety of underserved populations, ranging from those in isolated rural locations to those in low-income inner-city neighborhoods.

Pilot testing has shown that it is possible to transmit mammographic images to remote locations without losing information content.<sup>2</sup> Although technical feasibility has been demonstrated, telemammography is not yet clinically practical. There are several unresolved problems that must be overcome before telemammography will achieve widespread clinical use.

First, to be transmitted at the high degree of resolution needed for mammographic interpretation, images must be sent and received in digital format. This requires the use of a full-field digital mammography (FFDM) unit. (High-resolution digitization of conventional film-screen mammograms is far too time-consuming to be practical for telemammography.) The interpretation of digital mammograms is likely to be at least as accurate as that for conventional film-screen mammograms. A preliminary study suggested that using prototype FFDM units improved the recall rate and the positive predictive value for biopsy without any accompanying decrease in cancer detection rate.<sup>3</sup> The substantial acquisition and maintenance costs involved in digital mammography, however, limit the clinical acceptance of telemammography.

In addition, for telemammography to be clinically successful, the interpretation of transmitted digital images must be done at least as rapidly as conventional film-screen mammography (i.e., without reduction in throughput). This involves considerable expense because rapid transmission of digital mammograms, which are about 40 megabytes or larger, requires the use of high-priced infrastructure (e.g., T1, xDSL, or ATM communication lines or satellite transmission, a high-speed network).<sup>4</sup> Costs are expected to decrease substantially in the near future, and investment in a telemammography infrastructure can be justified primarily by the economies of scale that can be achieved by sharing the infrastructure with (1) all other teleradiology applications in a medical imaging practice or (2) with all other telemedicine applications in a clinical enterprise.

The need for rapid throughput performance renders impractical the display of telemammography images in laser-printed hard-copy format, which requires the time-consuming steps of image printing and mounting of films on viewboxes. Although the bulk of current telemammography research involves hard-copy image display,<sup>2,3,5,6</sup> routine clinical practice will not tolerate the resultant delay in throughput.

Rather, to achieve clinical acceptability, telemammography will require soft-copy image display on high-resolution monitors built into a user-friendly workstation. Important features of such a workstation include flexible display of up to eight standard-resolution images (four from the current examination plus four from a previous examination); a "smart" window-level function that automatically displays images at close to optimal settings; intuitive user-operated tools for window-level function and magnification; and a one-step process to archive optimized image-display settings for subsequent use. Also needed is the simultaneous display of the same images on workstations at two sites with on-screen display of dual cursors controlled by each site's user. This dual display, combined with voice communication by telephone, will facilitate (1) real-time telemanagement of diagnostic mammography examinations between the technologist at the image acquisition site and the physician at the image interpretation site and (2) real-time teleconsultation between physicians at two sites. Prototype telemammography systems have already been

constructed and pilot tested, demonstrating that real-time performance can indeed be achieved.<sup>7,8</sup> Preliminary experience showed that the elapsed time between completion of image acquisition and display of images for interpretation using telemammography is less than half the time required for conventional film-screen mammography.<sup>9</sup> At this time, however, no telemammography systems are in general clinical use.

In summary, despite the technical feasibility to perform telemammography interpretation at remote sites, several practical problems must be overcome before this method achieves widespread clinical acceptance. Clinical studies must be completed to demonstrate (1) comparable/superior diagnostic accuracy of off-site telemammography interpretation versus on-site interpretation of conventional film-screen mammograms and (2) the ability to conduct routine telemammography in a time-efficient manner. In addition, clinical acceptance of telemammography also requires the general deployment of FFDM units and user-friendly soft-copy display workstations, both at affordable cost.

### ***Technical Requirements***

The working group defined following technical requirements for successful telemammography applications.

#### **Operational**

- Images in digital format
- User-friendly interface
- Real-time operation for diagnostic and screening mammography
- Inclusion of nonmammographic imaging techniques (e.g., ultrasound, MRI)
- Patient centricity of record keeping, including confidentiality issues
- Intermanufacturer standardization of image storage and display.

#### **Functional**

- Data compression (determined transparently)
- Postacquisition image processing
- Reliable and robust voice recognition
- Security of patient records
- Image archival/retrieval.

#### **Performance**

- Acquisition-to-display time of less than 3 minutes
- Transmission of outside images is less than 5 minutes
- Prioritization of cases
- Three-level hierarchical data storage
- Retrieval rate from Level 1 storage at less than 6 seconds/image.

## Session 2: Operational Experience in Teleradiology

During this session, a review of current experience with tele mammography and teleradiology at 10 major academic and government institutions was provided (see Table 2). For example, the Mallinckrodt Institute of Radiology (MIR) provides radiology professional services—more than one million radiology studies per year—to the medical center and three off-site hospitals. The off-site hospitals require off-hours coverage and some consultation with the medical center specialists during the day. MIR's approach uses data acquisition systems at each site and a combination of both ISDN communications to the radiologists' homes and ATM links to the medical center. The ISDN lines provided adequate bandwidth to reduce the study transmission wait time well below the "drive to hospital" time. Direct cost-benefit ratios have been difficult to quantify, but a consensus viewed that night duty was less onerous with the home communications.

The University of California at San Francisco (UCSF) has two clinical mammography settings: the breast imaging radiology section and the radiology outpatient section where general radiologists read mammography cases. Using the ATM network as the backbone, UCSF set up a tele mammography system that includes two FFDM units; two dual-head high-resolution mammogram workstations; and a database server handling digital image archiving and retrieving. It shares the bandwidth of 620-megabit/second from the UCSF campus ATM network and is limited within a burst rate of 155-megabit/second. Point-to-point transmission of an FFDM image on this network requires less than 10 seconds. A thorough tele mammography study is being conducted using this system.

