Improving Breast Imaging Quality Standards

Sharyl Nass and John Ball, Editors, Committee on Improving Mammography Quality Standards, National Research Council

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IMPROVING BREAST IMAGING QUALITY STANDARDS

Sharyl Nass and John Ball, *Editors*

Committee on Improving Mammography Quality Standards
National Cancer Policy Board

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's (NRC's) Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Dr. Howard Rabinowitz, M.D.,** Professor of Family Medicine, Thomas Jefferson University, Department of Family Medicine, Jefferson Medical College, Philadelphia, PA; and **Dr. Harold C. Sox, M.D.**, Editor, Annals of Internal Medicine, American College of Physicians of Internal Medicine, Philadelphia, PA. Appointed by the National Research Council and Institute of Medicine, they were responsible for

making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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The Committee members all gave generously of their time to form a conscientious and hard-working collaborative team. Although the Committee was solely responsible for decisions regarding the content, conclusions, and recommendations of the report, four consultants and a liaison to the National Cancer Policy Board also attended the committee meetings and provided invaluable insight and information during the study process.

At the first Committee meeting, five working groups were established to take the lead in addressing specific charges put before the Committee in our statement of task. Etta Pisano chaired the "Mammography Quality Standards Act (MQSA) Regulations" working group and led her team (Priscilla Butler, Timothy Eberlein, Jane Henney, Carolina Hinestrosa, Lawrence Rothenberg) through a detailed examination of the current MQSA regulations and inspections. Patricia Carney chaired the "Interpretation" working group (Brad Hutton, Barbara Monsees, Edward Sickles, Robert Smith, Stephen Taplin), which took the lead on drafting Chapter 2 of the report. Edward Salsberg led the "Workforce" working group (Timothy Eberlein, Howard Forman, Barbara Monsees, Catherine Parsons, Etta Pisano), which took primary responsibility for Chapter 4. Robert Smith chaired a working group (Jane Henney, Carolina Hinestrosa, Catherine Parsons, Lawrence Rothenberg, Edward Salsberg) that was charged with examining issues that extended beyond MQSA, which led to Chapter 5 of the report. Howard Forman led the "Data" working group (Priscilla Butler, Patricia Carney, Brad Hutton, Edward Sickles, Stephen Taplin), which made important contributions to Chapters 2 and 4.

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John Ball
Committee Chair

Acronyms

AAFP	American Academy of Family Physicians
AAMC	American Association of Medical Colleges
ACCME	American Council for Continuing Medical Education
ACoS	American College of Surgery
ACR	American College of Radiology
ADEMAS	Association pour le Dépistage des Maladies du Sein
AHRQ	Agency for Healthcare Research and Quality
AIUM	American Institute of Ultrasound in Medicine
AOCR	American Osteopathic College of Radiology
ARDMS	American Registry of Diagnostic Medical Sonographers
ASRT	American Society of Radiologic Technologists
AUC	Area Under the Receiver Operating Curve
BCCMPA	Breast and Cervical Cancer Mortality Prevention Act
BCSC	Breast Cancer Surveillance Consortium
BIQSA	Breast Imaging Quality Standards Act
BI-RADS	Breast Imaging Reporting and Data System
CAD	Computer-Aided Detection
CEJA	American Medical Association's Council on Ethical and Judicial Affairs
CLIA	Clinical Laboratory Improvement Amendments
CME	Continuing Medical Education
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CSR	Center for Survey Research (University of Virginia)
CT	Computerized Tomography
DCIS	Ductal Carcinoma in Situ
EUSOMA	European Society of Mastology
FDA	Food and Drug Administration
FFDM	Full-Field Digital Mammography
FP	False Positive
FTE	Full-Time Equivalent
GAO	Government Accountability Office, formerly General Accounting Office
GPCI	Geographic Practice Cost Index

HCFA (now CMS)	Health Care Financing Administration
HELP	Senate Committee on Health, Education, Labor, and Pensions
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HRSA	Health Resources and Services Administration
IOM	Institute of Medicine
LCIS	Lobular Carcinoma in Situ
MISA	Mammography Interpretive Skills Assessment
MQSA	Mammography Quality Standards Act
MQSRA	Mammography Quality Standards Reauthorization Act of 1997
MRI	Magnetic Resonance Imaging
NBCCEDP	National Breast and Cervical Cancer Early Detection Program
NCI	National Cancer Institute
NEXT	1985 Nationwide Evaluation of X-Ray Trends
NHSBSP	National Health Service Breast Screening Program
NHSC	National Health Service Corps
NMQAAC	National Mammography Quality Assurance Advisory Committee
NPV	Negative Predictive Value
NSQIP	National Surgical Quality Improvement Program
OPPS	Outpatient Prospective Payment System
PFQ	Pay for Quality
PIAA	Physician Insurers Association of America
PPV	Positive Predictive Value
RA	Radiologist Assistant
RADIUS	Routine Antenatal Diagnostic Imaging with Ultrasound
RBRVS	Resource-Based Relative Value Scale
ROC	Receiver Operating Curve
RT	Radiologic Technologist
RVU	Relative Value Unit
SBI	Society of Breast Imaging
SCARD	Society for the Chairmen of Academic Radiology Departments
SEER	Surveillance, Epidemiology, and End Results
SOSS	Scheduled On-Site Survey
US	Ultrasound

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Executive Summary

Breast cancer is a leading cause of cancer death among women in the United States, but breast cancer mortality has been steadily declining since 1990. Early detection via screening mammography, coupled with improved therapy, has been credited with reducing the number of breast cancer deaths in the United States and other countries. Until research determines a way to prevent breast cancer, screening mammography will continue to be the primary tool in efforts to reduce the toll of the disease. Thus, ensuring the quality of mammography is important for women's health.[1]

The quality and accuracy of mammography depend on both technical and human factors. When screening mammography was widely adopted for breast cancer detection in the 1980s, facilities across the country varied considerably with regard to image quality and radiation dose. A voluntary accreditation program achieved limited gains, primarily due to low participation rates, so Congress passed the Mammography Quality Standards Act (MQSA) of 1992 with the aim of ensuring uniform high quality through comprehensive and standardized regulation of mammography. The Food and Drug Administration (FDA) was granted authority to implement and regulate the provisions of MQSA.

Studies indicate that the technical quality of mammography has improved significantly since the implementation of MQSA. Questions remain, however, regarding the quality of image interpretation, which depends on human factors and is difficult to measure in practice. The available evidence indicates that mammography interpretation is quite variable in the United States, similar to other areas of medicine where observation and interpretation are subjective. In preparation for reauthorization of MQSA, Congress commissioned a study from the Institute of Medicine (IOM) to determine whether additional steps could be taken to increase the accuracy of mammography interpretation and whether the current regulations should be modified to improve the oversight process. The IOM Committee was also asked to consider the effect of recommendations on access to mammography services and to identify steps that could be taken to ensure the safe and effective use of other screening or diagnostic tools, given that technology is continually changing. The recommendations, summarized in Box ES-1**,** represent Committee consensus that was developed through review and discussion of published literature as well as novel survey and modeling results. Most of these recommendations could be implemented immediately without waiting for the next MQSA reauthorization, projected in 2007. However, the Committee stresses that the recommendations are interconnected and implementing the entire set will be important to achieve the objective of further improving the effectiveness of breast cancer detection. In particular, implementing supportive elements in conjunction with additional regulatory requirements will be essential to sustain access to breast imaging services.

[1] This paragraph was added to the report after its prepublication release to provide additional introductory context on mammography.

BOX ES-1 Summary of Recommendations to Improve Breast Imaging Quality

Improve mammography interpretation

1. Revise and standardize the required medical audit component of MQSA.
2. Facilitate a voluntary advanced medical audit with feedback.
3. Designate specialized Breast Imaging Centers of Excellence and undertake demonstration projects and evaluations within them.
4. Further study the effects of CME, reader volume, double reading, and CAD.

Revise MQSA regulations, inspections, and enforcement

5. Modify regulations to clarify their intent and address current technology.
6. Streamline inspections and strengthen enforcement for patient protection.

Ensure an adequate workforce for breast cancer screening and diagnosis

7. Collect and analyze data on the mammography workforce and service capacity.
8. Devise strategies to recruit and retain highly skilled breast imaging professionals.
9. Make more effective use of breast imaging specialists.

Improve breast imaging quality beyond mammography

10. Mandate accreditation for nonmammography breast imaging methods that are routinely used for breast cancer detection and diagnosis, such as ultrasound and magnetic resonance imaging (MRI).

IMPROVING IMAGE INTERPRETATION

The effectiveness of mammography greatly depends on the quality of image interpretation, but reading mammograms and assessing interpretive performance are both challenging. MQSA regulations include requirements for interpreting physicians regarding initial training, Continuing Medical Education (CME), continuing experience, and medical audits. The Committee addresses three primary questions relevant to interpretive performance: (1) whether the current audit procedures are likely to ensure or improve the quality of interpretive performance, (2) whether additional audit procedures could allow for more meaningful estimates of performance, and (3) whether the current CME and continuing experience requirements enhance performance.

MQSA requires that mammography facilities track their performance by obtaining outcome data on women recommended for breast biopsy based on an abnormal mammogram. However, the Committee concludes that current MQSA medical audit requirements are inadequate for measuring or improving the quality of image interpretation. Ideally, medical audits should be designed to link practice patterns to patient outcomes in a way that can influence interpretive performance. Interpreting physicians need to know and understand their current level of performance before they can determine whether and how it could be improved. The first two recommendations aim to improve the quality of mammography interpretation through enhanced and standardized medical audits, one mandatory and one voluntary. The third recommendation, for demonstration projects

within Breast Imaging Centers of Excellence, attempts to combine many approaches—including double reading, high interpretive volumes, and systematic feedback—because in concert, these approaches appear to have contributed to successful screening programs in other countries. However, there is insufficient evidence to evaluate the individual components of these programs; thus the Committee cannot recommend incorporating them into MQSA regulations. Furthermore, the pluralistic organization of health care delivery in the United States precludes the adoption of some components such as systematic feedback. Therefore, the Committee believes that incentives to participate in the voluntary programs put forth in Recommendations 2 and 3 will encourage facilities to strive for a higher level of performance and that experience with these programs will eventually demonstrate their feasibility to achieve higher standards for all facilities. The fourth recommendation suggests studies that are needed to develop a stronger evidence base for specific program components, including continuing education and experience requirements, which could potentially improve interpretive performance.

Recommendation 1:

The FDA should revise and standardize the medical audit component of MQSA to make it more meaningful and useful.

A) The required basic medical audit of mammography interpretation should be enhanced to include the calculation of three core measures for internal review at the mammography facility, as follows:

- Positive predictive value 2 (PPV_2; proportion of women recommended for biopsy [BI-RADS[2] 4, 5] who are subsequently diagnosed with breast cancer)
- Cancer detection rate per 1,000 women
- Abnormal interpretation rate (women whose mammogram interpretations lead to additional imaging or biopsy)

The group of women that facilities are required to track should include not only women with BI-RADS 4 and 5 assessments, but also all women for whom additional imaging is recommended (defined in BI-RADS as Category 0; incomplete—needs additional imaging)[3] to facilitate resolution of all cases so that women for whom biopsy is recommended at final assessment will be included in the calculation of PPV_2.

B) All performance measures (PPV_2, cancer detection, and abnormal interpretation rate) should be stratified by screening and diagnostic mammography.

C) Facilities should have the option of combining medical audit measures for physicians interpreting at multiple facilities to allow for more meaningful data.

[2] The Breast Imaging Reporting and Data System (BI-RADS) provide a standardized method of categorizing mammography results. Biopsy is recommended for women assigned BI-RADS Category 4 or 5.

[3] FDA regulations and BI-RADS also permit the assignment of assessment Category 0 when awaiting comparison with prior films. All of such Category 0 assessments should be given final assessments within 30 days.

D) Audit data collection and analysis should be verified at FDA inspection, but not collected by FDA.

E) Reimbursement rates for mammography should be increased to account for the additional costs of these new audit procedures. The principles of RBRVS (resource-based relative value scale, which compares relative physician work for different types of services) should apply to both the physician and facility.

Rationale:

A) The current medical outcomes audit mandated by MQSA does not require mammography facilities to calculate any specific performance statistics. In practice, most facilities use one type of PPV as a performance measure. However, no single measure accurately reflects interpretive performance, and the method of PPV calculation varies widely. Given the challenges and limitations of the various possible performance measurements, the committee recommends use of PPV_2 because it provides more useful information than PPV_3,[4] and because it is easier to calculate than PPV_1.[5] Calculating the rates of cancer detection and abnormal interpretation would facilitate appropriate interpretation of PPV_2, which is influenced by the prevalence of cancer in the screening population. Universal adoption of these three measures, which are standard practice in successful screening programs of many other countries such as those in the United Kingdom, Sweden, and British Columbia, would be a significant and achievable, albeit imperfect, improvement over the current audit requirement, under which facilities need only collect and review data on the outcomes of women for whom a biopsy is recommended. This combination of measures would provide facilities with consistent and meaningful feedback, thus making it more feasible for audit interpreting physicians to identify the need for performance improvement plans. Measuring sensitivity and specificity would be more useful, but calculating these measures in community practices that do not have linkage with a tumor registry to determine the final diagnosis is not feasible.

Because most screened women who are referred for biopsy begin with a recommendation for additional imaging, the tracking requirement under current MQSA regulations produces a biased assessment of performance by focusing on only examinations initially assigned BI-RADS 4 and 5 assessments.

B) Combining medical audit data for screening with diagnostic examinations, as is permitted under current MQSA regulations, confounds the meaning of the results, making it difficult to interpret and compare performance with current literature or established databases.

C) Medical audit data are more meaningful when larger numbers of examinations are analyzed. Individual interpreting physicians at a particular facility may generate

[4] PPV_3 is the proportion of all women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy.

[5] PPV_1 is the proportion of all women with positive examinations (Category 0, 4, or 5) who are diagnosed with breast cancer.

insubstantial data; combining data from the multiple facilities where they practice would be more meaningful.

D) The current medical outcomes audit data are reviewed during inspection to ensure that the facility is complying with the regulations, but FDA does not collect the data. Each facility must designate an "audit interpreting physician" to review the audit data, notify other interpreting physicians of the result, and document the nature of any follow-up actions. No change in this procedure is warranted because regulators would not be able to verify the accuracy of audit data.

E) The workload and costs associated with meeting MQSA requirements are significant, and the new audit procedures proposed here will add to the workload and expense of adhering to MQSA requirements. Historically these costs have not been factored into reimbursement, placing a considerable financial burden on facilities. However, the Centers for Medicare and Medicaid Services (CMS) and other health care payers should account for both the technical and professional costs of adhering to federally mandated audit procedures when establishing reimbursement rates for mammography.

Recommendation 2:

Facilities should be encouraged to participate in a voluntary advanced medical audit with feedback. This should be facilitated by incentives for participation and the formation of a data and statistical coordinating center.

A) In addition to all tracking, measurements, and assessments in the enhanced basic required audit described in Recommendation 1, the voluntary advanced audit should include the collection of patient characteristics and tumor staging information from pathology reports.

B) A central data and statistical coordinating center, independent of a regulatory authority, should be established and maintained to collect and analyze the advanced audit data to provide feedback to interpreting physicians for quality assurance and interpretive improvement. Sufficient funding should be provided for (1) data collection, analysis, and feedback; (2) appropriate hardware and software for data management; and (3) appropriate information technology support personnel for data maintenance. The coordinating center should:

- Electronically collect, analyze, and report advanced-level audit data and provide regular feedback to interpreting physicians.

- Help develop, implement, and evaluate self-improvement plans for interpreting physicians who do not achieve performance benchmarks.

- Routinely release aggregate summary data on interpretive performance, including recall rates, PPV_2, and cancer detection.

• Test different methods of delivering audit results to improve interpretive performance.

• Undertake studies of randomly selected facilities using required basic audit procedures to ascertain the impact of these new measures on interpretive quality.

• Protect from discoverability the data collected for purposes of quality assurance.

C) Incentives must be provided to encourage mammography facilities to strive for a high standard of interpretive performance through participation in the advanced audit program. Facilities participating in the voluntary advanced audit should be exempt from FDA inspection of medical audit data (documentation of participation in the advanced audit process would be sufficient). CMS and other health care payers should pay for performance by providing a higher reimbursement rate in exchange for meeting performance criteria. Specific performance criteria should be determined (and periodically updated) by an informed group of experts and patient advocates.

Rationale:

A) Information from pathology reports can be difficult for facilities to obtain, but audit data will be more useful if the sizes of invasive cancers are recorded because interpretation of PPV_2 is informed by tumor size. Other staging indices, such as axillary lymph node status, are important to assess whether cancers are being detected early. In addition, performance data on individual interpreting physicians may be misleading without adequate consideration of patient characteristics such as age, family history, breast density, presence of prior films, and time since last mammogram.

B) Data collection is the catalyst for change, but data are inadequate without resources for accurate and uniform analysis and feedback to improve quality. A statistics and analysis group is crucial for quality assurance in successful organized screening programs of other countries. An analogous research effort was initiated by the original MQSA authorization.

Uniform feedback should help participating U.S. facilities attain a higher level of quality assurance than is feasible now. However, data are lacking on how feedback can best be used to improve performance, so studies are needed to optimize the impact of this approach. The statistical coordinating center could also aid the basic required audits by developing national benchmarks that facilities and interpreting physicians could use to assess their performance, and by testing the impact of the basic audit procedures. Public release of aggregate summary data and benchmarks will benefit all mammography participants.

Protecting audit data from discoverability is important to ensure accurate reporting and widespread participation. Regulatory oversight is unnecessary for a voluntary program, and there is potential for conflict if a regulatory body also provides analysis and feedback for quality improvement.

The Breast Cancer Surveillance Consortium (BCSC) has already developed effective procedures and guidelines for mammography data collection, and has demonstrated the feasibility of such an undertaking through a cooperative agreement with the National Cancer Institute (NCI). Given the established expertise and success of the BCSC, it is a model for this new endeavor. The Agency for Healthcare Research and Quality (AHRQ) also has many characteristics that make it a viable option.

C) CMS is developing a pay-for-performance policy, and private health insurers often follow the lead of CMS. The extensive quality assurance procedures proposed for the voluntary advanced audit justify the use of such an approach for mammography. Participation in the voluntary advanced medical audit will likely lead to a higher quality of performance and care, but it also will entail a considerable increase in cost and workload. Supportive elements such as feedback and protection of quality improvement data to improve interpretive performance may not be implemented as easily as regulations, but in their absence, the advanced audit would be viewed primarily as an added burden by mammography facilities and personnel, thereby limiting the number of facilities that participate.

Recommendation 3:

Establish a demonstration and evaluation project to designate and monitor the performance of specialized Breast Imaging Centers of Excellence that attempt to incorporate aspects of successful organized breast cancer screening programs. This undertaking should be rapidly initiated with high priority and will likely require cooperative efforts of several organizations, perhaps including NCI, CMS, and AHRQ. Patient advocates should be involved in the design and oversight of the Centers.

A) Centers would participate in the basic and advanced medical audits described in Recommendations 1 and 2, but would also test additional approaches to improving the quality and effectiveness of mammography. Centers of Excellence should incorporate and test the effects of the following attributes: high volume, double reading, demonstration of proficiency via comprehensive medical audit as defined in the BI-RADS atlas (which goes beyond even the voluntary advanced audit in Recommendation 2), a documented quality assurance process, and patient reminder systems. In addition, pilot projects should be established within selected centers to further develop and evaluate interpretive skills assessment exams. Centers should also incorporate expertise in accepted nonmammographic imaging modalities for breast cancer diagnosis (for example, ultrasound and magnetic resonance imaging, or MRI), with accreditation where applicable.

B) Incentives to seek this designation should be similar to those described in Recommendation 2 (e.g., higher reimbursement rates). Centers could also use the designation to recruit patients and referrals. In addition, high-performing interpreting physicians who work in Centers of Excellence should have the opportunity to participate in a program to determine the feasibility of a no-fault medical liability system.

C) Designated centers should be encouraged to serve as training centers for breast imaging and as regional readers of mammograms to alleviate access problems in underserved areas.

D) Ideally these Breast Imaging Centers of Excellence should be linked with facilities that provide comprehensive and multidisciplinary breast care.

Rationale:

A) Several countries have successfully developed integrated and centralized breast cancer screening programs that incorporate these attributes, but in the United States, screening is decentralized and offered in diverse practice settings. Although adapting quality assurance programs of countries with national health care systems to the fragmented delivery of U.S. health care may not be fully feasible, the challenge is not insurmountable—it has occurred within some integrated health plans and through the NCI Breast Cancer Surveillance System. It is urgent to further test the concept by designating specialized Centers of Excellence in Breast Imaging that would strive to achieve a higher level of integration, performance, and quality assurance in breast cancer detection and diagnosis by adopting many components of successful organized programs.

This multifaceted approach should contribute to the optimal performance of mammography, but mammography is not the only imaging tool used for breast cancer diagnosis. The Centers of Excellence could provide multidisciplinary training and work environments for diagnosis. Centers could increase job satisfaction, retention of practitioners, and the productivity and quality of all members of the breast care team—high-quality facilities would attract high-quality personnel at all professional levels.

B) As noted in Recommendation 2, supportive elements and incentives are critical to encouraging facilities and personnel to strive for higher quality. In their absence, meeting the requirements for designation as a Center of Excellence would likely be viewed as an unnecessary burden, thereby limiting participation. Nonetheless, incentive programs such as the no-fault insurance system must be tested as well.

As noted previously in the IOM report *Fostering Rapid Advances in Health Care: Learning from System Demonstrations* (2003), a no-fault system linked to high quality assurance could potentially benefit both patients and providers. Such a system has worked effectively for many years in other countries such as Sweden. In contrast, medical malpractice lawsuits generally have not been found to have a positive influence on quality of care, and compensation for misdiagnosis under the current system is inconsistent. The goal would be to provide patients with access to higher quality care, while offering consistent and fair compensation in the event of a misdiagnosis and eliminating the need for long, difficult lawsuits with uncertain outcome. Highly skilled physicians meeting stringent qualification criteria would practice in a safe harbor, without fear of lawsuits and the label of fault when cancers are missed by mammography. The threat of lawsuits and the cost of malpractice insurance are major concerns for interpreting physicians and mammography facilities, but even the most skilled and experienced interpreting physicians will miss some cancers because of the inherent limitations in mammography tech-

nology and interpretation. Approximately 30 percent of breast cancers can, only in retrospect, be seen on previous mammograms interpreted as normal.

C) Centers would have the expertise to develop and host training programs in breast imaging. Also, interpretation at centralized facilities could help alleviate access problems in low-volume areas. Implementation of centralized reading at designated high-volume/high-quality centers could be facilitated by either high-tech approaches (soft-copy telemammography) or low-tech approaches (shipping films).

D) In the United States, there is a lack of continuity among screening, diagnosis, treatment, and follow-up care. Breast imaging centers that incorporate all aspects of screening, diagnosis, and imaging-based patient management, and are linked with facilities providing comprehensive and multidisciplinary nonimaging breast care, can facilitate seamless transitions for patients as needed.

Recommendation 4:

Although some evidence suggests that additional approaches could also improve the quality of mammography interpretation, the data currently available are insufficient to justify regulatory changes. Thus, studies are urgently needed to:

A) Demonstrate the value of CME specifically dedicated to improving interpretive skills.