Recent progress on Project MISSION (Medical Image Sharing via Satellite Integrated Optical-fiber Network) at the University of Hawaii has demonstrated successful system integration of supercomputer simulation, three-dimensional rendering, and medical expertise for delivery of online services to clinical sites via on-demand satellite-terrestrial networking. The resulting system is capable of relieving the hospitals of the expense of running their own sophisticated computers and software, as well as maintaining their own staff and technologies. As another option, the remote services, including simulation and visualization, can be provided "transparently" to the users from any online

**Table 2: Ten Institutions with Experience in Tele mammography and Teleradiology**

Institution	Presenter
Massachusetts General Hospital	Daniel B. Kopans, M.D.
University of Virginia	Samuel J. Dwyer, III, Ph.D.
University of Washington	Brent K. Stewart, Ph.D.
Mallinckrodt Institute of Radiology	G. James Blaine, D.Sc.
U.S. Army	Maj. Greg T. Mogel, M.D.
U.S. Navy	Capt. Jerry A. Thomas, M.S.C.
High-Performance ATM Wide Area Network: UCSF Experience	Edward A. Sickles, M.D. Shyh-Liang Lou, Ph.D. <i>University of California at San Francisco</i>
U.S. Army-Funded Tele mammography System	Ellen Shaw de Paredes, M.D. <i>Medical College of Virginia</i>
On-Demand Delivery of Expertise and Computed Assistance for Imaged-Based Medical Services	David Y.Y. Yun, Ph.D. <i>University of Hawaii at Manoa</i>
Experience with the European ATM WAN	Heinz U. Lemke, Ph.D. <i>Technical University Berlin</i>

computing center with excess power available for "rent."

These examples of operational experience suggest that tele mammography is not only feasible but also increasing in use. Tele mammography is still in the experimental phase, however. Appropriate bandwidth is available but at a cost trade-off. Rural access also remains problematic. In addition, the cost-to-benefit ratio remains to be defined. Remaining issues include the following:

- Definition of standard image objects for transmission (DICOM)
- Establish viability of compression for this application
- Presentation—optimizing display parameters, end-to-end quality control, maintaining consistency
- Security of the transmission.

In order to evaluate clinical impact, cost-effectiveness, and safety of digital mammography, further research will need to demonstrate:

- Digital detection rate for carcinoma not lower than that of film-screen mammograms
- “No harm” (e.g., missed lesions, increase in negative work-ups or biopsy)
- Clinically acceptable trade-offs between sensitivity and specificity
- Histologic correlation to confirm efficacy.

### ***Research Priorities***

- Establish requirements for data compression.
- Establish metrics for cost-benefit evaluation.
- Ensure the availability of on-demand bandwidth (as opposed to leased circuits).
- Establish an approach for using national communications infrastructure for telemedicine (i.e., cost sharing across multiple institutions).
- Establish acceptable standards for telecommunications security.

## Session 3: Information Management

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In recent years, the prospects for telemammography have been greatly enhanced by the advent of full-field-of-view detectors, high-capacity storage systems, early versions of diagnostic workstations, high-speed networks, picture archiving and communications systems (PACS), and radiology information systems. Other relevant components include computer-aided detection tools, compression/decompression modules, structured reporting, and voice-recognition-based narrative reporting. These components are being integrated with one another through the evolution to distributed systems architectures and the adoption of integration methodologies such as common object request broker architecture (CORBA); messaging standards such as HL7, DICOM, and XML; and encoding standards such as BIRADS.

The process has been slow, however. At present, digital mammography systems do not appear to be easily scalable, integrated at an enterprise level, or cost-effective. Many existing health care information systems have monolithic architectures, are institutionally based rather than able to function in a multi-institution networked environment, are not Internet-capable, do not support image content, and are underpowered for the high capacities and bandwidths required.

### ***Recommendations***

To overcome current limitations, advances must be made in infrastructure, integrity of information, radiologist workstation, decision support, and education and information distribution.

### **Infrastructure**

Hospitals and practices are becoming increasingly combined into regional integrated delivery networks. New software architectures are emerging to support these enterprise systems, and new capabilities—telemedicine and teleradiology, decision support, consumer health education, and referral and logistic services—are beginning to be realized. To facilitate these distributed systems, a ubiquitous, cost-effective wideband network supporting both urban and rural access is required. Such a network will need reliable network management, security, and the ability to handle large volumes of data.

In addition, high-speed, scalable, distributed storage systems with a suitable archive strategy are required. For mammography, specialized storage demands

include the ability to store companion images such as pathology; ultrasound; photo images; comparison studies; or overlays resulting from annotation, measurement, or CAD functions. As mentioned, suitable compression/decompression schemes tailored for mammography must be identified.

### **Integrity of Information**

Systems must be fault-tolerant with respect to system or communication failures, with redundancy incorporated where needed. Systemwide procedures must be in place to ensure data integrity and concurrency, so that updates at one location are reflected wherever the information is used. Accurate patient identification and a reliable approach to managing the master patient index are essential. The system must facilitate error correction including reidentification of misidentified data, merges, and notification features. Audit trails and logging must be able to monitor quality and performance, reconstruct processes, and help to recover from errors.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) applies to all health care providers, payers, and others who are involved in provision of disease prevention, diagnosis, therapy, drug prescription, and patient rehabilitation. HIPAA provides underlying principles for boundaries, security, consumer control, accountability, and public responsibility.

Security issues are crucial, and patient confidentiality must be protected. Systems must provide:

- Physical safeguards
- Technical security services and mechanisms
- Administrative procedures (e.g., role-based security) to ensure only “need-to-know” individuals have access to particular information
- Electronic signatures.

### **Radiologist Workstation**

Substantial additional research is required to develop a suitable, user-friendly, soft-copy workstation for the diagnosis of digital mammograms. With proper contrast enhancement, images on a soft-copy display that are as good as or better than film images can be produced. In addition, to justify capital expenditures, workstations must be efficient, requiring less time to complete a clinical diagnosis than is needed for hard-copy film diagnosis. Other features, that require

attention in the design of a suitable diagnostic workstation are described below.

- Enabling interfaces with other medical information management systems will provide access to a full range of patient information at the time of diagnosis.
- The breast imaging field is fortunate to have completed important work with respect to structured reporting (BIRADS). Further elucidation, validation, and evaluation of these techniques are encouraged.
- Telemammography will require consultation among physicians and patients at a distance. The development of suitable systems for video telecollaboration over the telemammography network infrastructure is encouraged.
- The National Electrical Manufacturers Association (NEMA) proposal to develop a standard, under DICOM, for display system consistency is critically important to the diagnostic mammographer in a digital domain. The incorporation of this standard in future digital mammography workstations will be essential to ensure consistent image quality.