B) Determine the effects of reader volume on interpretive accuracy, controlling for other factors that improve interpretive performance.

C) Improve and measure the impact of double reading and computer-aided detection (CAD) on interpretive performance over time, in different practice settings, and at different levels of experience.

The funding for these studies should be provided through NCI, with the expectation that study results will motivate additional improvements to future reauthorizations of MQSA.

Rationale:

A) Requiring that a portion of MQSA-mandated CME be dedicated to mammography interpretive skills assessment could enable interpreting physicians to identify weaknesses and take steps toward improving interpretive performance. However, there is an urgent need to study specific educational approaches and determine their effectiveness. Continued development of innovative teaching interventions to improve mammography interpretive skills is also important.

B) Although the current minimum requirement for continuing experience (960 mammograms every 2 years) is quite low given the prevalence/incidence of cancer in the screening population (generally 4 to 6 cancers detected per 1,000 women), there is insufficient evidence at this time to recommend an increase in minimum interpretive volume. Published reports provide conflicting evidence regarding the relationship between

reader volume and interpretive accuracy, and there is no basis for specifying a higher level of reader volume.

A variety of approaches may improve reader performance, but it is unclear to what extent interpretive volume and experience alone contribute to that improvement. Volume alone cannot contribute to improvement unless it is accompanied by accurate feedback about performance. Given the uncertainty regarding the isolated effect of reader volume on interpretive performance, and given that increasing the minimum reader volume could reduce the supply of mammography services in some areas, maintaining access should be of primary concern.

C) Intuitively, a second look by another reader or a computer program should increase sensitivity, but the benefit has not been unequivocally characterized and quantified in prospective clinical trials. The effects on specificity are also not fully understood. Some studies indicate that any potential increase in sensitivity could be accompanied by a decrease in specificity. In addition, various CAD programs are still being refined, so the effect and use of CAD may change over time. Studies are needed to evaluate the impact of physician experience and lesion characteristics on the effectiveness of CAD. These studies should be done with a standard set of cases that were not used to develop the CAD systems. The findings could help physicians use CAD more effectively and could help improve the underlying algorithms.

There are many different ways to approach double reading, each requiring different amounts of personnel and time, with consequent differences in cost and effects on access to mammography services. Consensus double reading (one of the most costly and personnel-intensive approaches) may be the most effective, but formal studies are needed to confirm this.

CHANGES TO MQSA REGULATIONS, INSPECTIONS, AND ENFORCEMENT

Final MQSA regulations were promulgated in 1999, and a review is warranted at this time to identify areas in need of revision. Advancements in technology, particularly digital mammography, require expansion of the current regulations to ensure quality mammography. At the same time, revising the current FDA regulations, including some deletions, and streamlining the inspection process could reduce the burden on facilities and allow for increased focus on improving interpretation. FDA should be provided with adequate resources to revise, disseminate, implement, and enforce these changes.

Recommendation 5:

FDA should modify MQSA regulations to clarify the intent and to recognize current technology and applications. For example:

A) FDA should remove the exemption on interventional mammographic procedures such as stereotactic breast biopsy and preoperative mammographic needle localization, and develop specific regulations for these X-ray procedures and equipment.

B) Regulations specifically addressing the use of digital mammography need to be developed.

C) Regulations regarding mammography reports should be updated to reflect the most recent version of BI-RADS, including a new category for "known biopsy-proven malignancy."

D) FDA should establish luminance standards for viewing mammograms.

E) The requirement for modality-specific CME should be eliminated for interpreting physicians to allow them a broader choice of educational opportunities, including those that focus on interpretation skills.

A complete list of recommended changes to the regulations and the rationale supporting such changes can be found in Table 3-1 of Chapter 3.

Recommendation 6:

FDA should modify MQSA inspections to streamline the process, reduce redundancy, and address current technology and applications. Enforcement needs to be strengthened for further patient protection. For example:

A) Several onsite inspection tests are unnecessary and should be eliminated.

B) FDA should have the authority to require that facilities cease performing mammography after two consecutive unsuccessful attempts at accreditation, even if their MQSA certificate is still valid.

C) FDA should require a facility that closes for any reason or has its certification revoked to notify patients and their referring physicians. In addition, regulations for film retention should apply to facilities that close.

Rationale:

A) Several onsite inspection tests are redundant and have exceptionally low rates of failure; quality would not be adversely affected by their elimination because these parameters are monitored regularly.

B) Until 2003, FDA required facilities to cease mammography in such cases. In 2003, FDA informed accrediting bodies that they cannot require facilities to cease mammography if their MQSA certificate is still valid.

C) FDA has received a number of complaints from patients who were not informed when their facility closed and as a result were unable or unsure of how to access their mammography records. If facilities are incapable of notification, FDA should assume responsibility for notification.

ENSURING AN ADEQUATE WORKFORCE FOR BREAST CANCER SCREENING AND DIAGNOSIS

Results from surveys conducted by the American College of Radiology (ACR), the Society of Breast Imaging, and the American Society of Radiologic Technologists, as well as many anecdotes, suggest that the supply of mammography services may be decreasing in some areas. Furthermore, FDA data suggest that the number of interpreting physicians is decreasing. However, no systematic data collection and analysis has been undertaken, making it difficult to assess the current capacity for breast cancer screening and diagnostic services, and even more difficult to plan for the future. Early detection of occult breast cancer is a key element for reducing breast cancer mortality; it is therefore crucial to accurately monitor the capacity of mammography services, as indicated in Recommendation 7, and to ensure adequate access for women.

Demand is likely to increase in the future as population demographics change and the number of women eligible for screening mammograms increases. Increased use of other imaging technologies for breast cancer detection and diagnosis could also raise demand for breast imaging. However, in recent years, the majority of fellowship training slots in breast imaging have gone unfilled, and surveys indicate that many radiologists are uninterested in pursuing breast imaging as a specialty. Three basic strategies, as noted in Recommendations 8 and 9, could be used to ensure an adequate breast imaging workforce: increasing the number of new entrants to the field, retaining the current workforce, and increasing productivity of new and existing practitioners.

Recommendation 7:

Data describing the national mammography workforce, volume of services, and capacity should be immediately and routinely collected by FDA and made available to appropriate state and local agencies for tracking and monitoring. For example:

A) Volume information should be added to the data that FDA currently collects in the annual facility inspection, and the Health Resources and Service Administration (HRSA) should produce routine reports on the volume of mammography services by region, state, and type of service. Measures should include the number of facilities, number of certified mammography units per 10,000 women, and number of full-time equivalent (FTE) physicians reading mammograms per 10,000 women,[6] and should be stratified by type of service (e.g., screening versus diagnostic) where appropriate.

B) These data should be collected using unique identifiers for all certified physicians, technologists, and medical physicists to facilitate tabulation of volume of services by individual.

[6] For purposes of this report, a full-time equivalent physician is one who is employed full-time (37.5+ hours per week of paid employment for 40 or more weeks per year) and spends at least 80 percent of his or her time performing clinical radiology imaging interpretation. Note that an FTE radiologist is not necessarily an FTE breast imager. For example, a full-time radiologist who devotes 40 percent of practice time to breast imaging could be equivalent to a radiologist who works 40 percent of the time and devotes all of his or her practice to breast imaging.

C) FDA should also collect data by facility on waiting times for screening and diagnostic appointments. These data should be tabulated by region and state and be published routinely.

D) In addition to the funding needs for collection, analysis, hardware, software, and IT support, sufficient funding should also be provided to HRSA to model future workforce supply and demand on a regular basis.

Rationale:

There is a paucity of accurate "real-time" data available to monitor and track capacity on a national and regional basis. Without accurate tracking, it is impossible to determine the current status of the workforce and it is extremely difficult to plan actions for the future. In the absence of national data, there is also no consensus on appropriate waiting times for screening and diagnostic mammograms. There is an urgent need to begin data collection immediately because identifying trends will take several years. Tracking mammography capacity will also be important in monitoring the impact of new regulations and voluntary programs. If the fragile stability of the breast imaging workforce moves toward crisis, data will be needed to react swiftly and effectively.

Collection of workforce and capacity data would also simplify documentation of staff qualifications and continuing education and experience requirements.

Recommendation 8:

Devise strategies to retain highly skilled breast imagers and increase the number of new entrants into the breast imaging field, particularly in underserved areas. For example:

A) Encourage federal and state agencies and health care payers to develop incentives, both financial and otherwise, to recruit and retain skilled breast imagers. One such approach would be to encourage provision of pro-rated malpractice insurance to interpreting physicians skilled in mammography who wish to work part-time.

B) Appropriately qualified physicians who spend at least 50 percent of their professional time in breast imaging working in underserved areas should be eligible for loan repayment awards through the National Health Service Corps (NHSC) and for J-1 visa waivers authorized by federal and state agencies.

C) In order to target breast imagers to the highest need areas, HRSA should establish a process to identify and designate shortage areas for breast imaging.

Rationale:

The existing supply of physicians who read mammograms at a high level of interpretive performance is a valuable resource. It is unproductive to invest in efforts to increase the number of entrants into the specialty without also addressing factors that lead to early departures from the existing workforce.

Efforts directed at retaining already highly skilled practitioners, even for part-time work, could be a cost-effective way to maintain access to high-quality breast imaging

services. For example, interpreting physicians who wish to work part-time often find it difficult to interpret mammograms because malpractice costs are not adjusted for less than full-time work. Offering pro-rated malpractice insurance premiums would greatly reduce this barrier. The provision of reduced-rate malpractice tail coverage for part-time workers would also be beneficial.

The NHSC program and J-1 waivers have been used to bolster the workforce in other shortage areas in medicine and biomedical research. Together, these approaches would increase the number of interpreting physicians in areas with shortages and also increase the aggregate supply. It would also signify to medical students and physicians in training the need and importance of breast imaging specialists.

Recommendation 9:

Make more effective use of the existing supply of highly skilled breast imaging professionals.

A) Support radiologist assistant (RA) training programs and explore possible new roles for RAs in breast imaging.

B) Support demonstration projects to evaluate the potential for nonphysician clinicians (e.g., nurse practitioners, physician assistants, radiologist assistants, radiologic technologists, etc.) to double read mammograms accurately. These demonstrations should be undertaken within the Centers of Excellence described in Recommendation 3.

C) Support demonstrations to evaluate the roles of ancillary personnel in mammography, such as administrative and data entry personnel, and to assess the impact of alternative staffing configurations on the efficiency, productivity, and quality of breast imaging services.

Rationale:

A) RA programs offer an attractive career option for skilled radiologic technologists and also could be an incentive for new entrants into the field. Maximizing the potential role of RAs in breast imaging could improve quality as well as facility productivity and efficiency.

B) Double reading has the potential to improve the accuracy of mammography interpretation, but widespread adoption of double reading would strain the available interpreting workforce. Permitting nonphysician clinicians with special training to serve as second readers, only under the direct supervision of MQSA-certified interpreting physicians, could provide a cost-effective way to expand the use of double reading. Several small studies already suggest that this approach is feasible in mammography. In addition, Pap tests present an important precedent in women's health, as they are routinely read by nonphysician cytologists under the supervision of a physician.

C) Productivity will be maximized if radiologic technologists focus their efforts on imaging procedures and if breast imaging physicians focus on image interpretation and performing interventional breast imaging procedures. Ancillary personnel could

make an important contribution by taking on nontechnical responsibilities, including quality control and administration.

BEYOND MQSA TO BIQSA

Medical technology is constantly evolving. Although mammography is still the only recommended breast cancer screening test for the general population, a number of other breast imaging technologies are clinically available, and more are in development. Some of the available imaging technologies, including breast ultrasound and MRI, are already commonly used in the diagnosis of breast cancer. Furthermore, recent studies have suggested a potential role for specific technologies in screening some portion of the population, such as high-risk women. Of concern is the adoption of some technologies for screening despite the limited evidence of their effectiveness. There is no mandatory quality oversight of these other technologies, and quality is known to be variable. Thus, the goal of MQSA to ensure quality breast cancer screening and diagnosis could go unfulfilled if it continues to focus solely on mammography.

Recommendation 10:

Mandatory accreditation for breast imaging methods not utilizing ionizing radiation that are routinely used for breast cancer detection and diagnosis should be required under the next MQSA reauthorization. This would entail a name change to the Breast Imaging Quality Standards Act (BIQSA). Initially, breast ultrasound and MRI, along with associated interventional procedures, should be subject to mandatory accreditation, although in the case of MRI, accreditation programs specific to breast imaging must first be developed. In addition, a committee of experts and patient advocates should determine if and when other technologies should be subject to accreditation or certification.

Rationale:

Accreditation programs already exist for breast ultrasound through the American College of Radiology (ACR) and the American Institute of Ultrasound in Medicine. The ACR also has an accreditation program for general MRI, and has begun a dialogue regarding the development of a breast-specific MRI accreditation program. Compulsory accreditation for these breast imaging methods would lead to standardization and could greatly improve the overall quality of breast cancer detection and diagnosis.

1

Introduction

Mammography is currently the primary tool for detecting breast cancer at an early stage when it is most curable. When coupled with appropriate treatment, early detection can significantly reduce breast cancer mortality. Randomized clinical trials have shown that screening mammography can reduce breast cancer specific mortality by approximately 20 to 30 percent (reviewed by IOM, 2001, 2005). One evaluation of modern service screening in Sweden suggests mortality reductions as high as 40 to 50 percent are possible among women who actually are screened. Since about 1990, breast cancer mortality has been declining slowly but steadily in the United States (National Center for Health Statistics, 2004), and screening mammography, along with improved therapy, has been credited with reducing the number of breast cancer deaths in the United States and other countries (Peto et al., 2000; Duffy et al., 2002; Anttila et al., 2002; Jatoi and Miller, 2003; Beckett et al., 2003; Kobayashi, 2004; Coburn et al., 2004). But in order to maximize the potential benefits of mammography, high standards of quality assurance are necessary. Many factors contribute to the quality of mammography, including structural features such as the equipment used, the knowledge and skills of the staff providing the services, and the organization of service delivery at a given facility. Many of these factors are regulated by the Food and Drug Administration (FDA) under the Mammography Quality Standards Act (MQSA).

A study by the U.S. Government Accountability Office (GAO, formerly known as the General Accounting Office) found that the technical quality of mammography has increased since MQSA was enacted (GAO, 1998), and mammography facilities and personnel are to be commended for the efforts they have taken to meet the requirements of MQSA and to improve quality. Nonetheless, questions still remain regarding the impact of MQSA on access to mammography services as well as the impact on health outcomes for women who undergo mammography screening. With regard to the former, concerns have been raised about whether the additional workload and costs associated with meeting all the requirements of MQSA may be a disincentive for facilities to offer mammography services or a disincentive for medical personnel to enter or remain in the field. With regard to the latter, it is unknown whether the implementation of MQSA regulations has led to improved accuracy of mammographic interpretation, a crucial element of screening and diagnosis that is essential for reducing breast cancer morbidity and mortality. However, interpretive performance has been found to be variable in the United States.

The goal of this study was to examine the current practice of mammography and breast cancer detection, with a focus on MQSA oversight, and to identify areas in need of improvement. This report recommends strategies for achieving continued progress in assuring mammography quality, including additions, deletions, and changes to MQSA regulations, as well as approaches that do not fall within the purview of MQSA. These proposed strategies are based on careful consideration of the potential for feasibility and acceptability to patients and providers, and the available evidence to support them. The Committee stresses that the recommendations are interconnected, and that implementing

the entire set is critical for achieving the objective of further improving the effectiveness of breast cancer detection. In particular, adopting supportive elements in conjunction with additional regulatory requirements will be essential to sustain access to breast imaging services. Increasing regulation without providing financial and other support could not only fail to improve quality but could also result in decreased access. In addition, although this report was intended to inform the next reauthorization of MQSA, which is now projected for 2007, most of these recommendations could and should be implemented immediately. Indeed, adoption of many of the recommendations is long overdue.

A BRIEF HISTORY OF MQSA

The adoption and use of X-ray mammography increased greatly during the 1980s (Bassett et al., 1993; Lerner, 2001; IOM, 2001). As a result, mammography was included in the 1985 Nationwide Evaluation of X-Ray Trends (NEXT) study, organized by FDA and the Conference of Radiation Control Program Directors. That study determined that mammography facilities across the country varied widely with regard to image quality and radiation dose.

To combat the problem of poor mammography quality, the American College of Radiology (ACR) established the Mammography Accreditation Program in 1987, at the behest of the American Cancer Society. Although this was a critical first step toward improving mammography quality, the ACR program was voluntary; by 1992, only 7,246 facilities out of an estimated 11,000 had applied for accreditation, and many of these were motivated by awareness that MQSA was about to become law. Of those that had applied for accreditation, only 4,662 were fully accredited (Barr, 2004). In addition, the lack of onsite inspections potentially allowed substandard facilities to obtain ACR accreditation. Despite these limitations, the voluntary program resulted in some significant improvements, including improvements in quality control practices of medical physicists and radiologic technologists (Hendrick et al., 1998).

During this same time period, states began to pass legislation requiring health insurance coverage of mammography, and many stipulated quality assurance requirements as well. By 1993, 41 states and the District of Columbia had either passed legislation or established regulations addressing the quality of mammography (Smith and D'Orsi, 2004). In 1990, the first federal regulations of mammography quality went into effect via the Breast and Cervical Cancer Mortality Prevention Act, which aimed to increase access to mammograms for low-income women. Participating state facilities had to be ACR accredited, certified by the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services), and use the ACR's Breast Imaging Reporting and Data System (Barr, 2004). In addition, the Omnibus Budget Reconciliation Act of 1990 extended Medicare coverage to mammography facilities meeting certain standards (Houn et al., 1995). However, oversight was minimal at best. Clinical images were not evaluated for quality, and facilities merely claimed to meet the given standards (Barr, 2004).

In 1991 and 1992, the Senate Committee on Labor and Human Resources[1] discussed the quality of mammography programs across the country as part of a larger hearing on breast cancer. It was noted that the "patchwork of Federal, State, and private stan-

[1] The name of this committee was changed to Committee on Health, Education, Labor, and Pensions on January 19, 1999.

dards" regarding screening mammography were "confused and inadequate and point to the need for comprehensive regulation" (U.S. Senate, 1992). As a result, Congress passed the Mammography Quality Standards Act of 1992 (Figure 1-1). The Act presented a general framework for ensuring national quality standards for all facilities performing mammography, except those operated by the Department of Veterans Affairs. (The Department of Veterans Affairs requires accreditation, certification, and inspection for its mammography facilities, similar to MQSA.) The Secretary of Health and Human Services (HHS) was charged with establishing quality standards, determining accreditation and certification criteria, overseeing inspections, measuring compliance, directing enforcement, creating an advisory committee, and promoting education.

FDA was granted authority by the Secretary of HHS in June 1993 to implement and regulate the Act's provisions. MQSA required all mammography facilities to comply with the regulations by October 1, 1994 (21 C.F.R. § 900). In order to meet that deadline, FDA published interim regulations based largely on the ACR's voluntary accreditation program standards. On October 28, 1997, FDA published MQSA final regulations, which became effective in April 1999 (FDA, 2002a).

MQSA regulations include several key components (see Chapter 3 for more detail). First, FDA established national quality standards. Mammography personnel, including interpreting physicians, radiologic technologists, and medical physicists, are required to meet initial and continuing education and experience requirements. Only equipment specifically designed for mammography can be used. Documentation of the daily, weekly, quarterly, semiannual, and annual quality control tests performed at the facility must be retained for FDA annual inspections. Mammography equipment must have equipment evaluations and annual surveys by qualified medical physicists, although equipment used solely for interventional procedures is exempt from the regulations.

FDA regulations also require every mammography facility to obtain accreditation, become certified, and undergo annual inspection. FDA-approved accreditation bodies (ACR or states) review clinical and phantom images from every facility once every 3 years to monitor compliance with quality standards. Annual inspections are carried out either by FDA inspectors or state inspectors contracted by FDA. Facilities undergoing inspection are required to pay fees to cover the costs for these inspections

Finally, federal grant money was earmarked for research entities examining incidence rates, methods of detection, and diagnostic procedures for breast cancer (Ballard-Barbash et al., 1997). Efforts to measure participation rates in screening mammography and the effectiveness of screening programs in the United States also receive funding (FDA, 2002a).

MQSA was set to expire shortly after the final FDA regulations came into effect. Studies undertaken by GAO led to the conclusion that MQSA had had a positive effect on mammography quality. Between 1995 and 1997, the severity of violations at mammography facilities steadily decreased, and the proportion of facilities without violations jumped from approximately 30 percent in 1995 to 55 percent in 1997. In addition, GAO concluded that MQSA had not inadvertently limited access to mammography (GAO, 1998). A total of 163 facilities closed between 1994 and 1997, but the majority of these were either low-volume or low-quality providers. In a few cases, closure was due to consolidation with another practice (GAO, 1998).

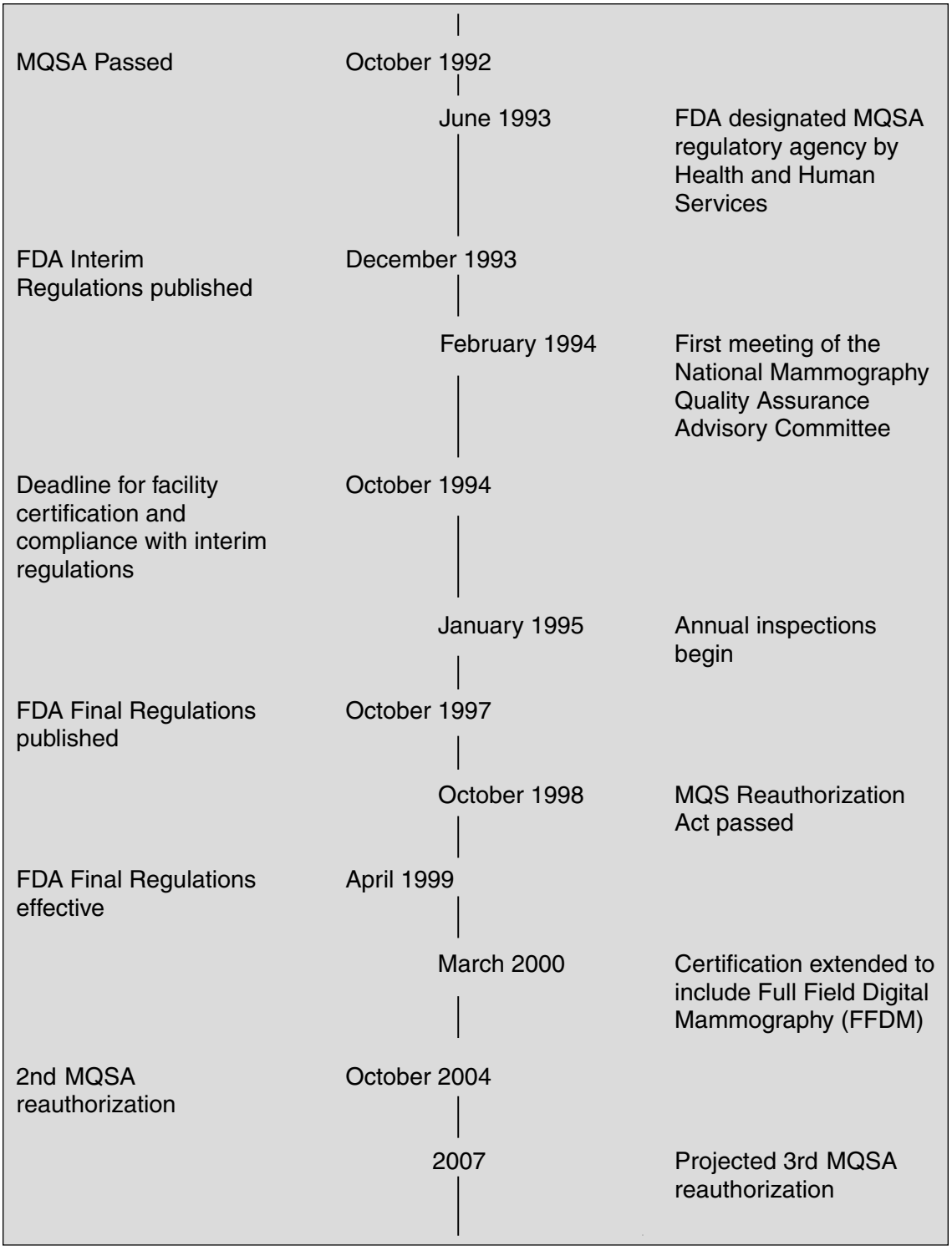

FIGURE 1-1 A history of MQSA. Time line of significant events relating to the enactment and enforcement of MQSA.
SOURCES: Mammography Quality Standards Act, 42 U.S.C. § 263b (2003) and 21 C.F.R. § 900.1 (2003).

In response to these findings, Congress passed the Mammography Quality Standards Reauthorization Act on October 9, 1998. The 1998 Act reflected several changes from the Act of 1992. For example, facilities were required to provide their patients with a written letter summarizing the results of the mammogram in lay terms. In addition, the original mammography films were to be provided to the patient on request.

Currently, nearly 70 percent of facilities pass inspection with no violations, and generally only about 2 percent of issued citations are for the most serious level of violations. GAO and FDA have both concluded that MQSA has significantly improved the quality of mammography over the past decade. Nonetheless, a 2001 FDA inspection survey found that inspections could be more efficient and inspectors more consistent (FDA, 2002b). In addition, there has been continuing concern about the quality of mammography interpretation. As described in Chapter 2, the available evidence indicates that interpretive performance is quite variable. There are also lingering concerns that the costs and workload associated with meeting MQSA requirements might lead to facility closures, with a subsequent reduction in patient access. Although a more recent study by GAO concluded that adequate access to mammography services exists, it also reported evidence of a decline in the number of radiologists and radiologic technologists entering the field of mammography in its April 2002 report (GAO, 2002). MQSA was reauthorized a second time in the fall of 2004, without major changes.[2]

COMMITTEE CHARGE

In preparation for the next MQSA reauthorization (originally anticipated in 2005, but now expected in 2007), Congress requested a study from the Institute of Medicine (IOM) to address remaining issues of concern regarding the quality and availability of mammography. In particular, the IOM Committee on Improving Mammography Quality Standards was charged with the task of proposing changes that could ensure and improve the accuracy of image interpretation while still ensuring adequate access to quality mammography services in the United States (Box 1-1).

METHODS

In addition to reviewing the available literature, the Committee obtained novel data and information from several sources. Data from two recent surveys by the ACR and the Society of Breast Imaging were used to evaluate the current status of the breast imaging workforce and available services. Detailed descriptions of the survey methods and analysis can be found in Appendixes A and B. The Committee also had access to workforce data collected by the American Society of Radiologic Technologists. Additionally, in an effort to predict the potential effects of present trends and possible changes in MQSA on future access to mammography, the Committee commissioned the Center for Workforce Studies at the State University of New York School of Public Health in Albany to model the supply and demand for interpreting physicians and radiologic technologists working in mammography (see Appendix C for methodological details). Staff at FDA, as well as the mammography accrediting bodies, were also very responsive to the

[2] One notable change is that the reauthorization allows FDA to grant a temporary (45-day) certificate to a facility going through the reaccreditation process in order to avoid temporary clinic closings.

BOX 1-1 Committee Statement of Task

The Labor–Health and Human Services (HHS) Appropriations Conference Report and the Omnibus Bill (H.R. 2673) requested an Institute of Medicine study that would provide information, analysis, and recommendations to inform the projected Mammography Quality Standards Act (MQSA) reauthorization. In a series of meetings and a workshop, a committee will review MQSA and recommend provisions to make improvements in areas of identified concern to Congress. Specifically, the committee will consider interpretation skills assessment as a possible tool to improve physician reading of mammograms and will also consider how the annual medical outcomes audit required under MQSA regulations could be used to improve mammographic quality and interpretation. The committee will examine:

(A) Ways to improve physicians' interpretations of mammograms, including approaches that could be taken under MQSA without negatively impacting access to quality mammography.

(B) What changes could be made in MQSA to improve mammography quality, including additional regulatory requirements that would improve quality, as well as the reduction or modification of regulatory requirements that do not contribute to quality mammography, or are no longer necessary to ensure quality mammography. Such reduction or modification of regulatory requirements and improvements in the efficiency of the program are important to help eliminate disincentives to enter or remain in the field of mammography.

(C) Ways, including incentives, to ensure that sufficient numbers of adequately trained personnel at all levels are recruited and retained to provide quality mammography services.

(D) (i) How data currently collected under MQSA could be used to improve the quality of, interpretation of, and access to mammography.

(ii) Identification of new data points that could be collected to aid in the moni toring and assessment of mammography quality and access.

(E) Other approaches that would improve the quality of and access to mammography services, including approaches to improving provisions under MQSA.

(F) Steps that should be taken to help make available safe and effective new screening and diagnostic devices and tests for breast cancer.

Committee's questions and provided valuable information and data, including files containing the names of all interpreting physicians listed on inspection reports. Input was also sought and obtained from experts in the field and interested individuals and institutions. The recommendations put forth in this report represent Committee consensus that was developed through review and discussion of the above information sources.

FRAMEWORK OF THE REPORT

This report builds on two previous IOM studies on early breast cancer detection and mammography: *Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer* (2001) and *Saving Women's Lives: Strategies for Improving Breast Cancer Detection and Diagnosis* (2005).

Chapter 2 describes the challenges associated with interpreting mammograms and measuring interpretive performance, and makes suggestions for how to ensure and improve the quality of mammographic interpretation.

Chapter 3 provides an overview of the regulation of mammography under MQSA, and suggests a variety of changes to the current regulations, inspections, and enforcement to streamline the process, reduce redundancy, clarify the intent, and address new technologies.

Chapter 4 characterizes the current mammography workforce and describes the challenges to maintaining women's access to quality mammography services in the future. Strategies to ensure an adequate breast imaging workforce are recommended.

Chapter 5 suggests additional measures that could be taken to optimize the early detection of breast cancer, including quality improvement strategies for other methods of breast imaging.

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2

Improving Interpretive Performance in Mammography

Breast cancer is a significant cause of morbidity and mortality in the United States. Until it can be prevented, the best approach to the control of breast cancer includes mammography screening for early detection. Mammography, however, is not a perfect test, due to the complex architecture of the breast tissue being imaged, the variability of the cancers that may be present, and the technical limitations of the equipment and processing. The technical aspects of mammography are now less variable since the interim Mammography Quality Standards Act (MQSA) regulations went into effect in 1994. At this point, the focus is shifting to the quality of mammography interpretation. The available evidence indicates that interpretive performance is quite variable, but the ambiguities of human decision making, the complexities of clinical practice settings, and the rare occurrence of cancer make measurement, evaluation, and improvement of mammography interpretation a much more difficult task.

The components of current MQSA regulations pertinent to interpretive performance include: (1) medical audit; (2) requirements related to training, including initial training and Continuing Medical Education (CME), and (3) interpretive volume, including initial and continuing experience (minimum of 960 mammograms/2 years for continuing experience). The purpose of this chapter is to explore current evidence on factors that affect the interpretive quality of mammography and to recommend ways to improve and ensure the quality of mammography interpretation. The primary questions that the Committee identified as currently relevant to interpretive performance include whether the current audit procedures are likely to ensure or improve the quality of interpretive performance, and whether any audit procedures applied to the current delivery of U.S. health care will allow for accurate and meaningful estimates of performance. In addition, the Committee questioned whether the current CME and volume requirements enhance performance. These issues will be described fully and the current state of research on these topics will be described in the sections that follow. The current state of knowledge about existing measures and standards is described first in order to define the terms needed to assess the medical audit requirement of MQSA.

CURRENT STATE OF KNOWLEDGE REGARDING APPROPRIATE STANDARDS OR MEASURES

Effectively measuring and analyzing interpretive performance in practice presents many challenges. For example, data must be gathered regarding whether a woman has breast cancer diagnosed within a specified timeframe after a mammogram and whether the finding(s) corresponds with the location in which the cancer is found. Other challenges include reaching agreement regarding the definition of positive and negative interpretation(s), standardizing the patient populations so that comparisons are meaningful, and deciding which measures are the most important reflection of an interpreting

TABLE 2-1 Terms Used to Define Test Positivity/Negativity in BI-RADS 1st and 4th Editions

ACR Category	BI-RADS Assessment	
	1st Edition	**4th Edition**
0	Need additional imaging	Need additional imaging evaluation and/or prior mammograms for comparison
1	Negative	Negative
2	Benign finding	Benign finding(s)
3	Probably benign	Probably benign finding—short-interval follow-up suggested
4	Suspicious abnormality	Suspicious abnormality—biopsy should be considered (4a, 4b, 4c may be included to reflect increasing suspicion)
5	Highly suggestive of malignancy	Highly suggestive of malignancy—appropriate action should be taken
6	NA	Known, biopsy-proven malignancy—appropriate action should be taken

SOURCE: American College of Radiology (2003).

physician's skill. In this section, current well-established performance measures are reviewed and their strengths and weaknesses are discussed. These measures should be made separately for screening examinations (done for asymptomatic women) and diagnostic examinations (done for women with breast symptoms or prior abnormal screening mammograms) because of the inherent differences in these two populations and the pretest probability of disease (Dee and Sickles, 2001; American College of Radiology, 2003). However, for simplicity, in the discussion below "examinations" or "mammograms" are used without designating whether they are screening or diagnostic because the mechanics of the measures are similar in either case.

Before describing the measures, it is important to clearly define a positive and negative test. The Breast Imaging Reporting and Data System (BI-RADS) was developed by the American College of Radiology (ACR), in collaboration with several federal government agencies and other professional societies in order to create a standardized and objective method of categorizing mammography results. The BI-RADS 4th Edition identifies the most commonly used and accepted definitions, which are based on a standard set of assessments first promulgated by the ACR in 1992 and modified slightly in 2003. Table 2-1 outlines terms used to define test positivity/negativity as found in the 1st and 4th editions of BI-RADS.

The assessments are intended to be linked to specific recommendations for care, including continued routine screening (Category 1, 2), immediate additional imaging such as additional mammographic views and ultrasound or comparison with previous films (Category 0), short-interval (typically 6 months) follow-up (Category 3), or biopsy consideration (Category 4) and biopsy/surgical consult recommended (Category 5).

Based on these assessments and recommendations, definitions of a positive mammography interpretation have also been suggested by the ACR BI-RADS Committee, as follows:

Screening Mammography:	Positive test = Category 0, 4, 5 Negative test = Category 1, 2
Diagnostic Mammography:	Positive test = Category 4, 5, 6 Negative test = Category 1, 2, 3

MQSA regulations, in contrast, define a positive mammogram as one that has an overall assessment of findings that is either "suspicious" or "highly suggestive of malignancy."

BI-RADS also now allows a single overall final assessment for the combined mammography and ultrasound imaging. Facilities that perform ultrasound online, at the time of diagnostic evaluation for an abnormal mammogram or palpable mass, will not have outcome statistics comparable to facilities where mammograms are reported without including the ultrasound evaluation. For example, a patient with a palpable finding may go to a facility and be found to have a negative mammogram and positive ultrasound, and the assessment will be reported as positive.

While there has been much improvement in mammography reporting since the adoption of BI-RADS, there is still inter- and intraobserver variability in how this reporting system is used (Kerlikowske et al., 1998). Some variability in calculated performance measures can, therefore, be attributed to variance among interpreting physicians on what constitutes an abnormal mammogram. Moreover, though the intent is clear, the linkage between assessment and recommendations is not always maintained in clinical practice. Indeed, Food and Drug Administration (FDA) rules require use of the overall assessments listed in Table 2-1, but the recommendations associated with each category are not mandated or inspected by FDA. Thus, considerable variability in recommendations exists. For example, 38 percent of women with "probably benign" assessments had recommendations for immediate additional imaging in one national evaluation (Taplin et al., 2002). Some analyses include Category 3 assessments associated with recommendations for performance of additional imaging as positive tests (Barlow et al., 2002). In addition, some women with mammograms interpreted as Category 1 or 2 have received recommendations for biopsy/surgical consult due to a physical finding not seen on the mammogram because mammography cannot rule out cancer (Poplack et al., 2000). Therefore, these standard definitions serve as a starting point, but in practice, adaptations may be needed to accommodate the reality of clinical care.

It is also important to define what constitutes "cancer." In the context of mammography practice, the gold standard source for breast cancer diagnosis is tissue from the breast, obtained through needle sampling or open biopsy. This tissue sample then leads to the identification of invasive carcinoma or noninvasive ductal carcinoma in situ (DCIS). Breast cancers are labeled invasive because the cells are invading surrounding normal tissue. Invasive cancers account for most (80 percent) of breast cancers found at the time of screening in the United States. DCIS is included as a cancer diagnosis primarily because standard treatment for DCIS currently entails complete excision, similar to invasive cancers. Approximately 20 percent of breast cancer diagnoses are DCIS (Ernster et al.,

TABLE 2-2 Possible Results for a Screening Test

		Cancer Outcome	
		+	–
Test Result	+	TP – True positive	FP – False positive
	–	FN – False negative	TN – True negative

2002). Lobular carcinoma in situ (LCIS) also is occasionally reported in the tissue, but should not be counted as cancer because it is not currently treated.

Interpretive performance can also vary as a function of the time since the prior mammogram (Yankaskas et al., 2005). Recognizing that differences exist among screening guidelines regarding the appropriate screening interval (annual recommended by the American Cancer Society [ACS] and the American College of Obstetricians and Gynecologists [ACOG], every 1 to 2 years recommended by the U.S. Preventative Services Task Force [USPSTF]) (U.S. Preventive Services Task Force, 2002; Smith and D'Orsi, 2004; Smith et al., 2005), the specification of the period of follow-up after a mammogram is needed to observe women for the occurrence of cancer and calculate performance indices that can be compared in a meaningful way.

With the above definitions, it is possible to identify several measures of interpretive performance. The measures of performance available to assess interpreting physician's interpretation all build from a basic 2 x 2 table of test result and cancer outcome as noted in Table 2-2. A one-year interval should be used to calculate the performance indices so that they are comparable. Standard definitions of these measures are well summarized in the ACR BI-RADS 4th Edition, and are highlighted here along with some of the strengths and weaknesses of each measure. Separation of the data of screening from diagnostic indications for mammography is absolutely essential if performance measures are to be meaningful.

Sensitivity

Sensitivity refers to the ability of a test to find a cancer when it is present [TP/(TP+FN)]. The challenge with this measure is determining whether a cancer has been diagnosed, particularly if a woman was given a negative mammogram interpretation. Those women are not necessarily seen back in the same facility for their next examination. Therefore it is not possible to know with certainty whether they have cancer or not. This problem is called verification bias. Because only those women sent to biopsy within a facility have their true cancer status known, verification bias may lead to an overestimation of sensitivity (Zheng et al., 2005). Relatively complete ascertainment of cancer cases can be expected only if a mammography facility is able to link its examinations to those breast cancer cases compiled in a regional tumor registry, and this is practical only for a very small minority (likely fewer than 5 percent) of mammography facilities in the United States.

Because the ultimate purpose of screening is to reduce disease-specific mortality by detecting and treating early-stage cancers, the sensitivity of mammography is important. However, sensitivity is affected by many factors, including whether it is a first (prevalent[1]) mammogram or subsequent (incident) mammogram, the distribution of patient ages and tumor sizes in the population of women being screened by the interpreting physician, the length of time since prior mammograms, the density of the breast tissue among women with cancer, and the number of women with cancer found by an interpreting physician (Carney et al., 2003; Yankaskas et al., 2005). Most screening populations have between 2 and 10 cancers per 1,000 women screened, and among women undergoing periodic screening on a regular basis, the cancer incidence rate is 2 to 4 per 1,000 (American College of Radiology, 2003). Under current MQSA regulations, a single interpreting physician must interpret 960 mammograms over 2 years to maintain accreditation. If he or she is reading only screening (and not any diagnostic) mammograms, he or she may, on average, see two to four women with cancer per year. Estimating sensitivity among such a small set of cancers affects the reliability of the measures. Random variation will be large for some measures, making comparisons among interpreting physicians very difficult, even if the interpreting physician has complete knowledge regarding the cancer status of all the women examined. Because most interpreting physicians do not have that complete information (no linkage to regional tumor registry) or the volumes to create stable estimates, measurement of sensitivity will be of very limited use for individual interpreting physicians in practice.

Specificity

Specificity is the ability of the test to determine that a disease is absent when a patient is disease-free [TN/(TN+FP)]. Because most screened women (990 to 998 per 1,000) are disease free, this number will be quite high even if a poorly performing interpreting physician gives nearly every woman a negative interpretation. But interpreting physicians must interpret some mammograms as positive in order to find cancers, so false-positive examinations occur. Estimates of the cumulative risk of a false-positive mammogram over a 10-year period of annual mammography vary between 20 and 50 percent (Elmore et al., 1998; Hofvind et al., 2004), and the risk of a negative invasive procedure may be as high as 6 percent (Hofvind et al., 2004). High specificity of a test is therefore important to limit the harms done to healthy women as a result of screening. Although one study of nearly 500 U.S. women without a history of breast cancer found that 63 percent thought 500 or more false-positive mammograms per life saved was reasonable (Schwartz et al., 2000), the cost and anxiety associated with false-positive mammograms can be substantial. Studies have shown that anxiety usually diminishes soon after the episode, but in some women anxiety can endure, and in one study anxiety was greater prior to the next screening mammogram for women who had undergone biopsy on the previous occasion of screening compared with women who had normal test results (Brett and Austoker, 2001). One study has shown that immediate interpretation of mammograms was associated with reduced levels of anxiety (Barton et al., 2004).

[1] The prevalent screen refers to the first time a woman undergoes a screening test. Incident screens refer to subsequent screening tests performed at regular intervals. One useful index of screening mammography performance is that the number of cancers per 1,000 women identified by prevalent screens should be at least two times higher than by incident screens.

Like sensitivity, specificity is a difficult measure to obtain for most interpreting physicians because it requires knowing the cancer status of all women examined (linkage to a regional tumor registry). Because it is difficult to ascertain the status of all women who undergo mammography with respect to the presence or absence of cancer, it is important to be clear about who is being included in the measure and what the follow-up period is. This has led to three levels of false-positive measurement (Bassett et al., 1994):

1. FP_1: No known cancer within one year of a Category 0, 4, or 5 assessment (screening).
2. FP_2: No known cancer within one year of a Category 4 or 5 assessment (usually diagnostic).
3. FP_3: No known cancer within one year of a Category 4 or 5 assessment, for which biopsy was actually performed.

If each of these measures is estimated for a year, they can also be called rates. The limitation in choosing only one of the three rates is that there is a trade-off between the accuracy of the measure and the insight it provides regarding an interpreting physician's performance. Although FP_3 involves the most accurate measure of cancer status, it reflects only indirectly on the interpreting physician's choice to send women to biopsy. Interpreting physicians' ability to make that choice, and to make the recall versus no-recall decision at screening, are important characteristics. The most accurate estimate of FP (FP_3) is therefore not necessarily the measure that provides the best insight into the interpreting physician's performance. Conversely, FP_1 includes BI-RADS 0's, a high percentage of which have a low index of suspicion. Furthermore, measuring FP_1 involves knowing the cancer status of all women for whom additional imaging was recommended (defined in BI-RADS as Category 0—incomplete, needs additional imaging). This is challenging because results of the subsequent evaluation may not be available. Currently, MQSA does not require that Category 0 examinations be tracked to determine the final overall assessment. The Committee recommends that for women who need additional imaging, mammography facilities must attempt to track these cases until they resolve to a final assessment. Although studies indicate that some interpreting physicians inappropriately assign women who need additional imaging a Category 3 BI-RADS assessment (Poplack et al., 2000; Taplin et al., 2002), this practice should be discouraged, and all women needing additional imaging should be tracked.

Positive Predictive Value (PPV)

There are three positive predictive values (PPV) that can be measured in practice, derived from the three false-positive measures described above. Again, these different measures are used to accommodate the challenges of data collection in practice. For example, though an interpreting physician may recommend a biopsy, it may not be done, and therefore the true cancer status may not be known. Thus, one must clearly state which PPV or PPVs are being monitored (Bassett et al., 1994), as recommended by the ACR.

1. PPV_1: The proportion of all women with positive examinations (Category 0, 4, or 5) who are diagnosed with breast cancer $[TP/(TP + FP_1)]$.

2. PPV_2: The proportion of all women recommended for biopsy after mammography (Category 4 or 5) that are diagnosed with breast cancer [TP/(TP +FP_2)].

3. PPV_3: The proportion of all women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy [TP/(TP +FP_3)].

MQSA requires that interpreting physicians have an established mechanism to ascertain the status of women referred for biopsy. With these data interpreting physicians can measure their PPV_2, but it is still subject to verification bias because not all women recommended for biopsy will have it done and because ascertainment of procedures is never 100 percent. The limitation of PPV_2 or PPV_3 is that many more women are referred for additional imaging (8 percent) than biopsy (1.5 percent) (Taplin et al., 2002). An important skill in interpretation involves sorting who needs additional imaging versus biopsy; PPV_2 and PPV_3 do not account for this because they only focus on women referred for biopsy. The ACR recommends that interpreting physicians who choose to perform one of the two types of audits described in the BI-RADS atlas should track all women referred for additional imaging for their subsequent cancer status (PPV_1) (American College of Radiology, 2003). Because measuring PPV_1 may not be possible in the absence of an integrated health system and registry, the Committee recommends use of PPV_2.

Another limitation of PPV that influences its usefulness is that it is affected by the rate of cancer within the population examined. The PPV will be higher in populations with higher cancer rates. For example, an interpreting physician practicing among older populations of women versus younger will have a higher PPV, just because the risk of breast cancer is higher among older women. PPV_1 will vary depending on the proportion of patients who are having an incident versus prevalent screen. Unfortunately, a high PPV does not necessarily correlate with better performance. For example, the interpreting physician who recommends biopsy for only larger, more classic lesions will have a higher PPV, but will miss the smaller, more subtle, and less characteristic lesions that may be more important to patient outcomes (Sickles, 1992). Therefore the Committee recommends measuring the cancer detection rate in addition to PPV_2 in order to facilitate interpretation of the measure. A higher PPV_2 should occur in a population with a higher cancer detection rate (see section below on Cancer Detection Rate).