### **Decision Support**

It is important to distinguish between computer-aided detection and computer-aided diagnosis. A number of promising computer algorithms are under development and evaluation to support computer-aided detection, where candidate lesions are identified for review by a suitably trained radiologist. In most cases, the most difficult challenge in developing effective computer-aided detection systems rests not so much in identifying possible candidates for pathology, but in making the identification without a large number of false positives which will distract and slow down the radiologist. Further work in this area is encouraged for, if successful, it can lead to more efficient, more accurate mammographic diagnosis.

Computer-aided diagnosis represents a far more difficult challenge, and most researchers believe that it will be many years before computer systems are capable of accurately diagnosing breast pathology in an unaided fashion. While the benefits of CAD are demonstrable, they cannot support the entire cost structure of digital imaging. Practical CAD must therefore fit into existing digital information infrastructure. Standards are needed to enable this integration of CAD into telemammography/teleradiology systems with multiple vendors—that is, standards for moving

information across proprietary boundaries between vendors, not across distances. A survey of standardization requirements and of existing and proposed imaging standards reveals that much of the needed standards are in place or will soon be adopted. Image input to CAD systems can be supported with existing DICOM storage class services; the pending DICOM structured reporting standards in their present draft form would provide the needed facilities for the representation of CAD results. Additional work is needed for defining standards for worklists that control CAD processing algorithms.

CAD algorithms remain sensitive to image acquisition characteristics of particular radiography systems, which may be addressed in the near term by vendor testing and validation of particular image source systems. In the longer term, standard communications of imaging characteristics, together with CAD algorithms more able to adapt to source differences, will be needed. CAD implementations employing the presently available standards will be needed to provide implementation experience to guide the next stage of algorithm and standards development.

In addressing the role of computer-aided diagnosis, the working group concluded the following:

- CAD is a necessary component of an optimal telemammography/teleradiology system.
- CAD's benefits are available only in a fully digital system.
- In digital mammography, incorporating CAD could shift the burden of proof from showing equivalence to showing superiority.
- DICOM structured reporting provides features needed for standardizing a representation of CAD output.
- DICOM structured reporting also serves general reporting requirements in radiology and other specialties.
- Prototype and commercial product support are needed to improve CAD's positive predictive value.

As medical information management systems become further integrated at the enterprise level, the development of enterprisewide mammography databases, including images and related clinical information (e.g., outcomes) will be a valuable resource for data mining and decision support.



### **Education and Information Distribution**

Information management systems, deployed at the enterprise level, provide an infrastructure that supports educational initiatives and information distribution. Capitalizing on evolving technologies, such as the Internet, expands the educational programs for patients. This will become particularly relevant as wideband Internet facilities become widely available in the home. These same information infrastructures can be used to develop suitable methods to distribute medical information and images to referring physicians in their home and office. Current medical information systems have focused primarily on hospitals, but dissemination of information to referring physicians will become an increasingly critical component of telemammography systems.

Continuing to promote and develop telemammography systems requires education of vendors, patients, and physicians. The education of hospital administrators, including chief executive officers and chief information officers, is particularly important as they influence decisions regarding radiology-related capital equipment purchases. Finally, it is important to work closely with the FDA to identify the problems as well as the significant benefits that are associated with the development and approval of future digital mammography systems.

### **Summary**

For the physicians of the future, the goal is to have a seamless integration of information among medical computer systems so that all of the relevant information is available for the medical decision maker. Currently, however, there is inadequate communication among information systems, information system companies, and standards organizations. The working group identified the following research priorities:

- Inventory existing models and standards relevant to digital mammography and identify areas where further evolution of the standards will be necessary.
- Standardize computer system interfaces to allow better communication among medical information systems, giving particular attention to those areas of information exchange that are important to mammography.
- Develop information architecture appropriate for the support of mammography information systems.

- Develop a process model for mammography data systems, which will help identify where additional development is required.

Much work remains to be done before distributed, efficient, cost-effective digital mammography systems that are scalable to the enterprise level can be achieved. The recent rapid progress in the development of commercially effective PACS technology for areas of digital radiology other than mammography is encouraged. One of the most important near-term requirements is the development of a suitable soft-copy diagnostic workstation, tailored for the demands of digital mammography and exceeding the efficiency and accuracy of film-based systems.

Breaking down the barriers among the various computer information systems also is important. Toward this end, a new initiative, "Integrating the Healthcare Enterprise" (IHE), has been spearheaded by the Radiological Society of North America and the Healthcare Information Management System Society. The objective of this multiyear initiative is to foster communication among developers of medical information systems and to promote the use of standards through public demonstrations. It is anticipated that an annual IHE symposium will provide a key forum for communicating progress in the development of scalable, cost-effective, enterprisewide information strategies.

## Session 4: Emerging Technologies and Concepts

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The general consensus of this session can be summarized as follows. In terms of setting up a quality telemammography service, the following basic components are required:

- FFDM units at the examination site to generate digital mammograms<sup>10,11</sup>
- A server for image archival and retrieval
- High-speed WANs connecting the examination site with the mammography expert center
- Data security measures to ensure the image and data authenticity and integrity
- High-resolution digital mammography display workstations at the expert center for interpretation or workstations at both the examination site and the expert center for teleconsultation.

In terms of telemammography applications, the following consensus was reached in the working group:

- Telemammography is possible.
- Quality assurance for image acquisition needs to be developed.
- Network speed and design should be application-driven.
- Lossy compression is not fully acceptable.
- Digital mammography workstations are not clinically acceptable yet, and further research is required.
- Digital archival will facilitate telemammography applications.

The FFDM unit is the fundamental requirement in telemammography application. This session identified major emerging technologies and concepts that are important for facilitating a successful telemammography application (see Session 1).

### ***DICOM Archive Server***

Images acquired with FFDM require a short- and long-term DICOM-compliant archive server. The short-term storage is for immediate image recall and interpretation, whereas the long-term is for archive purposes. The short-term storage method can provide rapid image retrieval by using redundant array of inexpensive disks (RAID) technology. RAID has an

input/output transfer rate of more than 30 megabytes/second (depending on number of disks and input/output channels), enabling the display of a 40-megabyte digital mammogram in several seconds. For the long-term image archiving and retrieval, either the optical disk library (ODL) or digital linear tape (DLT) library can be used. The DLT library is the current preferred technology because of its low cost and smaller “footprint” required compared to ODL. A hierarchical image management software package using the current PACS technology can be used to manage the patient worklist and image directory for efficient mammogram retrieval.<sup>12</sup>

### ***Next Generation Internet (NGI)***

The Internet has brought unexpected demands by various applications, including medical imaging, during the past several years.<sup>13</sup> Medical images, especially digital mammograms, are different from other types of data in two aspects: file sizes are very large, and some examinations require near real-time transmission for practical use. For these reasons, the standard Internet has not been able to fulfill the transmission bandwidth requirement for clinical applications. During the past several years, the federal government has undertaken NGI initiatives. Using various high-speed network backbones, including the CalREN-2 (California Research and Education Network), the vBNS (very high performance Backbone Network Service), and the Abilene, the NGI initiatives were designed to form the Internet2 infrastructure and provide an opportunity for tackling this problem.<sup>14</sup>

The next generation of Internet technologies focuses on extending the usability of the network to a wider range of applications. From a user perspective, this translates to an increased range of available services:

- Security built into the network through the use of network layer encryption
- A spectrum of service types from “best effort” service to guarantees on end-to-end latency
- Nomadicy, where the data follow the user.

Internet protocol (IP) security efforts focus on developing standard security services that include encryption of the data packets at the network level and standardized key management for both unicast and multicast flows. Efforts to increase service types

focus on the application, selecting from a number of service types depending on the application's requirements. Currently, the Internet only has best-effort service, which treats all traffic the same; however, multimedia traffic needs bounded delays and priority during periods of congestion. These services are particularly important for the teleradiology community, where image transmission, teleconferencing, and real-time sensor data predominate network-based applications. Nomadicy efforts range from allowing a single IP address to function anywhere in the Internet (i.e., mobile IP) to regional data storage or caching, where important information moves around the Internet as users access the network in various locations.

From a technical perspective, for the Internet to become a core service infrastructure, it must be able to provide connectivity anywhere, anytime for all users. Hence, the issues of scalability and access are important. The NGI will be able to transmit more data (tens of gigabits per second) than the current Internet, allowing increased scalability. In addition, high-bandwidth global wireless access is only a few years away as low earth orbiting satellite systems such as Teledesic emerge. These changes will significantly extend the service range of a radiology department and provide increased opportunities to reach patients in rural or inner-city areas that may not currently have access to medical services. In addition, ubiquitous connectivity between medical centers and medical research hospitals will allow the compilation of national and global archival of medical information and images that will aid researchers searching for diagnoses and cures of diseases.

Although NGI initiatives have been proposed for several years, the development of the Internet2 connectivity and security measures is still in its infancy. Extensive work is still required before it can be used for telemammography application efficiently and cost-effectively. Using the Internet2 for telemammography application requires consideration of its connectivity, performance, and security, as described below.

### **Connectivity and Performance**

In terms of connectivity, two issues must be resolved. First, although the global Internet2 is available in the United States, the linkage from the main circuit to local clinical sites (e.g., in the breast imaging laboratory) must be established. Second, because segments in the national Internet2 can be either ATM or GSR, a dual conversion must be established between ATM cells and GSR packets between the

global and the local network. The performance of the Internet2 for medical imaging applications is an open issue because its overall performance depends on the individual routers within each Internet2 local segment.

### **Image and Patient Data Security**

It is important to consider data security when using the public, high-speed Internet2 for the connection of examination sites with mammography expert centers.<sup>15</sup> There are three topics related to data security: privacy, authenticity, and integrity. Privacy is to restrict access to data, authenticity is to validate the source of transmission, and integrity is to verify that the image has not modified.

The privacy is the network authority's responsibility, while the onus for authenticity and integrity rests on those generating the digital mammogram. Existing cryptography can be used for these purposes.<sup>16</sup> One method is to embed some encrypted characteristics of the digital mammogram along with relevant patient information in the image at the examination site before it is sent. Data embedding is attractive in digital mammography because its file size is large and its data has high correlation. In addition, data embedding does not change the size of the image data file, thus preserving the DICOM data format.

### **Telemammography Workstation**

As mentioned earlier in this article, a display workstation for digital mammography requires certain characteristics that are different from other modality images.<sup>17,18</sup> A digital mammogram image is 4K x 5K, and, ideally, the display area should be able to accommodate the full resolution image. Since commercially available digital monitors can only display a 2K x 2.5K image, the workstation needs to have a zoom and scroll function. The workstation also must be able to display eight images simultaneously: four (i.e., left and right craniocaudal and mediolateral oblique views) current and four previous images. The time of displaying an image has to be within several seconds. The active matrix liquid crystal display (AMLCD) is an emerging display technology to replace the video monitor. The currently available prototype model has a 19-inch diagonal; brightness of 200 foot-Lambert; and 2048 x 2560 pixels, each with a 256 gray level range. The display area is thin and lightweight compared with video monitors, and can be tilted easily for comfortable viewing angles.

The workstation also requires a set of viewing tools, including automatic built-in lookup tables for

instantaneous tissue differentiation, to facilitate expert image interpretation. The execution time of these functions should be instantaneous. Some of these viewing tools are:

- Image positioning
  - Centering
  - Image flip
  - On screen image exchange
- Full resolution image display
  - Instantaneous full resolution image
  - Scalable magnifying glass
  - Zoom and scroll
- Precomputed lookup table
  - Soft tissues
  - Dense tissues
  - Skin and fatty tissues.

For teleconsultation between a generalist at a remote site and the mammographer at the expert center, a real-time dual cursor system in the workstations is required for instantaneous mutual image manipulation and annotation. Workstation design and implementation require continuing intensive research and development efforts to bring the potential of digital mammography into clinical usefulness.

### ***National Digital Archive***

The development of a national breast imaging archive with network connectivity to every mammography center could revolutionize the breast cancer screening program in the United States. A digital archive for mammography would leverage a high-speed network infrastructure with an imaging archive that supports storage, retrieval, and distribution of breast images for clinical, research, and educational purposes and ensures privacy and confidentiality with multilevel security embedded throughout the system. This system would address several critical issues in the implementation of breast cancer screening, such as the ability to:

- Improve access/performance of cancer screening
- Support the storage, retrieval, and timely distribution of digital images, including pre-scheduling
- Aid both clinical and research applications
- Maintain a digital record of prior examinations and history
- Permit access to specialists for consults and secondary reads

- Facilitate epidemiological research and data searches
- Provide tools for education and training.