Negative Predictive Value (NPV)

Negative predictive value (NPV) is the proportion of all women with a negative result who are actually free of the disease [TN/(FN+TN)]. Monitoring NPV is not a requirement of MQSA, and in practice, the NPV is rarely used because it involves tracking women with negative examinations (linkage to regional tumor registry is required).

Cancer Detection Rate

Cancer detection rate is the number of women found to have breast cancer per 1,000 women examined. This rate is meaningless unless screening mammograms are assessed separately from diagnostic evaluations. This measure is similar to sensitivity, but includes all examinations (not just cancer cases) in the denominator. The advantage is that interpreting physicians know the total number of examinations they have interpreted and can identify the cancers resulting from biopsies they recommended or performed.

The disadvantage is that differences in the cancer detection rate may reflect not only differences in performance, but also differences in the rate and risk of cancer in the population served. A high cancer detection rate relative to other interpreting physicians may simply indicate that the interpreting physician is caring for an older population of women who are at higher risk for cancer, not that he or she is necessarily highly skilled at finding cancer. This difference can be mitigated by adjusting the cancer rate to a standard population age distribution if adequate numbers exist in each age group to allow rate estimates. For radiologists comparing their own measures over time, these kinds of adjustments are less important if the population characteristics are stable.

Other factors that could influence the cancer detection rate include the proportion of women having their first (prevalent) screen and the proportion having a repeat (incident) screen, the interval since the prior screen, differing practices with respect to who is included in screenings, whether practices read examinations individually as they are completed or in batches at a later time (mode of interpretation), and how long a physician has been in practice (van Landeghem et al., 2002; Harvey et al., 2003; Smith-Bindman et al., 2003). Interpretive sensitivity and specificity are higher on first screens compared to incident screens, presumably due to slightly larger tumors being found at prevalent screens (Yankaskas et al., 2005). For incident screens, the longer the time since the prior mammogram, the better interpretative performance appears, again because tumors will be slightly larger (Yankaskas et al., 2005). Some practices offer only diagnostic mammography to high-risk women with a history of breast cancer, while others will offer screening. Excluding such women from the screening population will reduce the number of cancers at the time of screening and affect positive predictive values, but may also change a physician's threshold for calling a positive test. Changes in the threshold for a positive test can affect performance, and this threshold seems to change with experience (Barlow et al., 2004).

Abnormal Interpretation Rate

The abnormal interpretation rate is a measure of the number of women whose mammogram interpretation leads to additional imaging or biopsy. For screening mammography, the term "recall rate" is often used. The recall rate is the proportion of all women undergoing screening mammography who are given a positive interpretation that requires additional examinations (Category 0 [minus the exams for which only comparison with outside films is requested], 4, or 5). Desirable goals for recall rates for highly skilled interpreting physicians were set at less than or equal to 10 percent in the early 1990s (Bassett et al., 1994). This measure is easy to calculate because it does not rely on establishing the cancer status of women. The disadvantage is that differences in this measure may not reflect differences in skill except when the rate is extraordinarily high or low. Again, this will depend on the proportion of prevalent to incident screens (Frankel et al., 1995), on the availability of previous films for comparison (Kan et al., 2000), and on the mode of interpretation (Sickles, 1992, 1995a; Ghate et al., 2005).

Cancer Staging

Cancer staging is performed after a breast cancer is diagnosed. Stage, along with other tumor prognostic indicators (e.g., tumor grade, hormone receptor status, and other factors), is used to determine the patient's prognosis, and the combination of tumor

markers and stage influences treatment. Cancer staging takes into account information regarding the tumor histological type and size, as well as regional lymph node status and distant metastases. Staging information, which is generally derived from pathology reports in varying forms, is useful for the mammography audit because women with advanced, metastatic tumors are more likely to die from the disease. However, tumor staging information is not always easily available to the imaging facility, and thus, may be more of a burden to acquire.

Tumor Size

The size of the breast cancer at the time of diagnosis is relevant only for invasive cancers. All patients with only DCIS are Stage 0, despite the extent of the DCIS. An interpreting physician who routinely detects smaller invasive tumors is likely to be more skilled at identifying small abnormalities in a mammogram. The proportion of invasive tumors less than 1.5 or 1.0 cm could be used as one measure.

Using tumor size as a performance measure has several limitations; measurement of a tumor is an inexact science and may vary depending on what is recorded in a patient record or tumor registry (e.g., clinical size based on palpation, size based on imaging, size based on pathology), and who is doing the measuring. SEER (Surveillance, Epidemiology and End Results) registries use a hierarchy to choose which measurement to include. Heterogeneity will occur because not all measurements are available. Furthermore, the proportion of small tumors will be affected by the population of tumors seen by a given interpreting physician; for example, a physician reading more prevalent screens will have a greater proportion of large tumors because there are more large tumors in the population. The screening interval is also important when tumor size is used as a performance measure.

A shift toward smaller tumor size has been noted in screened populations such as those in the Swedish randomized trials of mammography (Tabar et al., 1992). A similar shift is expected in other screened populations. In one study of a National Screening Program, invasive breast cancer tumor size at the time of discovery decreased from 2.1–2.4 cm to 1.1–1.4 cm between 1983 and 1997, within which time period the national screening program had been implemented (Scheiden et al., 2001).

Axillary Lymph Node Status

The presence or absence of cancer cells in the axillary lymph nodes is one of the most important predictors of patient outcome. The prognosis worsens with each positive node (containing cancer cells) compared to women with histologically negative lymph nodes. Node positivity, however, is not necessarily a useful surrogate measure of an interpreting physician's interpretive performance because inherently aggressive tumors may metastasize to the axillary lymph nodes early, when the tumor is still small, or even before the tumor becomes visible on a mammogram.

Area Under the Receiver Operating Curve[2] (AUC)

Interpreting physicians face a difficult challenge. While trying to find cancer they must also try to limit the number of false-positive interpretations. If the distribution of interpretations among women with cancer and women without breast cancer were graphed together on one x/y axis, it would look like Figure 2-1. Focusing on sensitivity simply indicates how an interpreting physician operates when cancer is present. Focusing on specificity simply indicates how an interpreting physician operates when cancer is not present. What is really needed to assess performance is the ability of the interpreting physician to simultaneously discriminate between women with and without cancer. This is

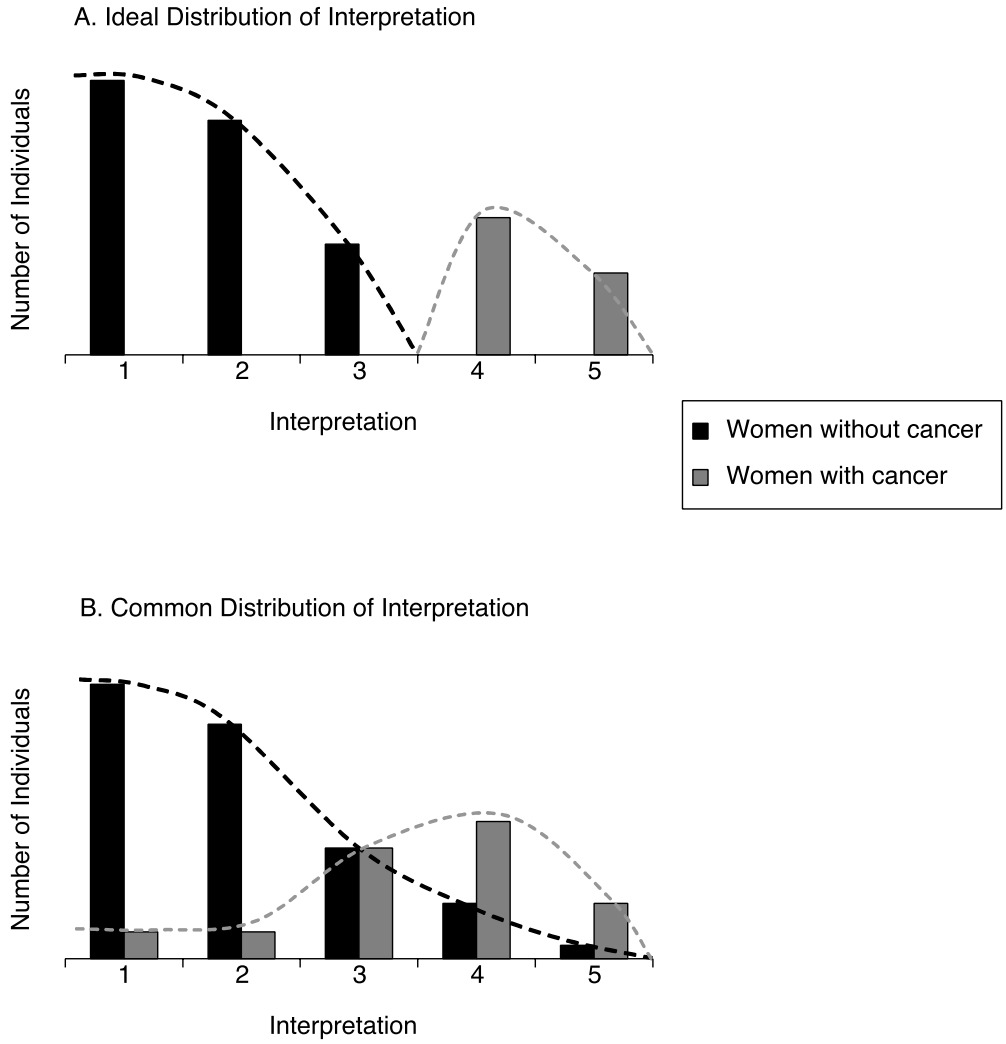

FIGURE 2-1 Ideal (A) and actual common (B) distribution of mammography interpretation (BI-RADS Assessment Categories 1–5).

[2] For a more detailed description of ROC curves, see Appendix C in *Saving Women's Lives* (IOM, 2005).

reflected in the overlap between the two distributions of interpretations in Figure 2-1, and is measured by the area (AUC) under the receiver operating curve (ROC) (Figure 2-2).

ROC analysis was developed as a methodology to quantify the ability to correctly distinguish signals of interest from the background noise in the system. The ROC curves map the effects of varying decision thresholds and demonstrate the relationship between the true-positive rate (sensitivity) and the false-positive rate (specificity). If a reader's interpretation is no better than a flip of the coin, the distribution of BI-RADS assessments in Figure 2-1 will overlap completely and the AUC in Figure 2-2 will be 0.5. If an interpreting physician has complete discrimination, the distribution of BI-RADS assessments will be completely separated for women with and without cancer, as in Figure 2-1a, and the AUC will be 1.0. An interpreting physician's AUC therefore usually falls between 0.5 and 1.0.

Estimating the AUC is possible if the status of all examined women is known and the appropriate computer software is employed. It has the advantage of reflecting the discriminatory ability of the interpreting physician and incorporates both sensitivity and specificity into a single measure, accounting for the trade-offs between the two measures.

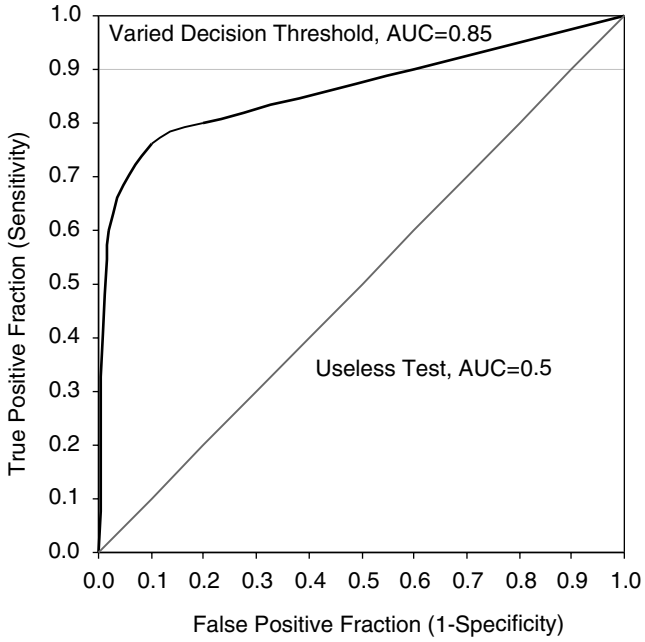

FIGURE 2-2 ROC analysis. If a reader is guessing between two choices (cancer versus no cancer), the fraction of true positives will tend to equal the fraction of false negatives. Thus, the resulting ROC curve would be at a 45-degree angle and the area under the curve, 0.5, represents the 50 percent accuracy of the test. In contrast, the ROC curve for a reader with 100 percent accuracy will follow the y-axis at a false-positive fraction of zero (no false positives) and travel along the top of the plot area at a true-positive fraction of one (all true positives). The area under the curve, 1.0, represents the 100 percent accuracy of the test. The hypothetical result for a reader with an area under the curve of 0.85 is shown for comparison.

The disadvantages include the challenges of data collection and the requirement for somewhat sophisticated software to estimate the value of the AUC. Of note, however, is that ROC curves may be problematic when using BI-RADS terminology if interpreting physicians do not accurately use the full range of values in the ordinal BI-RADS scale (1, 2, 3, 0, 4, 5). Even when providers use the full scale accurately, the interpretations do not fall into a normal distribution across the range of interpretations. Most screening interpretations (79 percent) are BI-RADS 1. Despite this, BI-RADS interpretations can be analyzed directly with models for ordinal-level data (Tosteson and Begg, 1988). An underlying latent distribution can be assumed to generate a continuous ROC curve and area under the curve. This assumption regarding a latent distribution also requires an assumption about the normality of the latent distributions and different standard deviations for the women with and without cancer. Using widely available software, these assumptions can be accommodated and ROC analysis is routinely performed (Tosteson and Begg, 1988; Barlow et al., 2004; Yankaskas et al., 2005).

In summary, there is currently no perfect measure of performance, even under the best of circumstances where all the necessary data are collected. In practice, such a situation rarely exists. In addition, appropriate benchmarks for screening may vary depending on the unique populations served by a particular facility. Measuring and assessing performance in practice therefore constitutes a considerable challenge if the goal is accurate comparisons between facilities. If the goal is consistent feedback to the interpreting physicians within a facility, the limitations are not so great, because the data challenges may be more consistent within facilities and therefore the measurements more comparable. Given the challenges and limitations, the Committee recommends a focus on PPV_2. Calculating the cancer detection rate and the rate of abnormal interpretation (women whose mammogram interpretation leads to a recommendation for additional imaging or biopsy) would facilitate appropriate interpretation of PPV_2, which is influenced by the prevalence of cancer in the screening population. Evaluating these three measures in combination would enhance the current required medical audit of mammography considerably and should be feasible for mammography facilities to achieve. Measures such as sensitivity and specificity would be even more useful, but it would not be feasible to calculate these measures in community practices that do not have linkage with a tumor registry. Suggested changes to the medical audit of mammography are described in more detail in the section entitled Strategies to Improve Medical Audit of Mammography.

FACTORS AFFECTING INTERPRETIVE PERFORMANCE OF BOTH SCREENING AND DIAGNOSTIC MAMMOGRAPHY

Despite evidence that mammography screening is an efficacious technology for reducing breast cancer mortality among women in certain age groups (Andersson et al., 1988; Shapiro et al., 1988; Roberts et al., 1990; Frisell et al., 1991; Tabar et al., 1992; Elwood et al., 1993; Nystrom et al., 1993; Fletcher et al., 1993; Bassett et al., 1994; Schwartz et al., 2000; Fletcher and Elmore, 2003), its full potential for mortality reduction in practice may be limited by the accuracy of interpretation. For example, a low sensitivity may indicate missed opportunities in diagnosing early-stage breast cancers, when the potential to save lives is highest. On the other hand, a low specificity may

TABLE 2-3 Recent Reports of Measures on Interpretive Performance of Screening and Diagnostic Mammography

Authors	Exam Type	Population	Years Studied	Sensitivity	Specificity	Cancer Detection Rate
Carney et al. (2003)	Screening	National sample (n=329,495)	1996–1998	75.0%	92.3%	4.8/1,000 (adjusted)[b]
Kerlikowske et al. (2000)	Screening	National sample (n=389,533)	1985–1997	80.9%	—	4.2/1,000 (unadjusted)
Poplack et al. (2000)	Screening	New Hampshire (NH) women (n=47,651)	1996–1997	72.4%	97.3%	3.3/1,000 (unadjusted)
Poplack et al. (2000)	Diagnostic	NH women (n=47,651)	1996–1997	78.1%	89.3%	—
Yankaskas et al. (2005)	Screening	National sample (n=680,641)	1996–2000	70.9–88.6%[a]	85.9–93.3%[a]	3.2–6.1/1,000[a]

Author	Exam Type	Population	Years Studied	PPV_2	Tumor Size	Cancer Diagnosis Rate
Sickles et al. (in press)	Diagnostic	National sample (n=332,926)	1996–2000	31.5%	20.2mm	25.3/1,000 (unadjusted)

[a] Depending on months since prior mammogram (9–15, 16–20, 21–27, 28+).
[b] Adjusted for patient characteristics in the screening population studied.

indicate high rates of mammograms interpreted as abnormal, requiring additional workup when the woman actually does not have breast cancer.

The Committee was not asked to assess the current quality of mammography interpretation in the United States, but the available evidence indicates that interpretive performance is highly variable. There is a range in reported performance indices for mammography. Sensitivity and specificity rates for mammography screening trials range from 75 percent to 95 percent and from 83 percent to 98.5 percent, respectively (Roberts et al., 1990; Frisell et al., 1991; Tabar et al., 1992; Nystrom et al., 1993; Elmore et al., 2005). Table 2-3 lists the most current information on interpretive performance inscreening and diagnostic mammography. Different indices for performance are used relative to the type of studies done.

Variability is common in areas of medicine where observation and interpretation are subjective (Feinstein, 1985; Elmore and Feinstein, 1992). Several studies on variability in interpretive performance of mammography have been conducted with radiologists both in test situations (Elmore et al., 1994; Beam et al., 1996; Elmore et al., 1997; Kerlikowske et al., 1998) and in medical practice (Meyer et al., 1990; Brown et al., 1995; Kan et al., 2000; Yankaskas et al., 2001; Sickles et al., 2002; Elmore et al., 2002; Smith-Bindman et al., 2005). These have revealed that recall rates (the proportion of screening mammograms interpreted as abnormal with additional evaluation recommended) range from 3 percent to 57 percent among facilities (Brown et al., 1995) and 2 percent to 13 percent among individual radiologists (Yankaskas et al., 2001). Recall rates are higher and false-positive mammograms are more common in the United States than other countries, although the cancer detection rates are similar (Elmore et al., 2003; Smith-Bindman et al., 2003; Yankaskas et al., 2004). Less research has focused on the performance of diagnostic mammography, though one recent paper reported on women with signs or symptoms of breast cancer (Barlow et al., 2002). A PPV of 21.8 percent, sensitivity of 85.8 percent, and specificity of 87.7 percent was found.

Although general guidelines for performance have been put forth previously (Bassett et al., 1994), there is no consensus in the United States on minimal performance standards for interpretation, in part because there tends to be a trade-off between sensitivity and specificity, and there is no agreement on how many false positives should be acceptable in order to maximize sensitivity. In addition, the optimal performance standards will vary depending on a variety of factors such as the patient population being served. Patient factors that affect test accuracy include the size of the lesion, characteristics of the breast under examination (e.g., breast density, previous breast biopsies), patient age, extent of follow-up required to detect cancer, existence of previous exams, availability of prior films for comparison (Steinberg et al., 1991; Saftlas et al., 1991; Reis et al., 1994; Laya et al., 1996; Litherland et al., 1997; Persson et al., 1997; Pankow et al., 1997; Byrne, 1997; Porter et al., 1999; Mandelson et al., 2000; Buist et al., 2004), and time interval between screening examinations (White et al., 2004; Yankaskas et al., 2005).

Interpretive Volume and Interpreting Physicians' Levels of Experience

Interpretive volume and interpreting physicians' levels of experience (length of time interpreting mammography) have also been identified as important factors affecting breast cancer detection (Sickles, 1995a; Elmore et al., 1998; Beam et al., 2002; Esserman

et al., 2002). Interpretive volume has recently received a great deal of attention, and it appears that when used in conjunction with other quality improvement strategies, higher volume may enhance interpretive accuracy. The findings and limitations of the several research studies discussed below are summarized in Table 2-4.

Perry (2003) described the UK National Health Program, in which there are minimum volume requirements that are much higher than in the United States: 5,000 mammograms interpreted per year per interpreting physician, and 9,000 screening mammograms performed per year per facility. Radiologists undertake a 2-week multidisciplinary course with specialist training at high-volume screening sites, which includes three sessions per week of interpreting screening mammograms. Radiologists additionally attend routine breast disease-related meetings and receive personal and group audit reports that include data on cancer detection rate, recall rate, and PPV_2. With all these combined activities, performance indices showed a reduction in the recall rate from 7 to 4 percent, and an increase in the small invasive cancer detection rate from 1.6/1,000 to 2.5/1,000.

Kan et al. (2000) studied 35 radiologists in British Columbia (BC), Canada, who work in the BC Mammography Screening Program. They derived a standardized abnormal interpretation ratio by dividing observed counts of the event by expected counts of the event. They found that abnormal interpretation ratio was better for readers of 2,000–2,999 and 3,000–3,999 per year compared to those interpreting less than 2,000 per year. These researchers concluded that a minimum of 2,500 interpretations per year is associated with lower abnormal interpretation rates and average or better cancer detection rates. Whether the findings from this small sample size from a program in Canada, where the qualifying standards for interpreting physicians are quite different, can be generalized to practice in the United States is not clear.

Another recent study from a population-based breast cancer screening program in Quebec showed that the rate of breast cancer detection was unrelated to the radiologist's interpretive volume, but increased with the facility's screening volume (Theberge et al., 2005).

A recent study that aimed to examine the relationship between reader volume and accuracy in the United States suggested that high volume readers performed better (Esserman et al., 2002). However, the study methodology included some artificial elements (e.g., it held specificity at a steady state and then recalculated each physician's sensitivity, rather than studying the interpretive trade-offs between the two measures) that weaken the strength of the findings and conclusions.

In another study, performed within a major U.S. health maintenance organization (HMO) (Adcock, 2004), radiologists were provided with personal and group audit reports, attended case review sessions, participated in a self-assessment program, and were required to interpret 8,000 mammograms per year per radiologist (n=21 radiologists). The author reported that sensitivity improved from 70 percent to 80 percent, with a mean cancer detection rate of 7.5/1,000 and a mean recall rate of 7 percent, two other indices that improved significantly. However, the analysis was not published in a peer-reviewed journal; the report was primarily descriptive and is analytically limited (confidence intervals were not calculated), which may influence its accuracy. In addition, it is hard to know whether findings from 21 radiologists within a single HMO-based health care setting can be generalized to U.S. interpreting physicians in other diverse practice settings.