While a national digital archive is feasible conceptually, a number of prior projects funded by the PHS OWH<sup>19</sup> and the National Library of Medicine<sup>20</sup> have demonstrated that there are numerous technical challenges involved in the implementation. Digital images create very large files with increased volume and capacity requirements, and the infrastructures or architectures to support these requirements have not been fully developed. Some of the critical technical issues include communications, security, database systems, information management within the archive, necessity for built-in redundancy, access controls, potential bottlenecks, and integration of key applications. Potential applications for a distributed digital archive include telemammography (both screening and diagnostic), computer-aided diagnosis and image processing, and tele-education to build case studies. Under the leadership of the PHS OWH, the University of Pennsylvania, the University of Chicago, and Lockheed Martin Energy Systems, together with researchers from Oak Ridge National Laboratory and members of the International Digital Mammography Development Group, have formed a partnership to design, develop, implement, and test a digital archive for mammography.

### ***Research Priorities***

#### **Develop Models for Improving Telemammography Applications**

- Protocols for screening examination
- Computer-aided detection
- Overread and second read
- More efficient batch read
- Better access to previous studies.

#### **Conduct Research in Digital Archival and Retrieval**

- Scalable modeling and testbed archive systems
- Data interchange formats
- Pilot data sets
- Data security (i.e., privacy, confidentiality, integrity)
- Archive media migration strategy.

## **Support R&D of Digital Displays and Workstation Design**

- Alternate hardware for display
- Factors affecting alternate hardware design
- Image navigation and enhancement
- Integration of computer-aided detection
- Work flow management.

### ***Acknowledgement***

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## Session 5: Implementation Issues

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A series of speakers addressed the key issues that will influence widespread implementation of telemammography.

### ***Privacy/Security***

The critical importance of data privacy and security has been highlighted in previous sections of this article. This session emphasized the need to achieve a balance between security and usability. Funding needs to be applied to researching how best to:

- Accommodate patient involvement (e.g., permission, review/correct, review custody chain)
- Provide end-to-end protection (i.e., minimizing gaps when information is exposed and vulnerable).

### ***Standards***

Standards of particular relevance to the communications of image information include the areas of image compression and display quality. Compression technologies will remain important until zero-cost, infinite-bandwidth channels become ubiquitous. Compression choices fall into three general categories:

- Original data/lossless (3:1 compression)
- Visually lossless, where the observer cannot detect any compression noise or artifacts (16:1 compression)
- Diagnostically lossless, where artifacts are detectable but do not impact accuracy (compression limits not well determined).

Establishing standard practices based on careful study of the visually lossless criteria may provide a defensible utilization of image compression.

Soft-copy display quality must consider display device parameters beyond addressable quantity of pixels and brightness. CRT luminance, dynamic range, spot profile, phosphor type, frequency response and gamma parameters, and other characteristics are important to achieving the level of quality needed for accurate diagnosis. The successful deployment of soft-copy displays requires methods for achieving quality assurance over time. While manual techniques with test patterns and external

photometers can be used, automated approaches based on internal calibration methods are needed for geographically dispersed display units.

Further research is needed for:

- Structured reporting applications
- Multicenter pooling of data from clinical trials
- Knowledge-sharing.<sup>21</sup>

Procurements from the U.S. Department of Defense, the Veterans Administration, and other major customers should contain affirmative guidelines and provide vendors incentives for implementation of DICOM Structured Reporting and Mammographic Image Interchange Standards.

Further research also is required for multidisciplinary clinical experts to enhance the content of clinical code sets (e.g., SNOMED, LOINC) and develop detailed reference terminology for clinically relevant indexing and selective retrieval of image-related information.<sup>22,23,24</sup>

There remains a need for additional standards for equipment quality assurance, particularly regarding display quality and assuring consistent display (presentation) of images on various CRT monitors.

### ***Medical/Legal Issues***

The medical/legal issues surrounding telemammography are highlighted in the following comments from Dr. R. James Brenner.

Medical malpractice is usually defined by the civil tort of negligence. This tort, which seeks to establish the conduct of a reasonable and prudent physician under similar circumstances, is defined by four elements—duty, breach of duty, causation, and damages. Liability may be found when the duty of the radiologists is not satisfied. This duty includes production of satisfactory images, reasonable interpretation, and effective communication of results. The promise of telemammography, predicated in large part on digitally acquired images, includes certain new legal exposures. Global issues related to teleradiology—privacy, storage, transmission capabilities, compression, and requirements for second opinions because of increased availability—also apply to telemammography, but other issues are

more specific. Workstation algorithms and display of transmitted images may not display information available to the source user. If breast cancer diagnosis is delayed, manipulation of the original image may better display features of malignancy, subjecting the off-site interpreting radiologist to liability; claims of having “no control” over the transmitted image may be legally insufficient. In addition, imaging interpretations often involve the concomitant use of ultrasound, especially for palpable areas where mammography demonstrates no lesion. On occasion, the ultrasound diagnosis of malignancy is straightforward. Thus, the transmission of mammographic images under such conditions without ultrasound may create issues of negligence. Furthermore, a common qualifier in interpretation of ultrasound hard copy images is that their production is operator dependent; this same concern may now apply to transmitted mammographic images digitally acquired.

Credentialing and reimbursement constraints are disincentives to electronic referral. In intrastate situations, problems include:

- Reimbursement from various carriers
- Data access, security, confidentiality
- Supervision, image quality
- Liability (jurisdictional)
- Legal standards of care.

In diagnostic interpretation, the duty of the radiologist includes production of satisfactory images, reasonable interpretation, and effective communication. Mammographic interpretation occurs in the context of other clinical information. Simple transmission of mammographic images without the ability to transmit ultrasound or other information may represent negligence.

### ***Regulatory***

Regulatory issues include:

- Who is the lead interpreting physician?
- What is the role of the physician receiving the images?
- What is the potential for violation of Stark Amendment on tele mammography referrals?

Continued participation by the FDA on the DICOM working groups is recommended, as is closer collaboration with the ACR on these issues. Efforts should be made to enhance communication among

FDA, NEMA, the National Institutes of Health, and the Centers for Disease Control and Prevention on issues relating to tele mammography, teleradiology, and telemedicine. Manufacturers of new tele mammography systems should consult with FDA early in the product development process.