TABLE 2-4 Summary of Recent Studies That Examine the Impact of Interpretive Volume and Experience on Accuracy

			Measures of Improvement				
Author	**Intervention/Evaluation/ Volume Level**	**Population**	**Cancer Detection Rate**	**Recall Rate**	**Biopsy Info**	**Sens/Spec/AUC**	**Analytic Considerations**
Perry (2003)	Audit with feedback, self-assessment program, and specialty training program with volume of 5,000/year	UK national sample (n=1,461,517)	Small invasive: 4.6/1,000[a] Noninvasive: 0.5/1,000	4.0%	Benign Biopsy Rate 0.8/1,000	—	• Significant improvements • Limited generalizability • Cannot isolate effect of volume
Adcock (2004)	Audit with feedback and case review with self-assessment program and volume of 8,000/year	Kaiser patients (n=101,000), 21 radiologists	From 6.3 to 7.5/1,000—all cancers combined	From 7.0% to 7.5%	PPV_2 from 31 to 37	Sens: from 70% to 80%	• Limited number of radiologists (n=21) • Cannot isolate effect of volume
Beam et al. (2003)	Examined the influence of volume after adjusting for other factors using multiple regression analysis	Random sample of 110 radiologists assessed using test set of 148 cases	—	—	—	On test set, mean Sens is 91% and Spec is 62%; neither volume nor years interpreting were found to influence accuracy	• Case set not representative of usual practice (43% were cancers) • Self-reported volume used as an input rather than studied with actual performance data

Continued

TABLE 2-4 Continued

Author	Intervention/Evaluation/ Volume Level	Population	Measures of Improvement: Cancer Detection Rate	Recall Rate	Biopsy Info	Sens/Spec/AUC	Analytic Considerations
Barlow et al. (2004)	Assessed the relationship between radiology characteristics (years interpreting and volume interpreted) to actual performance	National sample (n=469,512 women) (n=124 radiologists)	—	10.4%	—	Adjusted AUC for number of mammograms interpreted: 0.92 for <1,000; 0.92 for 1,001–2,000; and 0.92 for 2,000+ (p=0.94)	• Used actual practice data • Higher volume was related to higher recall and Sens but lower Spec; both volume and years of experience affected criterion for calling mammo positive, but neither affected overall accuracy
Smith-Bindman et al. (2005)	Identified practice patterns and physician characteristics associated with the accuracy of screening mammography	National sample (n=1,220,046 women) (n=209 radiologists)	—	—	—	Mean Sens: 77%; mean false + rate 10%; interpretation of 2,500–4,000 per year with high screening focus had 50% fewer false + exams	• Used actual practice data and included a focus on screening • Included novel metric of accuracy

TABLE 2-4 Continued

Author	Intervention/Evaluation/ Volume Level	Population	Measures of Improvement				
			Cancer Detection Rate	Recall Rate	Biopsy Info	Sens/Spec/AUC	Analytic Considerations
Kan et al. (2000)	Determined the relationship between annual screening volume and radiologists' performance (in BC, Canada)	35 radiologists	—	—	—	Standardized abnormal interpretation was better for readers of 2,000–2,999 and 3,000–3,999 per year than those less than 2,000	• Derived a standardized abnormal interpretation ratio by dividing observed counts of the event by expected counts of the event

[a] Incident round screening performance.

NOTE: AUC=area under the receiver operating curve, Sens=sensitivity, Spec=specificity, PPV=positive predictive value.

The above studies are important, but notable limitations exist regarding the study of volume or experience alone because other confounding factors were included in the interventions. For example, in the Perry study the specific contribution of the higher minimum interpretive volume requirement was not isolated from other program activities in the analysis of improved performance. The same is true for Adcock's study, where the specific contribution of interpretive volume versus other aspects of the intervention is unknown.

Some studies have been conducted in the United States that do examine interpretive volume alone, or in some cases, examine volume along with continuous experience. These are described below. Beam and colleagues (2003) used a test set of 148 mammograms, with 43 percent of the films having cancer, which was circulated to 110 randomly selected U.S. radiologists to assess the relationships between interpretive volume and accuracy. These researchers employed two different measures of accuracy, both using ROC analysis. The first was the area under the curve (AUC) estimated nonparametrically. This measure can be interpreted as the ability of the diagnostician to discriminate a mammogram showing breast cancer from one not showing breast cancer when two such mammograms have been randomly selected and presented together. Beam asserts the total AUC may not reflect the actual operating characteristics of radiologists because the full AUC includes high false-positive rates that are not relevant for screening. As a result, Beam has employed the use of partial AUC by restricting his analysis to the interval in which false-positive probability is less than 10 percent. This can be interpreted as the average sensitivity for the radiologist who reads within a clinically desirable range of false-positive values.

Briefly, they found that after controlling for the influence of radiologist- and facility-level factors, that neither interpretive volume nor years interpreting mammography was associated with screening accuracy. Rather, years since residency and having formal training in mammography during residency were both negatively associated with both of their ROC-based measures of accuracy, as described above. Several other factors were associated with one of the accuracy measures. Being the owner of the practice, increased use of diagnostic imaging and interventional procedures, and double reading were associated with increased accuracy, while presence of a computerized system to monitor and track screening, facility classification as hospital-based radiology department or multispecialty medical clinic (compared to breast diagnostic center, mammography screening center), and presence of a formal pathology correlation conference were negatively associated with accuracy. However, the Committee is not comfortable drawing conclusions about volume based on these findings alone. Because test sets have an extremely high percentage of abnormal films compared to usual clinical practice, data from "test" situations may be unreliable (Rutter and Taplin, 2000), although some work has suggested that giving specific instructions to reviewers prevents context bias in interpretive studies where images do not represent actual practice (Egglin and Feinstein, 1996).

Unfortunately two studies using data from clinical practice in similar populations in the National Cancer Institute's (NCI's) Breast Cancer Surveillance Consortium appear to show conflicting findings. In one, Barlow and colleagues (2004) studied 124 radiologists in 3 regions of the United States and found that increased radiologist experience was associated with a reduced recall rate and lower sensitivity but higher specificity. Using

ROC curves to account for the trade-off between sensitivity and specificity, with additional adjustments for patient characteristics, these researchers found that both interpretive volume and extent of interpretive experience affected radiologists' criteria for calling a mammogram positive, but overall accuracy of interpretation was not affected by either of these factors (interpretive volume and experience). These researchers concluded that direct feedback with audit results and focused training may result in more improved performance than increased volume or experience.

In the second study, Smith-Bindman and colleagues (2005) studied 209 radiologists and found an overall sensitivity of 77 percent (range 29 percent to 97 percent) and a false-positive rate of 10 percent (SD 5 percent; range 1–29 percent). They also found that more experience as a radiologist (25 years or more versus 10 years) was associated with lower false-positive rates, and an interpretive volume of 2,500–4,000 versus 481–750 was associated with a shift to a more accurate ROC curve after adjustment for both patient and radiologist characteristics. Using this technique, these researchers concluded that an annual interpretive volume of 3,000 screening mammograms per radiologist translated into 182 fewer false-positive mammograms and one missed cancer per year, though it does not show a significant improvement in their measure of accuracy (e.g., a new ROC curve). In fact, one table in the Smith-Bindman paper does indicate that overall accuracy is not influenced by volume with an odds ratio of 1.06, a finding that is not highlighted in the discussion of their results. No difference was shown in the odds of having a new ROC curve across the levels of volume. Thus, the Committee concludes that a recommendation to increase volume requirements cannot be justified based on this study. Smith-Bindman and colleagues' modeling effort is innovative and intriguing, but its validity is not widely accepted.

The analytic methods used in the Smith-Bindman paper differ significantly from those used by Barlow et al., though the data sources are very similar and to some extent overlapping. Based on discussions with these investigators and a neutral biostatistician, Anna Tosteson, Sc.D., who is an expert in this field, the Committee concludes that there were reasonable arguments for each analytic technique, but that regardless of which method was chosen, neither showed a significant influence of volume on overall accuracy. More study is needed to establish the implications, advantages, and disadvantages of statistical approaches to evaluating the influence of volume on interpretive performance.

Factors that should be taken into account in reviewing often conflicting results of these studies include the type of analysis—ROC is stronger than sensitivity or specificity alone because the trade-offs between these two measures are accounted for and adjustments can be made for both patient and interpreting physician characteristics. Other factors to be considered include test versus practice-based evaluations, interpreting physician training and subspecialization (e.g., breast specialist versus general radiologist), and context of the reading. Contextual factors include whether all cancer data are ascertained, and the practice environment in which interpretation is taking place. For example, it is clear that practices in the United Kingdom vary substantially from those in the United States (Smith-Bindman et al., 2003).

Finally, the effect of changes in minimal reader volume on access to mammography services must be considered along with the potential effects on reader performance. As noted in more detail in Chapter 4, results from the recent ACR Survey of Radiologists

of diagnostic radiologists suggest that raising the minimum reader volume to 1,000 every year would affect about 4,000 radiologists (25 percent of all practitioners), who accounted for approximately 6 percent of all mammograms interpreted in 2003. If the minimum limit of mammograms read were to increase to 2,000 every year, it would affect about 8,700 radiologists (54 percent of all practitioners), who accounted for approximately 23 percent of all mammograms interpreted in 2003.

In summary, a variety of approaches appear to offer benefits in improving physicians' performance in interpreting screening mammograms, but investigators have not been able to demonstrate a clear relationship between volume alone and accuracy, or experience alone and accuracy. This finding is consistent with a report published by the IOM's National Cancer Policy Board, which determined that a higher volume of care translates into improved short-term outcomes for certain complex treatments for cancer. However, the Board did not have evidence to support a broader application of volume recommendations to more common cancer treatments (IOM, 2001b).

The Committee discussed the potential impact of a modest increase in interpretive volume to 1,000 per year, and concludes that this increase alone was unlikely to change interpretive performance or to facilitate the ability of interpreting physicians to self-assess true-positive or false-negative interpretations. The requirement of 960 films/2 years was originally chosen with the intent of maximizing access, in the absence of any data to guide selection of a particular number. Given the uncertainty regarding the effect of reader volume alone, maintaining access should continue to be of primary concern because increasing the minimal reader volume could create access problems in some areas. Again, a combination of factors, most likely including helpful feedback, may be more effective in improving accuracy than volume alone.

Medicolegal Issues

There is some concern that medicolegal issues could also influence radiologists' behavior. Failure or delay in breast cancer diagnosis continues to be the leading cause of medical malpractice claims in the United States (Physician Insurers Association of America, 2002; Berlin, 2003) with the amount of indemnity payments for breast cancer-related claims increasing significantly in the past decade (Records, 1995; Physician Insurers Association of America, 2002). However, whether malpractice concerns are driving the recall rate up in the United States has not been determined definitively.

A recent cross-sectional study conducted by Elmore et al. (in press) found that 72 percent of radiologists believed their concern about malpractice claims moderately or greatly increased their recall rate (recommendations for diagnostic mammograms and ultrasounds), while no radiologists responded that malpractice concerns decreased their recall rate. More than half (59 percent) also believed their concern about medical malpractice moderately or greatly increased their recommendations for breast biopsies, while no radiologists reported a decrease in recommendations for breast biopsies due to malpractice concerns. Though recall rates of the individual radiologists ranged from 1.8 percent to 26.2 percent, no statistically significant associations were noted between recall rates and reports of prior medical malpractice claims or other malpractice variables, perhaps because concern about malpractice was so uniformly high among the radiologists. The number of radiologists in the study with mammography-related malpractice claims during the 1996 to 2001 interpretation period was small (n=18), and the legal process for these

claims often occurred over a long time period. Therefore, this study was not able to discern a direct effect of individual claims on recall rate.

DOUBLE-READING METHODS AND TECHNICAL TOOLS DESIGNED TO IMPROVE PERFORMANCE

Double Reading

One approach to improving interpretive performance is double reading. This approach may take several forms, but the two extremes include: (1) independent double reading where both readers interpret the films without knowledge of the other's assessment and the most abnormal reading is acted upon, and (2) consensus double reading where both learn the other's interpretation and resolve the differences together (arbitration). Between these two extremes are many blended forms where interpreting physicians may know each other's interpretations and discuss differences, differences are resolved by a third party, or the second reader makes the final assessment. At least half of the organized programs in continental Europe and 88 percent of programs in the United Kingdom use double reading in some form, but in the United States the rate is lower (Shapiro et al., 1988). A recent study of community-based mammography practices showed that half (51 percent) of the surveyed screening facilities perform some type of double interpretation of screening mammograms; only 11 percent of the surveyed screening facilities perform double interpretations of all screening mammograms (Hendrick et al., 2005).

Research indicates that two individual interpretations (rather than one) capture a small but not insignificant number of breast cancers (6–15 percent) missed on single interpretation (Anttinen et al., 1993; Thurfjell et al., 1994; Hendee et al., 1999). However, some studies indicate that increased sensitivity may be accompanied by decreased specificity. In a review of 10 cohort studies of double reading, Dinnes et al. concluded that double reading increases cancer detection by 3–11/10,000 women screened and recall may actually decrease, if consensus arbitration is used (Dinnes et al., 2001). The issue of arbitration is important because acting on the most abnormal interpretation increased recall from 38 to 149/10,000 women. A study of arbitration by a panel of three radiologists who each independently read mammograms in cases where the two radiologists could not come to agreement increased recalls slightly, but still missed some cancers (Duijm et al., 2004). No studies have examined the effect of double reading on the interpretations of interpreting physicians over time, or subsequent breast cancer mortality. Double reading increases the costs/cancer detected by £1,162 to £2,221 (approximately $2,185 to $4,177) (Dinnes et al., 2001). It also increases workforce needs. However, double reading is not reimbursed by third-party payers.

Computer-Aided Detection (CAD)

Computer-aided detection (CAD) is another method used to supplement a single reader's interpretation of screening mammograms. CAD can be performed on either standard film (analog) images or digitally acquired mammograms. CAD on analog images requires passing the films through a machine that creates a digital version of the images. The digital information is then analyzed by computer software that recreates the image on a monitor and flags areas of concern (e.g., clustered microcalcifications and masses)

(Warren-Burhenne et al., 2000; Brem and Schoonjans, 2001). The interpreting physician reads the original films and then looks at an annotated copy of the digitized image. CAD is more likely to mark calcified lesions compared to masses and architectural distortions (Baker et al., 2003; Taplin et al., submitted). Most studies have counted CAD as true positive even if the algorithm marked a finding only on one of the two standard mammographic views. FDA approved the first CAD software in 1998 based on work demonstrating it would mark abnormalities not identified by radiologists (Warren-Burhenne et al., 2000) and it is now being used around the country.

It is important to note that cancers account for less than 1 percent of findings marked by CAD (Freer and Ulissey, 2001). It is up to the interpreting physician to determine if the markings represent actionable findings, and thus, the interpreting physician will routinely disregard many findings. The proper study of CAD, therefore, does not test whether a given lesion is marked by CAD, but rather, whether a given interpreting physician decided to ignore or act on the CAD mark.

Unfortunately, the two published studies of CAD outside a test setting present somewhat conflicting results (reviewed by (Elmore et al., 2005). Freer and Ulissey (2001) reported an increase of approximately 20 percent in cancer detection rate using CAD versus without the use of CAD. However, the study was done using two radiologists whose characteristics and experience were not reported. Lesions that were judged to require additional evaluation (recall) only because they were marked by CAD were classified as additional detections. The radiologists could only add workups for lesions marked by CAD, and had to act on their own calls even if CAD did not mark the lesion. Although that is the recommended way to use CAD, evidence from a test setting (not actual clinical practice) suggests that radiologists may not act on their own findings if CAD does not mark the lesion (Taplin et al., submitted). In the second published study of CAD in clinical practice, Gur and colleagues (2004) found no overall difference in cancer detection rates among breast imaging specialists in academic practice (cancer detection rate of 3.49/1,000 without CAD versus 3.55/1,000 with CAD, p=0.68). However, the subset of studied radiologists who interpret a relatively low caseload did increase their cancer detection rate by approximately 20 percent (3.05/1,000 without CAD versus 3.65/1,000 with CAD; p=0.37), similar to the result report by Freer and Ulissey (Freer and Ulissey, 2001; Feig et al., 2004). More information is needed about CAD in practice—with special attention to how such factors as interpreting physician experience, lesion characteristics, practice settings, and specific CAD algorithms affect CAD performance—before it can be concluded that it will generally improve interpretation. Studies performed in a test setting should be undertaken with a standard set of cases that were not used to train the various CAD systems being tested.

CAD is reimbursed by third-party payers. Adding CAD into clinical practice is not likely to substantially increase the workload of the interpreting physician, but time and equipment are needed to scan analog films. In comparison, double reading will impact the workforce by increasing the workload for interpreting physicians to a much greater degree.

CAD and Double Reading Combined

Two studies have evaluated markings by CAD on films read as negative by two independent radiologists. Sensitivity increased by 7 percent with CAD and 10 percent

with double reading when the two approaches were compared (Karssemeijer et al., 2003). Both studies of CAD and double reading involved test sets and demonstrated that some missed lesions were marked by CAD, but the overall impact on practice was not evaluated (Destounis et al., 2004). Neither CAD nor double reading is addressed by current MQSA regulations.

THE IMPACT OF RESIDENCY/FELLOWSHIP TRAINING AND CME ON INTERPRETIVE SKILLS

The effectiveness of screening mammography greatly depends on the skills of the personnel interpreting the images. A portion of MQSA, consequently, addresses ways to ensure that physicians interpreting mammograms are adequately trained. Regulations stipulate that physicians must have received as initial training a minimum of 60 hours of documented medical education in mammography, and have interpreted at least 240 mammograms under the direct supervision of an interpreting physician. Board Certification or 3 months of training in mammography is also required (21 C.F.R. § 900.12, Quality Standards). Regulations do not require that the interpreting physician be a radiologist, but most are. There are no data to assess whether variations in interpretative performance exist due to medical specialty.

Some studies suggest that residency training in screening mammography is insufficient for adequate interpretation of mammograms when radiologists begin their first postresidency jobs. One study found that the perceptive and cognitive skills of radiology residents in interpreting a selected set of mammograms was equivalent to that of mammography technologists, and significantly lower than that of experienced, practicing radiologists (Nodine et al., 1999). Another study found that residents' sensitivity in detecting cancer in screening mammograms was less than half that of general radiologists (Newstead et al., 2003).

Although both these studies were small, they suggest that residency training alone does not adequately ensure accurate interpretation of mammograms. Presumably, continuing experience in interpreting mammograms in clinical practice improves lesion recognition and analysis skills. But improved performance could also be fostered by appropriate CME programs designed to meet gaps in knowledge or skills. Such programs are also vital for physicians to keep abreast of the rapid advances in biomedical knowledge and evidence-based medicine that suggest needed changes in how they perform or interpret mammograms.

CME is offered by a number of institutions nationwide, including academic organizations and medical device manufacturing and pharmaceutical companies. CME is a time-based system that awards credits when health professionals attend educational conferences, workshops, or lectures relevant to medical practice. A certain number of CME credits are often required to receive medical re-licensure, hospital privileges, specialty recertification, and professional society membership (Bennett et al., 2000). MQSA requires all physicians who interpret mammograms to teach or complete at least 15 CME hours in mammography every 3 years. It also stipulates that physicians must have an additional 8 hours of training in the use of any new mammographic modality (i.e., digital mammography) for which they have not previously been trained (21 C.F.R. § 900.12, Quality Standards).

Numerous studies have shown that, in general, CME programs enhance the performance of physicians. A synthesis of 99 studies found that most (70 percent) CME programs fostered positive changes in professional practice (Davis et al., 1995). Another research synthesis of three studies found CME programs improved the knowledge, skills, attitudes, and behavior of health professionals, and also improved patient health outcomes (Robertson et al., 2003).

How effective CME programs are at improving physicians' performance depends on how they are structured. Recent studies reveal that programs that offer an opportunity for attendees to interact with their educators and practice the skills learned are more effective than traditional didactic lectures. Such opportunities for interaction include case discussions, role playing, and hands-on practice sessions. One review of 10 studies of CME interactive programs (in fields other than mammography) found that attendance at 7 of these programs was linked to statistically significant improvements in professional medical practice and/or health care outcomes. In contrast, the same review examined seven studies of traditional lecture-centered CME presentations and found that only one led to statistically significant improvement in medical practice and/or health care outcomes following attendance (Thomson-O'Brien et al., 2004). Although this suggests interactive programs are more effective than didactic ones, the researchers pointed out they found only one study that directly compared a didactic presentation with an interactive workshop. This study had inconclusive results.

Another research review (again, not involving mammography) concluded that "continuing education that is ongoing, interactive, contextually relevant and based on needs assessment is more likely to improve knowledge, skills, attitudes, behavior, and patient health outcomes" (Robertson et al., 2003). The importance of physicians recognizing the need to change their behavior, knowledge base, or skills was underscored by a study that found physician performance improved when learning experiences incorporated tests of knowledge and assessments of clinical practice needs (Davis et al., 1992). Another non-mammography-related review found needs assessment positively affected physician performance in four of five studies (Davis et al., 1999).

Other non-mammography-related studies suggest additional factors may be needed to supplement CME programs. These factors include practice-enabling strategies, such as patient education materials and office facilitators, and reinforcing methods such as feedback and physician reminders to support physicians' ability to change an aspect of their practice (Davis et al., 1995). There is also some evidence for the theory that the peer group plays an important role in fostering or impeding the adoption of new information. This suggests that having all or most physicians at an institution attend the same CME program might create a "critical mass" of trainees to support new approaches (Davis et al., 1992, 1995; Robertson et al., 2003).

More specifically relevant to mammography, a comprehensive mammography audit of 12 radiologists in a group practice (performed before MQSA was enacted), revealed that following attendance at a 3- or 4-day mammography CME course, the radiologists detected a statistically significant 40 percent increase in numbers of cancers, with only a 6.5 percent increase in caseload (Linver et al., 1992). However, this 1992 study primarily involved radiologists who had never before had mammography CME. Insofar as all practicing interpreting physicians have been required by MQSA regulations to obtain substantial amounts of CME since 1994, these results do not address the ability of

mammography CME to provide incremental improvements in performance for interpreting physicians who have already had considerable CME experience.

The only available study involving relatively current CME experience shows a more modest improvement in radiologist performance. This study involved only 23 practicing general radiologists who attended a one-day CME lecture course on using the BI-RADS interpretation system (Berg et al., 2002). When given a selected set of mammograms before and after taking the course, the radiologists showed modest improvements in their analysis of lesion features, final assessment of cases, and recommendations to biopsy those lesions that proved to be malignant.

Thus, although the data on the effect of CME in general suggest effectiveness in improving performance, there is a paucity of data suggesting clinically relevant effectiveness of mammography CME in the current U.S. environment, in which MQSA regulations already require a large amount of CME.

In summary, the existing literature is insufficient to demonstrate either the effectiveness or lack of effectiveness of specific approaches to resident/fellowship training or specific CME course content in improving mammography interpretive skills. Thus, the Committee recommends that before establishing an MQSA-mandated requirement for CME specifically dedicated to mammography interpretive skills, there is need to demonstrate the value of this approach. Funding should be provided for comprehensive research studies on the impact of various existing and innovative teaching interventions on mammography interpretive skills.

THE INFLUENCE OF SKILLS ASSESSMENT AND FEEDBACK ON PERFORMANCE

Overview

Theoretically, assessment via medical audits is designed to link practice patterns to patient outcomes in a way that can influence provider behavior and performance. No studies have been done to determine whether mammography outcomes monitoring alone is effective, but in other areas of medicine, there are conflicting reports in the literature about the effectiveness of audits (Weiss and Wagner, 2000). However, a review of studies on the audit and feedback approach found it can be effective in improving professional practice, particularly when baseline adherence to recommended practice is low (Jamtvedt et al., 2003). Another systematic review found audit with feedback was more consistently effective when feedback was delivered in the form of chart review (Davis et al., 1995). A benchmarking approach, in which physicians can compare their personal performance with that of top performers in a peer group or assess if their practice conforms to accepted practice guidelines, also improved the effectiveness of physician performance in ambulatory care (Kiefe et al., 2001).

The majority of research using medical audits for physician self-assessment has been done in primary care to understand resource use and management of medical conditions (Cave, 1995; Roblin, 1996; Spoeri and Ullman, 1997; Greenfield et al., 2002). Ross et al. (2000) found that physician audits for specific diagnosis-related groups resulted in significant reductions in hospital lengths of stay. The Ambulatory Care Medical Audit Demonstration Project (Palmer and Hargraves, 1996), the largest formal study of the use

of audit information, was a randomized controlled trial to test the impact of peer-comparison audits along with other intervention strategies (including assistance with processing audit reports). Audits had a significant impact on the quality of care in monitoring hematocrit in anemic patients; performance of annual Pap test and clinical breast examination; follow-up of serum glucose in diabetics; and monitoring of patients on digoxin (Palmer and Hargraves, 1996). Medical audits and clinical prompts seem to be most effective when introduced at the point of patient care (Palmer and Hargraves, 1996). Weiner and colleagues (1995), using Medicare claims data to profile the care provided to diabetics, showed that even with adjustment for case mix of patients and characteristics of physicians, as many as 84 percent of patients were not receiving recommended care, such as hemoglobin A1c monitoring.

Adjustment for case mix of patients and characteristics of physicians is very important when profiling physician performance (Greenfield et al., 2002). For mammography, performance data on individual interpreting physicians may be misleading without adequate consideration of patient and physician characteristics (Elmore et al., 2002). Such adjustments reduce the noted variability in radiologist performance in mammography by approximately one-half (Elmore et al., 2002), as illustrated in Figure 2-3.

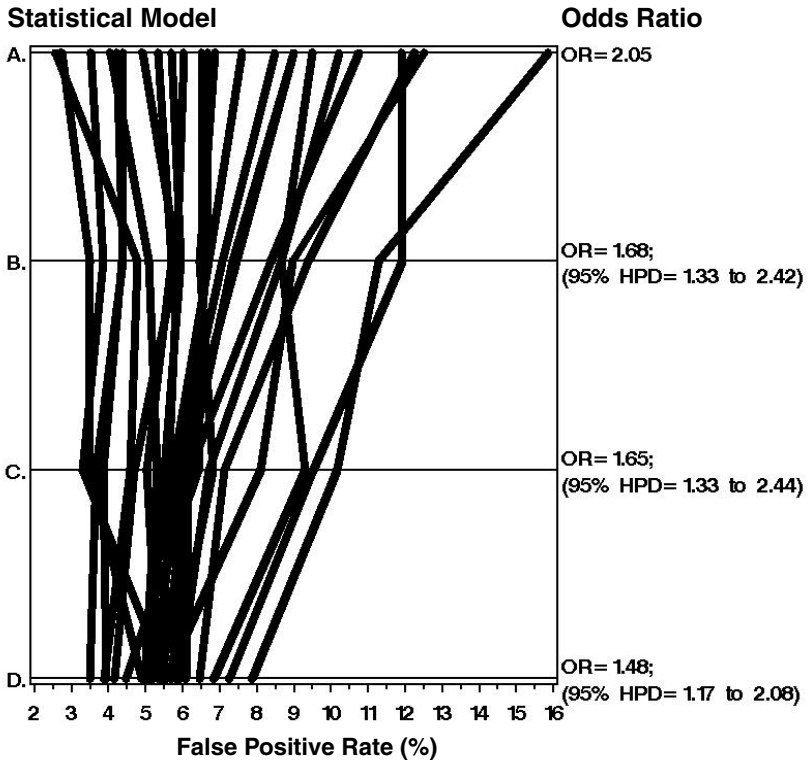

FIGURE 2-3 Results of statistical modeling for unadjusted (Line A) and adjusted (Line B for patient characteristics, C for radiologist characteristics, and D for both patient and radiologist characteristics) false-positive rates for 24 radiologists in a community setting. The variability in false-positive rates decreases with such adjustments.
SOURCE: Reprinted from Elmore et al. (2002) by permission of Oxford University Press and the *Journal of the National Cancer Institute*.

Therefore, physician profiling to assess performance can lead to incorrect and possibly dangerous conclusions without paying careful attention to adjustments for differences in patient characteristics (e.g., age and breast density). Because of the importance for adjustment in patient characteristics, and the small number of cancer cases seen by physicians each year, there is a need to develop appropriate statistical models and interfaces for use by clinicians in practice.

Landon et al. (2003) discuss numerous obstacles to the implementation of performance assessment programs, and propose standards for enhanced evaluation. They suggest ideal performance measures be established and standardized, evidence based, feasible to collect, representative of the activities of the specialty, adjusted for confounding patient factors, and applicable to an adequate sample size of patients to facilitate valid analysis. Unfortunately, evidence-based measures do not exist for each specialty, and it may not be possible to use a similar assessment program for each field. In addition, the widespread data collection necessary for adequate programs is costly, and current infrastructure is not capable of supporting it (Landon et al., 2003).

Examples of Mammography Audit and Quality Improvement Programs

Several other countries have rigorous quality assessment and improvement programs as part of their national breast cancer screening programs. These all involve centralized large-scale screening programs, so the effectiveness of such approaches has not been tested in the community practice setting in which most mammography is provided in the United States. Nonetheless, a review of these programs might prove instructive.

The United Kingdom's National Health Service Breast Screening Program (NHSBSP) sets highly specific national quality assurance standards for mammogram interpretation, and regularly monitors adherence to its standards by a quality assurance network. This network includes regional professional quality assurance coordinators who meet regularly with radiologists in their region to review performance and outcomes of mammography screening, to share good practice, and to encourage continued improvements (IOM, 2005). Radiologists are required to rotate through screening and diagnostic clinics and participate in all activities of the breast care team, including multidisciplinary meetings (National Radiographers Quality Assurance Coordinating Group, 2000).

A supportive environment has been essential for the successful quality improvement of this program (Perry, 2003). Peer review and self-audit foster an environment of learning, rather than blaming, which is thought to be a key strength of the NHSBSP (Perry, 2004a). Annual audit results for the program are public domain and are disclosed to patients; individual performance results are provided only to the radiologist (Applied Vision Research Institute, 2004). In the unusual event that an individual or unit fails to meet these standards, a series of remedial actions are undertaken (Perry, 2003). Interpreting physicians, who undergo specific training in order to participate in the NHSBSP, are reported to be satisfied with these monitoring and review processes.

Australia's national mammography screening program is also known for its uniform interpretation standards and rigorous monitoring to ensure its physicians comply with those standards. Participating radiologists are required to read 2,000 screening mammograms a year, and their performance is measured against a set of standards for

cancer detection, early-stage cancer detection, and recall rates. Each mammography facility is required to inform radiologists annually of their performance compared to the minimum set standards, as well as compared to their peers. Mammogram readers are also given at least quarterly feedback on cancers that they did not recall (Kossoff et al., 2003).

If the detection rate for a radiologist falls below the 95 percent confidence interval of the benchmark rate, each Australian mammography facility has a designated radiologist who must implement a strategy to improve that individual's performance. This strategy targets the specific weaknesses revealed by a detailed evaluation of the radiologist's performance, and may require the radiologist to attend additional training courses, assessment clinics, or have his or her interpretations regularly reviewed by a more experienced reader. Alternatively, a change in work practices may be instituted, such as switching to more optimal work times, or limiting the number of films read per session. Underperforming radiologists are required to adhere to the plan for improvement, and their performance is monitored closely for 2 years after starting the plan (Kossoff et al., 2003).

The Netherlands' national breast cancer screening program also relies on a national system for quality control and monitoring. This system collects data on true-positive rate, false-positive rate, positive predictive value, and cancer detection rate, and evaluates the data in aggregated form for every central screening facility that interprets mammograms. In addition, a small contingent of experts from the National Training and Expert Center for Breast Cancer Screening conducts onsite audits of every interpretation facility once every 2 to 3 years. These audits involve reviewing interval and screen-detected cancer cases to realistically assess the false-negative rates of the facility. A report prepared after the audit includes suggestions for possible improvements. When necessary, a screening facility is prompted to make improvements. Gradual improvements in screening parameters were noted in second audits of facilities compared to first audits, including higher detection rates and lower false-negative rates (van der Horst et al., 2003). Mammography screening programs in Sweden and in several Canadian provinces also have high performance standards (IOM, 2005).

In some circumstances, such quality improvement programs can be implemented in the United States as well. For example, the interpretation of mammograms improved following the institution of an extensive quality improvement program at Kaiser Permanente (KP) Colorado. Begun in 1998, this program created a centralized facility for reading mammograms, in which radiologists had access to specialized training, were required to participate in self-assessments three times a year, and had to read a high volume of mammograms (Adcock, 2004). The performance of individual radiologists was continually monitored with a number of measures, including proportion of early-stage cancers detected, sensitivity, recall rate for screening mammograms, positive predictive value, and diagnosis of new, probably benign lesions. These measures were derived from the KP Colorado Tumor Registry, from reports of mammogram results, and from Radiology Information System extracts. The measures were compared to published benchmarks, and radiologists received feedback on their results. Performance gaps were analyzed and targeted with specific interventions, such as securing second opinions from another radiologist until performance improved (Adcock, 2004). Within a few years after instituting this quality assurance program, there was a statistically significant increase in the sensitivity for cancer detection and in the proportion of early-stage cancers detected, without an in-

crease in the number of recalls. Improvements in efficiency have also produced substantial cost savings; for example, by 2004, the professional component of the cost per mammogram interpreted by the group had declined to $28 (77 percent of the Medicare benchmark). In a recent survey of radiologist satisfaction (which did not distinguish between mammography subspecialists and other radiologists), 15 of 16 anonymous respondents agreed that if they had the opportunity to revisit their choice to join the group, they would do so again.

CHALLENGES TO USING MEDICAL AUDIT DATA TO IMPROVE INTERPRETIVE PERFORMANCE IN THE UNITED STATES

A Lack of Data and Information to Guide Audit and Feedback

U.S. radiologists appear not to be aware of their own interpretive performance levels, but they need to know and understand what their current levels of accuracy are and understand what this means before they can determine whether and how to improve. Both patients and clinicians are often confronted with a baffling array of percentages and probabilities related to mammography. Research indicates that some individuals, including practicing clinicians and highly educated participants, experience difficulty in understanding rates, risks, and proportions (Gigerenzer, 2002). This is illustrated in Figure 2-4, which shows that more than 90 percent of radiologists overestimated a woman's 5-year risk of breast cancer based on a patient vignette. The use of frequencies (rather than probabilities), visual aids, and individualizing the data may improve clarity and understanding about mammography performance.

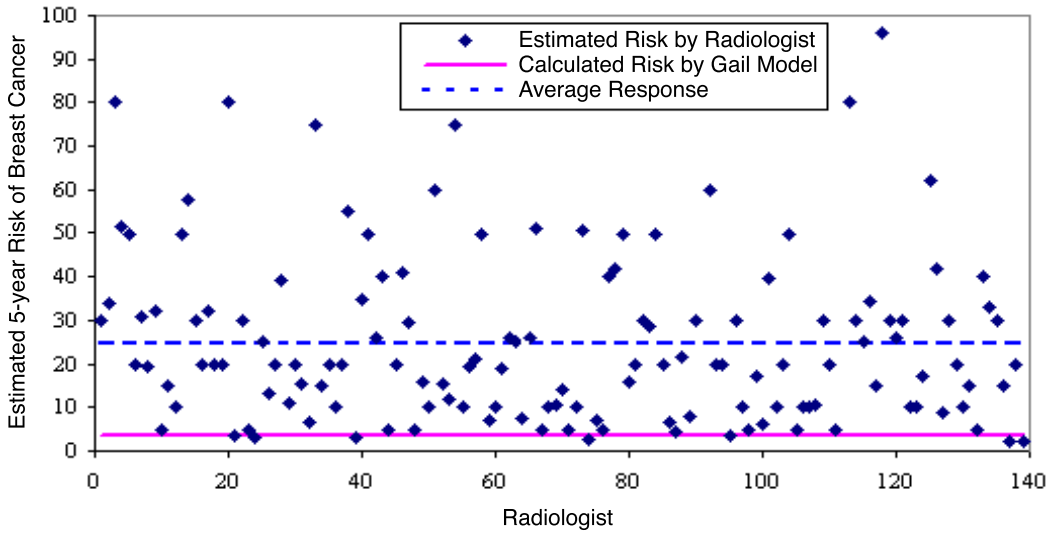

FIGURE 2-4 Radiologists' perceived 5-year risk of breast cancer for a vignette of a 41-year-old woman whose mother had breast cancer, who had one prior breast biopsy with atypical hyperplasia, and who was age 40 at first live birth.
SOURCE: Reprinted with permission from Egger et al. (in press).

However, as noted previously, the estimates of accuracy at the level of individual interpreting physicians are subject to variation and may not adequately describe interpretive performance for individual physicians. For example, sensitivity calculations may not be reliable for physicians interpreting only 960 films every 2 years, because in a given year, they may see few or even no films of women with breast cancer. This problem could potentially be overcome by using well-characterized test sets for self-assessment, although data from "test" situations may be unreliable (Rutter and Taplin, 2000) because the conditions under which such testing takes place may be quite different from those used in conventional practice. For example, a nationwide test would likely need to be implemented using digital images because of the difficulty and expense of circulating films, but the majority of mammograms in the United States are done on film, so the viewing conditions for the test may be inconsistent and different from common practice. Also, test sets are heavily weighted with cancers compared to the usual screening population, leading to higher than normal recall rates.

A few self-assessment programs already exist for mammography, but are not widely used in the United States (Box 2-1). The ACR has several self-assessment programs called Mammography Interpretive Skills Assessment (MISA) (Sickles, 2003). There is no requirement for interpreting physicians to use this assessment program, and most do not. This is in stark contrast to the 90 percent of British interpreting physicians who use a similar mammography self-assessment program called PERFORMS. The Screening Mammography Program of British Columbia uses an interpretive skills test as an acceptance test for screener candidates (Warren-Burhenne, 2003).

The Committee does not recommend mandatory proficiency testing via self-assessment exams for all interpreting physicians at present because the available testing procedures have not been rigorously evaluated and proven to have a direct positive impact on interpretive performance in clinical practice. The ACR's MISA exam has been evolving over the past 12 years and was not designed to be sufficiently rigorous to permit valid assumptions or inferences regarding actual performance of an individual examinee in clinical practice (Sickles, 2003). Certain steps in test validation that would be required for legal defensibility if licensing were intended as the primary purpose of the examination have not been undertaken (Sickles, 2003). Furthermore, the MISA test sets, which currently include less than 30 cases, most of which contain cancers, would need to be greatly expanded and frequently refreshed if they were to be widely used for proficiency testing. Although these are not insurmountable obstacles, the time and costs associated with further development and validation would be substantial. Thus, the Committee recommends pilot projects be undertaken within breast imaging Centers of Excellence (described in the section entitled "Breast Imaging Centers of Excellence") to test the value and feasibility of proficiency testing.

BOX 2-1 Mammography Self-Assessment Programs

The American College of Radiology (ACR), the United Kingdom's National Health Service Breast Screening Programme (NHSBSP), and the Screening Mammography Program of British Columbia (SMP-BC) have developed self-assessment programs for the interpretation of mammograms. The ACR's Mammography Interpretive Skills Assessment (MISA) offers two CD-ROMs that show the mammograms of 28 and 29 cases, respectively. The radiographic images can be magnified and panned on the computer screen, and the location of abnormal findings on each displayed image can be identified with a mouse click. The images are accompanied by multiple-choice questions that test important aspects of breast imaging practice. The programs also provide instant feedback and text explanations for correct and incorrect responses.

The Personal Performance in Mammographic Screening (PERFORMS) program put out by the NHSBSP is more comprehensive. Each year this program offers 2 film sets, each with 60 two-view cases. The feedback given to radiologists who evaluate the films is extensive; the radiologists are not only informed of how many malignant cases they missed, but whether those missed cases showed any patterns, such as the presence of dense tissue or multiple microcalcifications. The program also provides details concerning the cases a radiologist incorrectly recalled for further assessment (false positives).

In addition, particular film sets also allow the individual to see a large number of examples of one particular abnormality, and have been shown to improve radiologists' detection of these specific features. Additional advanced training sets enable radiologists to concentrate on the types of cases they are most likely to misinterpret. The participating radiologists are also informed of how they performed in comparison with their anonymous colleagues. An individual's results are anonymous and are made available only to the radiologist who takes the test.

The SMP-BC test set includes about 100 cases, of which one-third to one-half contain malignant or premalignant lesions of varying conspicuousness. The sensitivity and specificity of each reader is calculated in a case-based and breast-based manner, and acceptance as a screener depends on performance. A minimum threshold is set for both sensitivity and specificity, and all obvious cancers must be identified. For active screeners who do not meet the minimal criteria, additional training is provided and double reading with an approved radiologist is required until the test is retaken and passed.

SOURCES: National Health Service (2003); Gale (2003); Wooding (2003); Sickles (2003).

Lack of a Centralized Source of Information for Outcomes Data

The vastly decentralized system of health care in the United States is a large reason for the great variability in the methods of collecting and using mammography data that are described in the previous sections. As noted above, mammography programs in Canada, the United Kingdom, and other European countries have the benefit of national or regional surveillance data systems in which a centralized data repository is used to capture accurate data and feed it back to radiologists and facilities. These systems allow for the calculation of medical outcome audit measures by a centralized entity, thereby limiting the variability in data definitions and calculation methods that complicate efforts

in the United States. Such surveillance systems also provide more complete case ascertainment for calculation of measures such as sensitivity. In the United States, sensitivity and specificity data cannot be collected unless periodic linkage to data in a regional tumor registry can occur, precluding use by the vast majority of mammography facilities.

There are a few large surveillance systems in the United States that demonstrate the feasibility of medical outcomes monitoring. The National Breast and Cervical Cancer Early Detection Program (NBCCEDP), sponsored by the Centers for Disease Control and Prevention, maintains a large data system for tracking breast and cervical cancer screening provided for uninsured women across the country (Henson et al., 1996). Although this has been used to conduct quality assurance activities in New York state, not all mammography facilities participate in the NBCCEDP, and the underserved population screened through the program has important demographic differences and prior screening history that may limit its generalizability (Hutton et al., 2004).

The NCI-sponsored Breast Cancer Surveillance Consortium (BCSC) has successfully linked screening mammogram data with population-based cancer registries in seven regional areas of the United States: North Carolina, Colorado, Seattle (Group Health Cooperative), New Hampshire, New Mexico, San Francisco, and Vermont. Established in 1994 to study breast cancer screening in the United States, the consortium's database contains information on millions of screening mammograms. Each mammography registry sends its data electronically to a centralized Statistical Coordinating Center for pooled analyses, and is linked to cancer registries to enable the determination of predictive value, sensitivity, and specificity of mammography, as well as practice patterns (Ballard-Barbash et al., 1997). Although the BCSC could provide benchmark data useful for an audit of a mammography facility (Ballard-Barbash et al., 1997), its mechanisms for encrypting data preclude the ability to identify individual performance of interpreting physicians or facilities, and its focus on the facilities precludes its use as a national repository in its current format. Although the individual registries that contribute data to the BCSC do collect radiologist-specific and facility-specific data that could be used for quality improvement, the BCSC was not intended to be used for quality assurance purposes and facilities may be less likely to participate in the BCSC if data are used for purposes other than research. Each registry undertakes audits for participating facilities. Several medicolegal protections have been employed to prevent forced disclosure or uses of BCSC site data for medicolegal purposes, as outlined by Carney et al. (2000).

In contrast to the BCSC, which is primarily research oriented, the National Consortium of Breast Centers, Inc. is planning to collect data for the specific purpose of quality improvement (National Consortium of Breast Centers, Inc., 2004). The group is developing a set of core measures to define, improve, and sustain quality standards in comprehensive breast programs and centers. Participation is voluntary, and centers can contribute data using a unique identifier code to a large database on a dedicated server. The initial goal is to identify benchmarks for services and procedures within breast centers through standardized data input and statistical review and analysis. To start with, the project will only inform a participating center how it compares to the benchmark. Each center will then self-evaluate and develop improvement plans.[3]

[3] Personal communication, D. Wiggins, National Consortium of Breast Centers, Inc., January 17, 2005.

Examples from other areas of medicine in the United States also could be informative. Regular quality assessments and appropriate feedback following audits is thought to underlie the improvements seen in the outcomes of surgeries conducted at Veterans Administration (VA) hospitals. Since 1994, the VA has operated a National Surgical Quality Improvement Program (NSQIP) in which all medical centers performing major surgery participate. Data on postoperative mortality and morbidity are collected at each of these facilities and analyzed at two centers. The expected outcomes are determined based on the risk factors of the population treated, and the hospital is rated according to how closely it matches those expected outcomes. These outcomes are reported to the facilities each year. Hospitals with lower than expected outcomes are provided with self-assessment tools and site visits to help them identify and address deficiencies in the quality of care they deliver. In addition, the NSQIP disseminates, through its annual reports distributed to participating hospitals, the good practices thought to underlie the greater than expected outcomes of some of its facilities. Since the NSQIP began, the 30-day postoperative mortality after major surgery in the VA has decreased by 27 percent and the 30-day morbidity by 45 percent (Khuri et al., 2002). However, the extent to which mammography facilities can adopt strategies used in surgical studies is unclear because the disciplines are so vastly different.

Part of the feasibility and success of the NSQIP is due to its centralized authority and advanced medical informatics infrastructure, which enabled it to develop national averages and risk adjustment models, and set up a model system for the comparative assessment of quality surgical care among its hospitals (Khuri et al., 2002). But a pilot study that used the same methods followed by NSQIP to provide quality improvement to the surgeries performed by three academic hospitals found it to be a feasible and valid system that is applicable to non-VA medical centers (Waynant et al., 1999; Khuri et al., 2002).

Although the above examples demonstrate the feasibility of collecting and analyzing large amounts of medical data from several disparate areas of the country, and maintaining patient, provider, and facility confidentiality while collecting and using electronic records, the advent of electronic records that enable the sharing of large datasets has been accompanied by increasing concern about protections for confidential medical information (Carney et al., 2000). Inappropriate access of such information could enable it to be exploited for marketing or insurance purposes, or could damage the reputation of patients, providers, or facilities and lead to malpractice lawsuits and loss of income (Carney et al., 2000). Thus, protecting audit data from discoverability is important to ensure accurate reporting and widespread participation in a self-assessment program designed to improve quality.

To maintain confidentiality of the medical information it uses, the NSQIP relies on a federal statute governing veterans' benefits (Title 38) that contains provisions specifying the protection of confidential medical information used in quality management activities of the VA (Veterans Health Administration, 2004). There are a number of other federal and state statutes designed to protect the confidentiality of medical information used in quality assessments. The scope of protection offered by state statutes relevant to quality assessments varies widely and depends on how the information is handled and by whom. Furthermore, these statutes cannot be relied on to protect confidentiality when

data are collected from more than one state and transferred across state lines (Carney et al., 2000).