## Session 6: Clinical Evaluation

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As concluded earlier in this article, telemammography appears to be feasible and potentially beneficial to patients. Investigators are moving beyond the technical issues, and are beginning to focus on practical issues, such as connectivity, user interfaces, and cost. Thus, it seems likely that digital mammography will be beneficial for at least some patients in some settings.

One of the challenges is that FFDM systems are still evolving. There are a variety of experimental systems, resulting in changing cost/technology tradeoffs. The benefits to economic evaluation are (1) understanding major cost drivers; (2) placing bounds on outcome effects; and (3) focusing research, engineering, and development. The first step in any evaluation should be to specify clearly which components of the system are being evaluated (e.g., the transmission network, the security system, the workstation, the image archive, CAD, or the system as a whole.)

The most appropriate framework in which to conduct a comprehensive and definitive evaluation of digital mammography is the randomized clinical trial. The trial should include conventional and digital arms, and the digital data should be reviewed with and without the help of CAD software. The trial should be designed to allow evaluation of the equivalence of digital mammography systems from multiple vendors, so that equivalence (or lack thereof) can be established. A multi-institutional trial will establish the performance of the technology in a routine setting, rather than in a setting in which the technology was pioneered.

Two presentations illustrated the issues surrounding design of clinical trials to evaluate telemammography, as described below.

### ***Teleconsultation and Telemangement Protocols for Evaluation of the Effectiveness of Telemammography***

The purpose of the proposed evaluation is to assess whether an FFDM system could be integrated successfully into breast imaging practice in various nonuniversity clinical settings. In particular, the evaluation will determine whether telemangement and image interpretation of FFDM by off-site breast imaging specialists is at least as accurate and efficient

as on-site management and image interpretation by nonuniversity general diagnostic radiologists using conventional film-screen mammography.

The first phase will consist of 450 patients, participating at three satellite sites, with confirmed, known diagnoses of calcifications and masses. The general radiologist will choose a case randomly from the set and initiate the consultation session. This includes reading and scoring the film examination, initiating telephone contact with the expert, and using the additional digital mammograms reviewed simultaneously by the general radiologist at the satellite site and expert radiologist at Mt. Zion Medical Center (MZMC) using their workstations. This teleconsultation will result in the completion of a computer-generated form containing examination scores. The end points are whether the initial film diagnosis of the general radiologist was changed by the consultation and changed in the degree of confidence in interpretation between the pre- and postconsultation readings. Data will be collected on time required for teleconsultation as well as the time involved in the usual method of film shipment and consultation on a 10 percent random sample of the cases.

The telemangement study begins with diagnostic film mammography examinations read and scored by the general radiologist at each satellite site. Then digital mammograms are obtained, read, and scored immediately by the expert at MZMC, while the patient is still in the examination room at the satellite site. The expert reading is then given to the general radiologist at the satellite site, who then decides whether or not to follow the expert's recommendations in terms of immediate additional imaging and subsequent management. The general radiologist then records reasons for accepting/rejecting the expert's recommendations. End points are procedure times of both film mammography and digital mammography (i.e., from image exposure to image processing to image display to image interpretation) and whether the general radiologist's initial diagnosis was changed by the expert's telemangement interpretation, and the diagnostic accuracy of the general radiologist's initial (film-based) interpretation versus the expert radiologist's off-site (digital-based) interpretation. Follow-up data on the patient will be used as truth.



The comparison between initial general radiologist interpretation and teleconsultation interpretation at each of the three satellite sites will be conducted using a chi-squared statistic by Bennett. A repeated measures analysis of variance will be used to test the differences between the general radiologist's numbers of masses/calcifications and the true number and the differences between the teleconsult number of masses/calcifications and the true number.

### ***Field Trial of Mobile Digital Mammography in Remote and Underserved Native American Populations***

The general hypothesis to be tested in the proposed field trial may be stated as: Mobile digital mammographic services linked by high-speed telecommunication media to "centers of expertise" are as clinically efficacious as conventional film-screen procedures performed at these centers. Further, the use of this technology in remote and underserved locations improves patient care in these areas, particularly with regard to participation and with follow-up compliance. Among the many parameters to be measured in testing the general hypothesis is the accuracy of digital image interpretation, which will be compared with film-screen accuracy until FDA approves digital mammography for clinical use. Also measured will be access by underserved population groups, acceptance by patients and health care providers, and relative costs and benefits related to mobile digital mammography.

The principal technical objectives of the research are (1) to validate the accuracy of interpretations of both screening and diagnostic examinations performed on digital mammographic units compared with those produced by conventional film-screen techniques; (2) to identify and resolve patient and provider acceptance issues associated with real-time capture, transmission, storage, retrieval, and interpretation of digital mammographic images produced in a mobile setting; (3) to measure changes in patient participation in screening programs and compliance with follow-up recommendations related to the mobile digital mammography procedures; (4) to resolve clinical issues identified as barriers to the efficacious use of digital mammography in a mobile health care setting; and (5) to determine the societal and economic costs, as well as the benefits, of mobile digital tele mammography in remote and underserved Native American communities.

An advanced telemammography system will be used to support the clinical trials. The mobile unit will contain both film-screen and digital mammographic units to provide both types of examinations. The digital mammographic unit will be interfaced to a workstation that will support image acquisition; temporary storage; interim diagnostic reports; control, monitoring, and logging of transmissions; and teleconsultations between the staff in the mobile unit and the radiologists in the clinical center. Mammograms will be received at Walter Reed Army Medical Center and interpreted by Mammography Quality Standards Act of 1992 certified radiologists using a PACS with dual monitor diagnostic workstations. Additional participating reading centers will be located at The Johns Hopkins University School of Medicine, and the FDA Center for Devices and Radiological Health. The interpretation will be made in accordance with the ACR BIRADS.

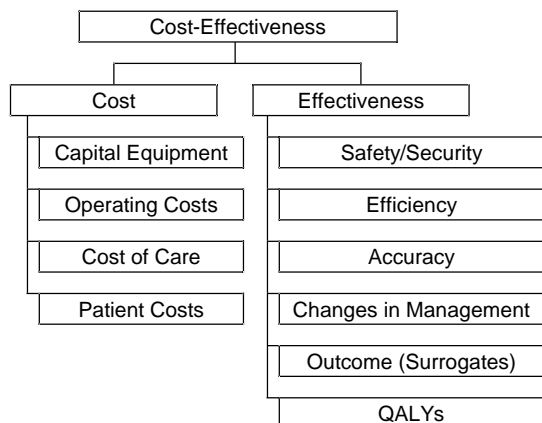
Research study patient education protocols will be modified to be "site specific" through discussions with designated coordinators at each tribal location. Particular attention will be given to the guidance of the digital mammography staff and data acquisition personnel. Recommended follow-up of patients with suspected abnormal findings will be the responsibility of local health care providers. Following completion of the program at the Mohawk site, the Navajo and Cherokee organizations will support the digital mammography field trial using similar protocols. The results of the research will be published promptly in appropriate peer reviewed journals and presentations will be made by the investigators to participating agencies to encourage the implementation of proven components of the innovative techniques.

### ***Cost-Effectiveness***

The data from studies such as those described above should be used as input to a cost-effectiveness model, in which cost is the numerator, and some measure of effectiveness, such as quality-adjusted life years (QALY), is the denominator (see Figure 1).

Cost-effectiveness metrics allow the comparison of systems like telemammography to other disparate medical interventions and can help guide policy decisions. Cost-effectiveness analyses should be conducted as incremental analyses (i.e., comparing the index technology to the next best technology). Costs are summarized using net present value calculations to ensure comparability of cash flows over time.

**Figure 1: Taxonomy of End Points to Evaluate Telemammography**



Cost-effectiveness analyses can be performed from a variety of perspectives. The societal perspective is most widely accepted because it takes into account all resources, regardless of how they are expended. Nevertheless, there also may be a role for incorporating other perspectives, such as that of the local site. If cost-effectiveness is demonstrated from that perspective, it may foster the appropriate adoption of such systems.

Costs related to telemammography can be categorized broadly as equipment, maintenance, personnel, space, and supplies. One additional cost measure, which is quite expensive to measure, is any change in the cost of care downstream from the initial diagnostic test. For digital mammography, one such potential area for investigation is the change in costs of biopsy due to changes in the need for subsequent negative biopsies.

There are many potential measures of clinical effectiveness. The optimal measure is in QALY; however, it may be impractical or too expensive to attempt to measure changes in outcome to that level of detail. Instead, less expensive surrogates of outcome can be attempted first. Table 3 shows a list of potential outcomes and outcome surrogates that might be affected by digital mammography systems. Promising metrics include the frequency of prior exam availability (which is likely to be greater with a digital archive, has been shown to improve the quality of mammographic interpretations, and is likely to speed patient throughput) and the accuracy of interpretation with CAD prompting.

A cost-effectiveness model of digital mammography will likely provide incorrect modeling results initially, due to the rapidly changing technology and steep

**Table 3: Potential Measures of Effectiveness for Use in Evaluation of Digital Mammography Systems**

Safety/Security	
Efficiency	<ul style="list-style-type: none"> <li>• Frequency of prior exam availability</li> <li>• Speed of interpretation</li> <li>• Need for special views</li> <li>• Patient throughput</li> <li>• Communication among providers</li> </ul>
Accuracy	<ul style="list-style-type: none"> <li>• ROC area, predictive values</li> <li>• Number, size, and stage-distribution of cancers</li> </ul>
Outcome (Surrogates)	<ul style="list-style-type: none"> <li>• Compliance with screening</li> <li>• Patient satisfaction</li> <li>• Age-adjusted survival</li> </ul>

decreases in costs. Nevertheless, these early economic assessments will help to determine the major drivers of cost and will begin answering questions about the effect of digital mammography on surrogate markers, such as the availability of prior examinations, and the effect of CAD on interpretation accuracy.

These assessments could appropriately be incorporated into a cost-effectiveness model whose cost and effectiveness inputs could be updated over time. At each stage, sensitivity analysis will help to indicate whether further changes in technology or cost will have a significant effect on the results of the evaluation.

Despite the generalizability and wide acceptance of the cost-effectiveness methodology, some important methodologic difficulties in evaluating information technology should be considered. For example, the effects of information technology are ubiquitous, but subtle in any given instance, making comprehensive evaluation extremely complex and expensive. A technology and a system often change together, raising the question whether changing the system without implementing the technology would provide equivalent benefits. Randomized studies of information technology are extremely difficult to design. Thus, pre/post or on/off studies are typically preferred. These latter studies are susceptible to secular trends in patient mix, referral patterns, and learning curves. Allocating costs of information technology, such as the network, to other activities that use that technology can be time-consuming. Standard economic analyses often fail to capture the unanticipated value of new things. For example, PACS provide economic benefits to the practice by

saving film and personnel costs. An unmeasured benefit is the ability of the practice to rapidly expand practice volume through teleradiology.

Any evaluation model should be generalizable to practice settings other than the one in which it was conducted. Such generalizable models should be adaptable to several aspects of a particular clinical practice:

- The examination volume of the practice
- The fraction of mammograms that are interpreted in a screening mode
- The age of existing image acquisition hardware
- The degree to which extra analog film copies are made and manual methods of information transmission are used.

## Summary of Research Priorities

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### *Summary Recommendations*

In summary, several goals were identified where further research can dramatically advance the field of telemammography:

- Establish requirements for data compression.
- Establish metrics for cost-benefit evaluation.
- Ensure availability of on-demand bandwidth (as opposed to leased circuits).
- Establish an approach for using national communications infrastructure for telemedicine (i.e., cost sharing across multiple institutions).
- Establish acceptable standards for telecommunications security.

Within this overall list of research priorities, there are some areas where more specific research needs were identified, as described below.

### **Models for Improving Telemammography Applications**

Research is required to better understand how the implementation of telemammography will impact:

- Screening
- Computer-aided detection
- Over-read and second read
- Efficient batch read
- Access to previous studies.

### **Information Management**

To achieve seamless information management across medical computing systems, it is important to:

- Inventory existing models and standards relevant to digital mammography and identify areas where further evolution of the standards will be necessary.
- Standardize computer system interfaces to allow better communication among medical information systems, giving particular attention to those areas of information exchange that are important to mammography.
- Develop information architecture appropriate for the support of mammography information systems.