The best protection of research data is offered by Federal Certificates of Confidentiality, which are granted to federally funded research projects or institutions, or for research of a sensitive nature, such as research on sexuality or the use of recreational drugs. The privacy protection afforded by these certificates extends not just to patients, but also to health care providers (Carney et al., 2000). The recently adopted federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule offers extensive safeguards to ensure the confidentiality of medical information. But it exempts from its stringent requirements the disclosure of protected health information that is used for "conducting quality assurance and quality improvement, including outcomes evaluation and development of clinical guidelines," provided that the work is mainly intended to improve the operations of a specific organization rather than for research (FDA, 2004; Gunn et al., 2004). Thus, such an undertaking for quality improvement in mammography should be feasible.

Regardless of the statutory requirements already governing patient confidentiality, a national database for collecting and analyzing data to improve mammogram interpretation must use a number of safeguards to ensure confidentiality of the medical information it collects. These safeguards include preventing inappropriate access to electronic data with passwords, firewalls, and data encrypting techniques, as well as paper shredding and other proper disposal of sensitive printed information that is no longer needed (Carney et al., 2000).

Facility-Based Challenges

Several facility characteristics have an important impact on statistical measures of performance. Although there are accepted ranges for many mammography performance measures, the lack of a current system to control for variation of facility characteristics greatly limits the utility of performance measures and confounds facilities' ability to compare their performance to accepted benchmarks. The following is a summary of several relevant facility characteristics that affect performance measures.

Practice Type and Setting

Based on the ACR's 2003 Survey of Practices, 18 percent of radiologists in academic practice reported interpreting mammograms, but 73 percent of radiologists in multispecialty or private radiology facilities interpret mammograms. Furthermore, 55 percent of radiologists who reported that their practice setting was a hospital interpreted mammograms as compared with 68 percent of radiologists who reported working only in a nonhospital setting.

Hospital-based and medical center programs typically have affiliated departments of surgery, pathology, and oncology within the institution that can perform all necessary diagnostic testing and treatment. Patients who receive mammograms at facilities that are affiliated with a hospital are often diagnosed and treated within the same institution. As a result, efforts to track positive mammograms may require less time and be more complete in hospital-based mammography facilities than in those that are not hospital based. Hospital-based and medical center practices may use computerized radiology information

systems, simplifying access to data for audit analyses. Hospital-based mammography and/or academic practices are more likely to interpret mammograms for patients who are at greater risk for developing breast cancer than other practices in the community.

Mode of Interpretation

Another important factor that can influence the performance characteristics of mammography is a facility's mode of film interpretation. There are two commonly used interpretation modes for screening mammography, online (interpretation while the woman is still at the facility) and batch (screening mammograms are grouped by facility personnel for later interpretation by an interpreting physician during a focused, uninterrupted period of time).

Batch mode interpretation of screening mammograms allows interpreting physicians to focus their attention and allows interpretation of screening films in a quieter environment with fewer distractions and less ambient light, factors that are important for the conspicuity of subtle lesions. Batch interpretation is also a more cost-efficient method of practice for radiology facilities (Feig et al., 2000). Online reading offers women same-day resolution of their mammogram because additional diagnostic imaging or tissue sampling can be performed immediately after the initial interpretation, but it is more costly for mammography facilities and also involves inefficient use of interpreting physician time (Raza et al., 2001). Online interpretation also disrupts the workflow of interpreting physicians and can even result in misinterpretations (Raza et al., 2001). The current levels of reimbursement for mammography and perceptions of a shortage of radiologists who interpret mammograms likely account for the more widespread use of batch than online interpretation of screening mammograms (Raza et al., 2001). In 2002, 84 percent of community-based mammography facilities were batch interpreting screening mammograms (Hendrick et al., 2005). Those facilities that choose to perform screening mammography in an online mode often base their decision on the potential marketing advantage over other competitors by providing same-day results to patients.

However, for patients to receive results on the same day may be an unrealistic expectation for screening mammography, especially given that there is wide acceptance by patients for a wait of a week or more for laboratory test results, including Pap cytology. Hulka et al. (1997) have shown that women may be more accepting of delayed interpretations if the mammograms yield higher sensitivity, and Raza et al. (2001) have shown that although two-thirds of women would prefer online interpretation accompanied by a 30- to 60-minute wait for results, only about 10 percent would be willing to pay for the extra cost of the service.

A facility's mode of interpretation can affect its performance as measured by clinical outcomes, thereby limiting interfacility comparison of measures such as specificity (Raza et al., 2001). Interpreting physicians are more apt to request additional diagnostic imaging when a patient is waiting in a nearby exam room than if she needs to be recalled at a later date (Raza et al., 2001; Ghate et al., 2005). Thus, same-day interpretations may perhaps result in higher recall rates (additional diagnostic breast imaging) and potentially lower specificity than interpretations performed in batch mode. Note that if a screening mammogram is interpreted as abnormal and additional diagnostic imaging evaluation is performed on the same day, it can be converted to a diagnostic mammogram using a billing code modifier. However, for auditing purposes, such a case

should be considered to be an abnormal screening examination (BI-RADS 0), and the subsequent diagnostic examination should be audited separately.

Mobile Mammography

Mobile mammography is thought to address many of the barriers that prevent women, especially underserved women, from obtaining regular exams (Sickles et al., 1986). However, the overhead costs are significant (Wolk, 1992).

Mobile mammography programs use one of two types of vehicles, a recreational vehicle/coach that has been customized to fit a mammography unit, processor, and exam rooms (mobile van), or a standard passenger van that has been customized to allow for the transportation of a mammography unit to various indoor locations (portable unit). The most recent national survey of mobile mammography facilities in 1995 found that 37 percent operated portable units and 63 percent operated mobile vans (Brown and Fintor, 1995).

Most mobile mammography programs process all of the day's films as a batch at the end of the day at a fixed location (De Bruhl et al., 1996). This saves money by eliminating the need to purchase a separate, dedicated processor for the mobile unit and allows for nearly twice as many women to be screened because the radiologic technologist does not need to process each set of films between patients (Sickles et al., 1986). Batch processing allows for a more controlled environment for processing, but causes inconvenience for women whose films need to be retaken. Because the films are not processed until the van has returned to its sponsoring facility, women whose films display movement, inadequate compression, or other problems must be recalled to the facility to have images retaken (Monsees and Destouet, 1992). It can be especially challenging to obtain retakes and additional diagnostic workup for women who have geographical or cultural barriers that prevented them from coming to the facility for screening in the first place (Pisano et al., 1995).

Images that would otherwise result in a retake at a fixed-site screening facility are sometimes deemed abnormal in a mobile setting in order to increase patient adherence with a recommendation for additional imaging, resulting in a greater percentage of abnormal mammograms that turn out to be false positive (Sickles, 1995b). Film quality problems can, therefore, manifest themselves as either high retake rates or high recall rates.

Current Radiology Information Systems Used by Mammography Facilities

Following implementation of MQSA regulations, several computerized mammography management systems were developed to assist mammography facilities in collecting, organizing, and linking mammography information to assist with reporting requirements. These include but are not limited to:

- Insight Radiology Information System
- PenRad
- Amber Diagnostics Radiology Management Systems
- iCAD Radiology Information Management
- OmniCare Mammography Management Systems

- CPU Medical Management Systems
- VitalWorks Radiology Information Systems
- IDX-Rad
- MRS

Examples of the services these systems provide include: patient registration and scheduling; dictation and transcription; multisite support, data access, management reporting (e.g., physician and patient letters), and mammography tracking; image routing and archive management; and staff competency tracking. The mammography tracking functions often collect and summarize data elements for the required audit. Though no studies have examined how these systems calculate performance data, anecdotal reports have indicated that significant variations and errors in calculation methods do occur[4,5] and limit the ability to pool data generated from these systems using the data tables they generate. This could be corrected if market forces drove these businesses to reprogram their databases to collect the same data using the same definitions and calculate biopsy yield and other accuracy indices using exactly the same methods. If this occurred, it would be possible for such computerized facilities to pool data centrally. However, some mammography facilities still do not have computerized information systems, making it very difficult to collect, tabulate, and update audit data.

LIMITATIONS OF CURRENT MQSA AUDIT REQUIREMENTS

MQSA regulations require that facilities establish and maintain a mammography medical outcomes audit program (21 C.F.R. § 900.12(f)). The results of the audit are not collected by FDA. To meet the regulatory requirements for the medical outcomes audit program, facilities need only demonstrate during their annual inspection that:

1. All positive mammograms (BI-RADS 4 or 5 assessments) are entered into the system.
2. Biopsy results are present (or the facility attempts to get them).
3. There is a designated reviewing interpreting physician.
4. An analysis is done annually, done separately for each individual, and done for the facility as a whole.

When issuing the 1997 MQSA final regulations, FDA noted that the medical audit process was in its infancy and stated that "in the absence of any consensus standards for either mammography outcomes or data collection methods, FDA has chosen to defer proposing these parameters and methods until more research has been completed and clear guidelines can be formulated for mammography centers." FDA further noted that "results and outcomes of the [Breast Cancer Surveillance] Consortium will help establish performance standards for mammography and FDA will evaluate these for appropriateness for future standards under MQSA" (FDA, 1997).

[4] Personal communication, E. Sickles, M.D., Chief of Breast Imaging, University of California, San Francisco, School of Medicine, October 15, 2004.

[5] Personal communication, B. Yankaskas, Ph.D., Department of Radiology, University of North Carolina, Chapel Hill, October 15, 2004.

Unfortunately, although the expressed purpose of the medical outcomes audit program in MQSA Final Regulations was "to ensure the reliability, clarity, and accuracy of the interpretation of mammograms" (21 C.F.R. § 900.12 (f)), in its current form it does little more than burden facilities with processes that generate data that are inadequate for ensuring or improving interpretive performance.

First, facilities are allowed to develop systems for tracking positives that work best for them. Tracking systems can be maintained on computer or in paper form. MQSA requires that facilities attempt to collect cancer versus no-cancer outcomes for women referred for consideration of biopsy (Category 4 or 5), but no actual measurement of performance is required by FDA. Furthermore, although facilities may also choose to track women for whom additional imaging is recommended (defined in BI-RADS as Category 0; Incomplete—needs additional imaging), few track this latter assessment category, even though most screened women who are referred for biopsy start out with a recommendation for additional imaging. As many as 1 to 8 percent of mammography assessments are Category 0 (Poplack et al., 2000; Taplin et al., 2002; Geller et al., 2002; Colorado Mammography Project, 2003; Kerlikowske et al., 2003). While encouraged to have ongoing tracking systems in place, facilities are not required to follow up on positives more than once per year. FDA inspectors check to see that reasonable efforts have been made to obtain the pathology results of positive mammograms, but most facilities perform passive surveillance by contacting referral facilities episodically.

Second, no specific statistics are required to be calculated and reviewed as part of the annual medical outcomes audit. In practice, most facilities calculate only one type of PPV, and the method of calculation of this measure varies widely. Facilities are not required to stratify their analyses by screening and diagnostic mammograms and there is variation among facilities with respect to which mammograms are included in calculations. In addition, analyses must be facility specific, even though combining data for individual interpreting physicians who interpret for different facilities is more useful for assessing interpretive skill and less burdensome. Most important, the regulations require only that biopsy outcomes be reviewed. Although interpreting physicians and the facility are to be informed of the results of the audit, there is no further requirement for use of this data, such as for skills improvement. Facilities are not required to explore reasons for variability among interpreting physicians or undertake efforts to improve the quality of their performance. As a result, only facilities that are self-motivated to improve the quality of their mammograms undertake this feedback component, which appears to be the most important element for quality improvement.

Third, while a review of interval cancers has been useful for providing feedback to radiologists in other health care systems such as the United Kingdom (Perry, 2003) and British Columbia (Warren-Burhenne, 2003), MQSA-required review of false-negative cases of breast cancer that become known to a facility has little impact on performance. Facilities are not required to conduct active surveillance for false negatives and the fragmented nature of health care in the United States increases the likelihood that future mammograms and breast health care will occur in facilities other than the one that provided the initial mammogram. The potential medicolegal implications of finding cancers that were potentially misinterpreted serve as a strong deterrent to active efforts to identify false negatives for the purposes of quality assurance. Also, there are few centralized surveillance systems that link mammograms with subsequent diagnoses, thus allowing for

more complete case ascertainment of false negatives; existing cancer registries are not a practical resource for this purpose.

STRATEGIES TO IMPROVE MEDICAL AUDIT OF MAMMOGRAPHY

The Committee concludes that current medical audit requirements under MQSA are inadequate for measuring or improving the quality of image interpretation. Thus, the Committee recommends that the basic MQSA-required medical audit of mammography interpretation be enhanced and standardized to require the calculation, for internal use within a given mammography facility, of the following core measures: PPV_2, cancer detection rate per 1,000 women, and abnormal interpretation rate (women whose mammogram interpretation led to additional imaging or biopsy). These three measures should be stratified by screening and diagnostic mammography. Readers working at multiple facilities should be able to combine their data from each facility to calculate one set of measures for their overall performance. In addition, the group of women with positive mammograms that facilities are required to track should include not only those with BI-RADS 4 or 5 assessments, but also all screened women for whom additional imaging is recommended (defined in BI-RADS as Category 0—needs additional imaging) until a final assessment is rendered, so that if biopsy is recommended (i.e., final assessment of BI-RADS 4 or 5), the appropriate examinations will be included in the calculations of PPV_2 and cancer detection rate. Implementing these enhanced and standardized audit procedures will provide facilities with consistent and meaningful measures of performance and will thus make it more feasible for audit interpreting physicians to develop performance improvement plans as needed. Facilities should receive additional reimbursement for undertaking these new audit activities (see section titled The Need for a Supportive Environment to Promote Quality Improvement).

To encourage physicians and facilities to achieve an even higher level of performance, the Committee also recommends a voluntary advanced-level audit that would involve obtaining breast pathology reports for tumor size, grade, and lymph node status, and collecting data on patient characteristics, in addition to all tracking, measurements, and assessments in the basic required audit. In order to achieve substantive improvements in the quality of mammography interpretations, broader changes are needed that will help facilities to conduct more meaningful analyses and to use the results to improve performance and quality assurance. However, to create a system that could accurately perform an advanced medical audit with feedback is well beyond the staffing and expertise of mammography facilities. Thus, an inherent component of this advanced audit program is the creation of a centralized data and statistical coordinating center, where standardized pooled data are electronically compiled, analyzed, and reported back to participating facilities to provide the type of meaningful feedback that is given in organized screening programs in some other countries.

Statistical coordinating center staff should be qualified to collect and maintain data from disparate sources, standardize data collection procedures, conduct accurate advanced-level audits, provide feedback, and help develop, implement, and evaluate self-improvement plans for interpreting physicians or facilities that do not achieve performance benchmarks. The statistical coordinating center should also test different methods of delivery of audit results and other uses of “feedback” to improve interpretive

performance. The center could increase the impact of the basic required audits as well, by developing benchmarks that facilities and individual interpreting physicians could use to compare their performance to national performance benchmarks. In addition, the center could also undertake studies of randomly selected facilities using required basic audit procedures to ascertain the impact of these new procedures on interpretive quality. Public release of aggregate summary data and benchmarks will benefit everyone who participates in mammography.

The Breast Cancer Surveillance Consortium has already developed effective procedures and guidelines for mammography data collection and has demonstrated the feasibility of such an undertaking. Given the established expertise of the BCSC, it is a model for this new endeavor. The Agency for Healthcare Research and Quality (AHRQ) is also a possible choice for this role because it routinely collects and analyzes data for quality assessment and improvement purposes. Furthermore, it is able to afford such data the necessary protection from public disclosure that is essential to facilitate collection of accurate data.

The Committee believes FDA should not collect these data. Rather, FDA's onsite inspectors should simply verify that the data have been collected and reviewed by interpreting physicians in each mammography facility. Current regulations require that each facility designate at least one "audit interpreting physician" to analyze and review the medical outcomes audit data, report the results to other interpreting physicians, and document the nature of any follow-up actions. No change in this procedure is warranted. It is impractical to subject these data to independent verification, and regulatory oversight is unnecessary for a voluntary program. There is potential for conflict if a regulatory body also provides analysis and feedback for quality improvement.

Incentives to participate in this voluntary audit should be incorporated into the program, such as paying for quality performance, as described in the section titled The Need for a Supportive Environment to Promote Quality Improvement.

BREAST IMAGING CENTERS OF EXCELLENCE

As noted previously, centralized breast cancer screening programs with extensive interpretive quality assurance activities currently operate in several other countries, and some organized screening programs have been established in the United States as well. Although evidence is lacking to assess the impact of individual elements of these programs, when implemented together, they appear to be effective for improving interpretive performance and quality assurance. While adapting health care quality assurance practices of countries with national health care systems to the diverse and fragmented delivery of health care in the United States may not be fully feasible, the challenge is not insurmountable as it has occurred within some integrated health plans, and through the NCI Breast Cancer Surveillance System. There is an urgent need to further test the concept by establishing demonstration and evaluation programs to designate and monitor the performance of Breast Imaging Centers of Excellence. These specialized Centers of Excellence could encourage a higher level of integration, performance, and quality assurance in breast cancer detection and diagnosis.

The Breast Imaging Centers of Excellence should have and test the following attributes:

- High-volume mammogram interpretation
- Double reading
- Proficiency of interpretation demonstrated by comprehensive medical audit as defined in the BI-RADS atlas, which exceeds the voluntary advanced audit
- Systematic feedback and an infrastructure linking mammography performance to patient outcomes
- Patient reminder systems

In addition, pilot projects should be established within selected centers to further develop and evaluate interpretive skills assessment exams such as MISA. Centers of Excellence should also incorporate expertise in currently accepted nonmammographic imaging modalities for breast cancer diagnosis, such as ultrasound and magnetic resonance imaging, with accreditation where applicable. Centers would thus have the expertise to develop and host on site training programs in breast imaging—for mammography as well as other imaging modalities. Programs could be tailored for initial training and CME, as well as personalized training for interpreting physicians whose medical audit results indicate that they need to improve their skills. Interpretive skills assessment exams could be administered before and after training.

By providing multidisciplinary training and work environments for diagnosing women with breast cancer, Centers could increase job satisfaction and retention of practitioners and increase the productivity and quality of all members of the breast care team; high-quality facilities will attract high-quality personnel at all professional levels.

Breast imaging centers could also potentially improve access to mammography in low-volume areas by offering centralized interpretation through either soft-copy telemammography or by receiving films shipped from remote and/or mobile facilities. In their capacity to serve as regional readers of mammograms, Centers of Excellence should improve the ability of currently underserved populations and communities to access mammography services.

While specialized breast imaging centers that obtain the designation of Breast Imaging Center of Excellence would be expected to gain patients and referrals by reputation, additional incentives should be offered to encourage the delivery of demonstrably high-quality care. Such incentives should include higher reimbursement rates for breast imaging procedures, and eligibility to test a no-fault medical liability insurance program, discussed in Chapter 5. In the absence of such incentives, existing breast imaging centers are likely to view the extra cost and effort required for designation as a Center of Excellence as an unnecessary burden, thereby limiting the number of facilities that participate.

Integrating Breast Imaging Centers of Excellence into Interdisciplinary Breast Care

Ideally, Breast Imaging Centers of Excellence will be linked with facilities that offer comprehensive and multidisciplinary treatment and support for breast cancer (Box 2-2). The best among such facilities feature interdisciplinary care based on ongoing communication and collaboration among the multiple disciplines involved in diagnosing and treating cancer (Rabinowitz, 2004). This approach to disease management is intended to optimize the broad range of diagnostic techniques and therapies now available to ad-

BOX 2-2 Models of Integrated Breast Care

During three decades, a growing recognition of the complexity of treating breast disease and the need for coordination among the many contributors to that process have led to the development of breast cancer clinics, mammography centers, and comprehensive breast cancer centers. Although diverse in scope and setting, such "clinic-based" organizations have sought several common goals: to decrease morbidity, mortality, and anxiety associated with breast cancer detection and treatment; to increase coordination and communication among patients, multiple professionals, departments, and health care facilities; to foster participation in behavioral and translational research; and to define, measure, and monitor quality determinants of clinical, operations, and financial success for the sponsoring organization.

An interdisciplinary approach to breast cancer detection and treatment may be especially important in the United States, with its fragmented and specialized delivery of medical care. Initially, this led to the development of freestanding, comprehensive breast care programs such as the Van Nuys (California) Breast Center, founded in 1979. Advances in information technology have since permitted the development of "breast centers without walls" that allow clinicians involved in separate practices and locations to collaborate effectively on the care of individual patients.

In 2000, the European Society of Mastology (EUSOMA) published a paper defining the requirements of a "specialist breast unit" and establishing critical standards for such units, including the size of the patient population, the type and qualifications of its personnel, and a scope of care encompassing all stages of breast disease and evaluated through a common quality assurance system and database. According to these guidelines, which were intended to unify and standardize heterogeneous European breast care programs (Mansel, 2000), each member of a breast unit's core team (consisting of a clinical director, surgeons, radiologists, a pathologist, nurses, an oncologist, diagnostic radiographers, and a data manager) is required to have advanced skills, obtained by spending a year in a specialized training unit. While the EUSOMA model continues to be discussed and refined, it remains to be implemented across Europe, and large variations in breast cancer service delivery persist among European countries.

SOURCES: Rabinowitz (2000, 2004); Kolb (2000); Coleman (2005); Silverstein (1973, 2000); Coleman and Lebovic (1996); EUSOMA (2000); de Wolf (2003); Multidisciplinary coordination (2003).

dress breast cancer, as well as other diseases (August et al., 1993; Kolb, 2000; Rabinowitz, 2004).

A conceptual framework for improving health outcomes for cancer patients, Quality in the Continuum of Cancer Care (QCCC), recognizes the critical importance of the steps in the process of cancer care from prevention, screening, diagnosis, and treatment to end-of-life care. The implication of this conceptualization is that the transitions between being at risk in the population and coming in for screening, or having an abnormal test and getting treated, are as important as each of the steps (Zapka et al., 2003). Failures in the transitions are associated with later stage cancer occurrence (Sung et al., 2000; Yankaskas et al., 2005). By focusing on the steps and transitions in care where failures can occur, the QCCC framework aims to facilitate more organized systems of interdisci-

plinary medical practice that improve care, and establish meaningful measures of quality that promote improved outcomes.

Some reports suggest that interdisciplinary breast care may facilitate timelier treatment as well as less invasive surgery and better patient satisfaction (Rabinowitz, 2004). Higher rates of breast-conserving surgery and lower rates of false-negative breast biopsies have been observed in high-volume, specialized settings (Chang et al., 2001; Smith-Bindman et al., 2003; Tripathy, 2004); however, it remains to be determined whether care in such facilities is associated with improved rates of recurrence or survival (Tripathy, 2004). More specifically, advocates of interdisciplinary breast cancer care stress its advantages in promoting communication between radiologists and pathologists, particularly regarding prospective treatment planning (Rabinowitz, 2004).