- Develop a process model for mammography data systems, which will help identify where additional development is required.

### **Research Support in Digital Archives**

In developing the required digital archives, researchers must focus on:

- Scalable modeling and test beds
- Data interchange formats
- Pilot data sets
- Security (i.e., privacy, confidentiality, integrity)
- Media migration.

### **Display and Workstation Research**

Since displays and workstations are the fundamental current limiting factors to digital mammography, extensive research is required in:

- Alternate hardware for displays (e.g., AMLCD)
- Factors affecting alternate hardware design
- Image navigation and enhancement
- Integration of computer-aided detection
- Work flow management.

### ***Vision Statement***

It is very useful to have a guiding framework for a team of individuals pursuing a goal. For the Joint Working Group on Telemammography/Teleradiology and Information Management, the guiding framework used is the vision statement. The vision statement consists of a purpose and a mission. The purpose is a brief statement of the direction or goal that the team is undertaking. The mission consists of key areas of focus that will enable the team to achieve the purpose. The working group drafted the following vision statement for telemammography/teleradiology and information technologies:

**Purpose:** To provide access and availability to health care that will improve quality of life

#### **Mission:**

- Clinically guide the development of improved imaging systems that are safe, effective, and reliable.
- Encourage the establishment of an appropriate common carrier information infrastructure.

- Provide acceptable security, privacy, and confidentiality.
- Implement integrated, multimedia patient records.
- Establish the business model that is acceptable to patients, providers, and payers with respect to cost, cash flow, and resource management.
- Provide continuing education and training.

## References

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- <sup>1</sup> Asher S, Shtern F, Winfield D, et al. Final report of the technology transfer workshop on breast cancer detection, diagnosis, and treatment. Washington, D.C., USA. May 1-2, 1997. *Acad Radiol* 1998; 5:S465-501.
- <sup>2</sup> Kopans DB. Operational experience in telemammography: current experience and future strategies. Presented at the Working Group on Telemammography/Teleradiology and Information Management, Washington, D.C. March 15, 1999.
- <sup>3</sup> D'Orsi CJ. Novel digital technologies for breast imaging. Presented at the Working Group on Telemammography/Teleradiology and Information Management, Washington, D.C. March 15, 1999.
- <sup>4</sup> Huang HK, Lou SL, Sickles EA, et al. Technical issues in full-field direct digital telemammography. In: Lemke HU, Vannier MW, Inamura K, eds. *Computer assisted radiology and surgery*. Amsterdam: Elsevier Science, 1997; 662-667.
- <sup>5</sup> Fajardo LL, Yoshino MT, Seeley GW, et al. Detection of breast abnormalities on teleradiology transmitted mammograms. *Invest Radiol* 1990; 25:1111-1115.
- <sup>6</sup> Maitz GS, Chang TS, Sumkin JH, et al. Preliminary clinical evaluation of a high-resolution telemammography system. *Invest Radiol* 1997; 32:236-240.
- <sup>7</sup> Lou SL, Sickles EA, Huang HK, Cao F, Hoogstrate D, Jahangiri M. Full-field direct digital telemammography: preliminary. *SPIE Proc Med Imaging* 1997; 3035:369-379.
- <sup>8</sup> Lou SL, Sickles EA, Huang HK, et al. Full-field direct digital telemammography: technical components, study protocols, and preliminary results. *IEEE Transact Inform Tech Biomed* 1997; 1:270-278.
- <sup>9</sup> Sickles EA, Lou SL. High-performance ATM wide-area network for telemammography: UCSF experience. Presented at the Working Group on Telemammography/Teleradiology and Information Management, Washington, D.C. March 15, 1999.
- <sup>10</sup> Yaffe M. Digital mammography. *RSNA Categorical Course in Physics* 1993; 271-282.
- <sup>11</sup> Nelson M. A clinician's view of digital mammography. *Proc 4th Intern Conf Imag Management and Comm* 1995.
- <sup>12</sup> Huang HK. *PACS: basic principles and applications*. New York, NY: John Wiley's & Sons, 1999; 521.
- <sup>13</sup> Huang HK. Teleradiology technologies and some service models. *Comp. Med. Imaging & Graphics* 1996; 20:59-68.
- <sup>14</sup> <http://www.internet2.edu>
- <sup>15</sup> Zhou XQ, Lou SL, Huang HK. Authenticity and integrity of digital mammographic images. *Proc SPIE, Medical Imaging* (in press).
- <sup>16</sup> Schneier B. *Applied cryptography: protocols, algorithms, and source code in C*. New York, NY: John Wiley & Sons, 1995.
- <sup>17</sup> Lou SL, Sickles EA, Wang J, Huang HK. A high-resolution display system for mammograms. *Radiology* 1994; 193(P):474.
- <sup>18</sup> Shtern F, Winfield D, eds. Report of the working group on digital mammography: digital displays and workstation design. *Academic Radiology* 1999; 6(suppl. 4):S193-S220.
- <sup>19</sup> Transfer of intelligence technologies to improve breast cancer imaging (RFP 282-96-0026). Principal Investigator: Mitchell D. Schnall, M.D., PhD, University of Pennsylvania.
- <sup>20</sup> Telemammography for the next generation Internet: Phase I (Contract # N01-LM-8-5598). Principal Investigator: Mitchell D. Schnall, M.D., PhD, University of Pennsylvania.

- <sup>21</sup> Bidgood WD Jr. Clinical significance of the DICOM structured reporting standard. *International Journal of Cardiac Imaging* 1998; 14:307-315.
- <sup>22</sup> Bidgood WD Jr. Documenting the information content of images. *Journal of the American Medical Informatics Association. Symposium Supplement: Proceedings of the 1997 AMIA Annual Fall Symposium.* 1997:424-428.
- <sup>23</sup> Bidgood WD Jr. The SNOMED DICOM microglossary: controlled terminology resource for data interchange in biomedical imaging. *Methods of Information in Medicine* 1998; 37:404-414.
- <sup>24</sup> Bidgood WD Jr, Bray B, Brown N, et al. Image acquisition context: procedure description attributes for clinically relevant indexing and selective retrieval of biomedical images. *J Am Med Inform Assoc* 1999; 6:61-75.