The future expansion of interdisciplinary breast cancer care programs is expected to emphasize participation in clinical trials, research and research training, and the use of emerging technologies to promote information sharing and to facilitate the transition between care in urban-based cancer centers and physicians serving medically underserved populations (Garcia, 2004). Such improvements could equally enhance Breast Imaging Centers of Excellence.

THE NEED FOR A SUPPORTIVE ENVIRONMENT TO PROMOTE QUALITY IMPROVEMENT

Increased regulations alone may cause facilities to focus on meeting mandatory minimum requirements rather than motivating them to strive for maximal quality assurance and improvement that could additionally benefit the public's health. Supportive elements to help improve interpretive performance may not be as easily implemented as regulations, but in their absence, new requirements may not manifest meaningful improvements and would be viewed primarily as an added burden by mammography facilities and personnel. Mammography is already one of the most highly regulated medical procedures in the country, so if radiologists believe that additional regulations and oversight with respect to interpretation are merely punitive and burdensome, they may find other areas of practice more appealing.

Many countries with organized breast cancer screening programs have implemented extensive quality assurance procedures that require additional resources for that purpose (Klabunde et al., 2001). For example, most have designated staff with special training for data quality assurance. Furthermore, improvements in interpretive quality within programs such as the UK National Screening Programme have been highly dependent on a supportive environment and on funds specifically designated for quality assurance (Perry, 2004b). The workload and costs associated with meeting MQSA requirements are significant, and the new audit procedures proposed here will add to the workload and expense of adhering to MQSA requirements. However, historically these costs have not been factored into reimbursement, placing a considerable financial burden on facilities. Hence, the Centers for Medicare and Medicaid Services (CMS) and other health care payers must account for the cost of adhering to federally mandated audit procedures when setting reimbursement rates for mammography. Adequate reimbursement for MQSA compliance will be essential to maintain women's access to mammography services.

In the United States, some disincentives to practice mammography already exist (see Chapter 4 for more detail). Thus, the Committee believes that it is essential to provide positive incentives for facilities and individual interpreting physicians to aim for the highest level of quality assurance. Participation in the voluntary advanced audit process will likely lead to a higher quality of performance and care, but it will also entail a considerable increase in workload and paperwork, so a supportive approach is critical. Past experience with voluntary mammography accreditation suggests that participation in new voluntary quality assurance activities will be limited in the absence of incentives.

One strong incentive would be paying for quality. A number of large health insurers have recently initiated "pay for quality" (PFQ) programs (see Box 2-3). CMS is also developing a PFQ policy, and private health insurers often follow the lead of CMS. The extensive quality assurance procedures proposed for the voluntary advanced audit justify the use of such an approach for mammography. Eligibility to participate in such a program should depend on documentation that the facility meets specific performance criteria. Although general guidelines for performance have been put forth previously (Bassett et al., 1994), the performance criteria for this specific program are different, and they should be determined and periodically updated by an informed group of experts and patient advocates.

BOX 2-3 Paying for Quality

The National Committee for Quality Assurance (NCQA) report *The State of Health Care Quality* discusses at length the quality gaps present in our existing health care system. The quality gap between the top 10 percent of health care plans and the national average was estimated at 20 percent across the medical field, far higher than most other industries. For example, in the airline industry, the quality gap in terms of safety is less than 1 percent. Providing incentives for physicians striving to improve quality is an option receiving significant attention, despite considerable obstacles to implementation. The most effective "pay for quality" (PFQ) programs in operation today encourage cooperation among health care plans, providers, consumers, and patients, potentially advancing our health care system on both the whole-system and individual levels.

Two core principles guide PFQ programs: a common set of metrics used to assess performance, and funding to support performance improvement. Ensuring the success of PFQ programs requires that funding is aligned with program goals. Payment should reward effective care and encourage the development of effective care delivery systems. PFQ programs can, in theory, have far-reaching benefits. Participating health plans could profit from increased provider quality and consumer satisfaction. Improvements in medical care should result in a healthier general workforce, benefiting employers. Individual physicians receive direct feedback on performance, while physician groups actively improving quality receive direct monetary rewards. Moreover, care centers that achieve a higher level of quality assurance will likely encounter indirect rewards through increased patient enrollment.

Continued

BOX 2-3 *Continued*

A crucial step in improving quality care is utilization of information technology. Electronic patient records enhance access to patient information and allow the use of reminder systems. Although implementing electronic record systems can prove costly, with some estimates of $10,000 to $20,000 per physician per year, a 5-year cost-benefit analysis found a net gain of $86,400 per provider. Despite this potential profit, only 7 percent of U.S. physicians use electronic records. PFQ programs can provide the incentive for physician groups to take on this burdensome, yet valuable task.

Currently, physicians are reimbursed for basic care through fee-for-service programs, capitation, or salary rewards, yet each is inadequate for a true PFQ program. Fee-for-service does not provide incentives to improve the quality of care delivery, while salaries hinder innovation and may reduce productivity. Capitation does not provide reimbursement for additional expenses accrued to improve quality. Better methods of reimbursement are necessary to properly reward quality and promote improvement.

Advocates believe that orienting treatment groups around a common clinical purpose could facilitate quality improvement. Overall, the prevalence of PFQ programs has increased, and they vary in method and scope. One example is the "Bridges to Excellence" program, funded by General Electric, which established a partnership that includes Partners HealthCare, Tufts Health Plan, and several other Massachusetts health groups. Physician groups pursuing improvement systems and meeting specific standards of care, including electronic records and disease registries, receive up to $55 per patient per year. Anthem Blue Cross and Blue Shield is also offering programs in several locations, including New Hampshire and Michigan. This program uses the Health Plan Employer Data and Information Set (HEDIS) quality measures published by NCQA to assess and reward physicians providing excellent care; practices received up to $12,062 in 2002. The most advanced PFQ program to date, California's Integrated Healthcare Association (IHA), involves six major health plans. Assessment includes clinical measures, patient satisfaction, and information technology/infrastructure investment.

The Centers for Medicare and Medicaid Services (CMS) is currently in the design and development phase of the Healthcare Quality Demonstration, established by the Medicare Modernization Act of 2003 and set to begin January 1, 2006. The program will investigate shared decision making for patient-centered care, redesign of care networks to focus on outcome improvement, methods to reduce practice variation, and quality incentives. The Physician Group Practice Demonstration combines fee-for-service payments with incentive programs to reward group practices for financial performance and quality improvement. Additionally, CMS is funding a study at the Institute of Medicine, titled "Redesigning Health Insurance Benefits, Payment, and Performance Improvement Programs," which focuses, in part, on how improvements in quality and care delivery can be rewarded.

SOURCES: CMS (2004); Epstein et al. (2004); Integrated Healthcare Association (2004); National Committee for Quality Assurance (2004); Casalino et al. (2003); Wang et al. (2003); DiSalvo et al. (2001); Deloitte & Touche (2000); IOM (2001a); Personal correspondence, J. Pila, Centers for Medicare and Medicaid Services (September 29, 2004).

SUMMARY AND CONCLUSIONS

The effectiveness of mammography greatly depends on the quality of image interpretation, but reading mammograms and assessing interpretive performance are both quite challenging. The Committee concludes that current medical audit requirements under MQSA fail to fulfill a meaningful function for measuring or improving the quality of image interpretation. Medical audits should be designed to link practice patterns to patient outcomes in a way that can influence provider performance. Interpreting physicians need to understand their current level of performance before they can take action to improve their interpretive accuracy.

Thus, the medical audit required under MQSA should be enhanced and standardized to include the calculation of three core measures, calculated separately for screening and diagnostic mammograms. In addition, the group of women that facilities are required to track should be expanded to include not only women with BI-RADS 4 and 5 assessments, but also all women for whom additional imaging is recommended, until a final assessment is rendered.

Facilities should also be encouraged to strive for a higher level of quality performance through participation in two voluntary programs. These programs should be given a high priority so that more specific recommendations about monitoring and feedback requirements can be established in the future. Mandating these approaches for all mammography facilities in the United States is not feasible at present because of the fragmented nature of health care delivery, but experience with them on a voluntary basis eventually could lead to higher standards for all facilities. First, a voluntary advanced audit should include the collection of tumor staging information from pathology reports and collection of patient characteristics in addition to all tracking, measurements, and assessments in the basic required audit. This should be facilitated by the formation of a data and statistical coordinating center that would collect the data and conduct accurate and standardized advanced-level audits, provide feedback, and help develop, implement, and evaluate improvement plans. The BCSC and AHRQ both have characteristics that make them viable options for undertaking the endeavor.

Second, the establishment of Breast Imaging Centers of Excellence could encourage U.S. facilities in diverse settings to adopt—and adapt—features of successful foreign programs. Evidence is insufficient to assess the impact of individual components of these programs on performance, but when implemented together, with systematic feedback, they appear to be effective for improving quality. This undertaking will likely require cooperative efforts of several organizations, perhaps to include NCI, CMS, and AHRQ.

A supportive environment is also essential for improving interpretive performance, as demonstrated by high-quality programs in other countries. The expanded audit procedures proposed here will increase the cost of compliance. Thus, reimbursement rates for mammography should be reformulated to account for the costs of complying with federally mandated regulations. In addition, developing a "pay for quality" program to reward high levels of performance and quality assurance would be a strong incentive to participate in the advanced-level audit and to seek designation as a Breast Imaging Center of Excellence. Testing an alternative "no fault" approach to medical liability insurance that is linked to high performance standards (described in detail in Chapter 5) could provide an additional incentive to seek designation as a Center of Excellence.

The Committee also considered a number of other approaches that could potentially improve interpretive performance, such as double reading, use of CAD, increased continuing experience (interpretive volume) requirements, and CME programs that focus on interpretation and self-assessment. While there is some evidence to suggest that these approaches could also improve the quality of mammography interpretation, the data available to date are insufficient to justify changes to MQSA legislation or regulations. However, the Committee recommends that additional studies be rapidly undertaken to develop a stronger evidence base for the effects of CME, reader volume, double reading, and CAD on interpretive performance.

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3

MQSA Regulations, Inspections, and Enforcement

Mammography Quality Standards Act (MQSA) regulations have been in effect for more than 10 years, so a review at this time is appropriate to identify areas in need of enhancement. In addition to making suggestions for changes and possible additions to enhance the quality of mammography, the Committee examined the current regulations and Food and Drug Administration (FDA) data from inspection reports in an effort to identify components that could potentially be eliminated without a detrimental effect on quality. This was an important consideration because unnecessary regulations and tests add to the cost and workload of facilities, but do not benefit patients.

REGULATIONS OVERVIEW

Congress passed the Mammography Quality Standards Act of 1992 to provide a general framework for ensuring national quality standards in facilities performing screening mammography. The Secretary of Health and Human Services assigned FDA the authority to implement and regulate the Act's provisions. FDA Final MQSA Regulations became effective in April 1999. A detailed outline of these regulations can be found in Box 3-1.

Briefly, FDA requires that each mammography facility be accredited and certified. Several accreditation and certification bodies exist today. Facilities must apply for accreditation once every 3 years, a process that requires review of both clinical and phantom images. Accrediting bodies are also responsible for reviewing equipment evaluations and quality control tests performed by each facility and reviewing the qualifications of mammography personnel.

All personnel at mammography facilities, including interpreting physicians, radiologic technologists, and medical physicists, must meet initial qualifications, demonstrate continued experience, and complete continuing education programs. To ensure the quality of patient care, FDA requirements also specify that facilities provide a summary of the mammographic assessment in lay terms to each patient in a timely manner.

The states and FDA perform annual inspections to verify personnel and quality control data and to examine compliance with quality standards such as radiation dosage and image processing. Inspectors also ensure that each facility has established a system to record medical outcomes audit data, such that positive mammographic results can be correlated with pathology outcomes. In order to measure and enforce compliance, FDA established a three-tiered violation system, with Level 1 being the most serious. Sanctions, such as directed plans of correction, civil money penalties, and certificate suspensions, can be imposed on delinquent facilities (Mammography Quality Standards Act Regulations, 21 C.F.R. § 900.12 [2003]).

BOX 3-1 MQSA Regulations Overview

I. Quality Standards
   a. *Personnel*. Interpreting physicians, radiologic technologists, and medical physicists must meet initial and continuing requirements. Documentation of these requirements must be available for inspection.
   b. *Equipment*. Only equipment designed specifically for mammography qualifies for certification.
   c. *Medical Records and Mammography Reports*. Summary data written in lay terms must be sent directly to all patients as soon as possible. Mammography films and reports must be retained for at least 5 years and up to 10 years, and labeled according to Food and Drug Administration (FDA) regulation.
   d. *Quality Assurance*. Quality control testing protocols must be used and maintained by each facility, including mammography equipment evaluations and an annual physics survey. Documentation of daily, weekly, quarterly, semiannual, and annual quality control tests must be retained for FDA inspections.
   e. *Mammography Medical Outcomes Audit*. An interpreting physician must annually review the medical outcomes audit data.
   f. *Consumer Complaint Mechanism*. Facilities must establish a written and documented system for collecting consumer complaints.

II. Accreditation
   a. *Current Accreditation Bodies*. American College of Radiology (ACR), Iowa, Arkansas, and Texas.
   b. *Responsibilities of Accreditation Bodies*. Accreditation bodies must monitor facility compliance with quality standards, review clinical and phantom images from each facility at least once every 3 years, conduct annual onsite visits of at least 5 percent of the facilities it accredits, and maintain a consumer complaint system.
   c. *Accreditation Body Audit.* FDA will evaluate the performance of each accreditation body annually.
   d. *Facility Accreditation*. Facilities must submit verification that personnel, equipment, and practices conform to established quality standards to be eligible for accreditation.

III. Certification
   a. *Current Certification Bodies*. FDA, Iowa, Illinois, and South Carolina.
   b. *Responsibilities of Certification Bodies*. Certification bodies must issue Mammography Quality Standards Act (MQSA) certificates allowing accredited facilities to operate lawfully, and must perform annual inspections of each certified facility.
   c. *Facility Certification*. Accredited facilities are eligible for certification. Certificates are valid for 3 years, and are renewable.

IV. Inspections
   a. *General*. Facilities must undergo annual inspections.
   b. *Inspectors*. Facilities may be inspected by FDA inspectors, state or local agency inspectors under FDA contract, or inspectors from states that are certifying agencies. Federal facilities can be inspected only by FDA inspectors.

Continued

BOX 3-1 *Continued*

c. *Inspector Audit*. Annual assessment of state performance is carried out by FDA auditors.
d. *Fees*. The facility undergoing inspection is responsible for all inspection fees. As of October 1, 2003, a fee of $1,749 is charged for the first mammography unit inspected, and $204 for every unit thereafter. Follow-up inspection fees are $991.

V. Compliance and Enforcement
   a. *Levels of Noncompliance*
      i. Level 1: Failure to meet a key MQSA requirement that may seriously compromise mammography quality. The facility is given 15 days to respond with corrective actions.
      ii. Level 2: All critical MQSA requirements met, yet a significant mammography quality item overlooked. The facility is given 30 days to respond.
      iii. Level 3: A minor deviation from MQSA standards. The facility is given until next annual inspection to address the problem, although it is advised to correct it as soon as possible.
   b. *Enforcement/Sanctions/Other*
      i. FDA may impose one or more of the following sanctions:
         1. Directed Plan of Correction, allowing facility to correct violations in a timely manner, while being monitored by FDA.
         2. Patient and Physician Notification, requiring facilities to inform those that may be at risk due to unacceptable image quality or other conditions that could cause significant negative impact on patient health.
         3. Follow-up Inspection.
         4. Certificate Revocation or Suspension.
      ii. Civil Money Penalties of up to $10,000 per examination or per violation per day may be applied to facilities performing mammography services without proper certification or for other significant violations.

VI. Advisory Committee
   a. *Title*. The establishment of a National Mammography Quality Assurance Advisory Committee (NMQAAC) was mandated by MQSA.
   b. *Members*. FDA appoints members from the community of physicians, health professionals, consumer organizations, and industry representatives.
   c. *Responsibilities*. The NMQAAC advises FDA on appropriate quality standards, assists in the development of sanctions, designs a method to investigate consumer complaints, reports on new developments in breast imaging, determines whether a shortage of health professionals exists, and measures the costs and benefits of MQSA compliance.

SOURCE: Mammography Quality Standards Act, 42 U.S.C. § 263b (2003). 21 C.F.R. § 900.1 (2003).

SUGGESTED CHANGES TO FDA REGULATIONS

The Institute of Medicine Committee on Improving Mammography Quality Standards was charged with making recommendations for changes to existing regulatory requirements in order to further improve quality and to reduce unnecessary burdens on mammography facilities. FDA citation data were one source of information used to identify inspection criteria that may be unnecessary to ensure quality mammography (FDA, 2004a). FDA should take responsibility for reviewing the current regulations to delete obsolete language, reduce redundancy, and improve overall clarity. Furthermore, review of regulations should be an ongoing process undertaken by FDA. The following is a summary of the Committee's views on the current FDA regulations; a complete summary of suggested regulation changes is presented in Table 3-1.

Accreditation

Sections 900.3 and 900.4 of FDA regulations discuss application for approval as an accreditation body and standards for accreditation bodies, respectively. The Committee agreed on several changes to simplify the accreditation process. First, facilities should submit only the results of the medical physicist's equipment evaluation to the accreditation body, not the full evaluation, during initial application of a new unit for accreditation. (This is the current FDA-approved practice for accrediting bodies; the regulation change would clarify the practice.) Second, facilities should no longer be required to submit surveys and equipment evaluations to their accreditation body annually; instead, they should be submitted every 3 years as consistent with the renewal process. This information is already being reviewed during the annual MQSA inspection, and additional submission to accreditation bodies is unnecessarily redundant.

New Mammography Units

Qualifications for MQSA certification in Subpart B should be expanded to require facilities to undergo accreditation of all new mammography units, including digital equipment. Inspection data collected since 2001 have revealed numerous citations for nonaccredited units (FDA, 2004a). FDA should employ a more strict enforcement policy for facilities lacking accreditation for all units. Additionally, the accreditation process for any newly purchased units should begin prior to use.

Luminance and Illumination

Viewing conditions are critical for accurate interpretation of subtle contrast differences on mammography films (Haus et al., 1993; Wang and Gray, 1998; Waynant et al., 1998, 1999). The 1999 American College of Radiology (ACR) mammography quality control manual suggests standards for viewbox luminance and illumination levels; however, compliance with these recommended standards varies. An estimate from facilities in North Carolina in 2002 suggests approximately 15 percent (40 out of 248 total) of facilities did not meet the recommended ACR viewing standards.[1] FDA should require that viewboxes used for interpreting mammograms should produce a

[1] Personal communication, G. Britt, North Carolina Department of Health and Human Services, Division of Public Health, Cancer Prevention and Control Branch, February 10, 2004.

TABLE 3-1 Suggested Changes to MQSA Regulations

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.2(aa) Definitions	Mammography means radiography of the breast, but, for the purposes of this part, does not include: (1) Radiography of the breast performed during invasive interventions for localization ~~or biopsy~~ procedures; or (2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.	Mammography means radiography of the breast, but, for the purposes of this part, does not include: (1) Radiography of the breast performed during invasive interventions for localization procedures; or (2) Radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.	(1) Stereotactic breast biopsy procedures utilize X-ray imaging. In the preamble to the final rules, the FDA stated the following: "Since the publication of the proposed regulations on April 3, 1996, significant progress has occurred in the professional community and FDA now believes that there is enough information to begin the development of interventional mammographic regulations. However, that development requires a comprehensive and careful approach that addresses all the factors involved in such procedures. The agency has already begun the development process by bringing this issue before NMQAAC during its October 1996 meeting and is continuing to gather information and data. Although the agency has concluded that the final regulations should exclude coverage of interventional mammography, FDA expects to propose regulations covering all aspects of interventional mammography in the near future." Because the profession has considerably more experience with stereotactic breast biopsy since 1996, the FDA should remove this exemption. (2) FDA should not require accreditation specifically for non-stereotactic biopsy interventional procedures (e.g., wire needle localization), since accreditation programs do not exist for these procedures. Instead, FDA should only require that all mammography machines used for non-biopsy interventional procedures be accredited under the basic MQSA requirements.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.4(c)(5)(i) Review physicians	**Have at least 50% of each year's practice in breast imaging, be currently actively practicing in the modality reviewed at an MQSA-certified mammography facility,** meet the interpreting physician requirements specified in Sec. 900.12(a)(1) and meet such additional requirements as have been established by the accreditation body and approved by FDA.	Have at least 50% of each year's practice in breast imaging, be currently actively practicing in the modality reviewed at an MQSA-certified mammography facility, meet the interpreting physician requirements specified in Sec. 900.12(a)(1) and meet such additional requirements as have been established by the accreditation body and approved by FDA.	It is essential that accreditation body reviewers passing judgment on the performance quality of mammography facilities have considerably more experience than the minimum established by the regulations for physicians interpreting mammograms. Likewise, reviewers evaluating images of a specific modality (e.g., digital) should have current experience with that modality.
900.4(e)(1)(i)	With its initial accreditation application, **the results of** a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in Sec. 900.12(e).	With its initial accreditation application, the results of a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in Sec. 900.12(e).	The ACR currently requests only the equipment evaluation results with the initial accreditation application. The FDA has approved this process.
900.4(e)(1)(ii) Reports of mammo equipment evaluations, surveys, and QC	Prior to accreditation, a**n annual** survey that was performed no earlier than ~~6~~**14** months before the date of application for accreditation **or accreditation renewal** by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.	Prior to accreditation, an annual survey that was performed no earlier than 14 months before the date of application for accreditation or accreditation renewal by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.	"Annual" and "or accreditation renewal" should be included to be consistent with other regulations in this part and minimize confusion about what is required. "Six months" should be changed to "14 months" to make this requirement consistent with the current MQSA inspection process as well as the process currently used by ABs. The way it is currently written may force a facility to unnecessarily have more than one annual survey in the same year.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.4(e)(2)(iii) Reports of mammo equipment evaluations, surveys, and QC	~~Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.~~	(NONE)	Inspectors currently review annual surveys and equipment evaluations during the facility's annual MQSA inspection. The current requirement that facilities also submit annual survey results to the AB each year is a redundant process and an unnecessary burden for mammography facilities. Eliminating this redundancy would allow the AB to focus on obtaining important identification and contact information.
900.4(h)(1)	Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited, **when notified by the facility** and **every three years during renewal,** in a manner and at a time specified by FDA.	Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited, when notified by the facility and every three years during renewal, in a manner and at a time specified by FDA.	Consistent with the suggested change to 900.4(e)(2)(iii).
900.11(b)(1)(i) Certificates	In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by the FDA **for accreditation of all mammography units.** The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).	In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by the FDA for accreditation of all mammography units. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).	Add "for all units" to ensure all new mammography units, including digital, are accredited.
900.11(b)(1)(iii) Certificates	**Facilities must notify their accrediting body of new units and begin accreditation before use.**	Facilities must notify their accrediting body of new units and begin accreditation before use.	Ensures all new equipment is reported to the accrediting body.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.11(c) Reinstatement policy	A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may ~~be considered to be a new facility and thereby~~be eligible for a provisional certificate.	A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be eligible for a provisional certificate.	The current wording confuses facilities. In practice, a reinstating facility is not "considered to be a new facility" because they retain their MAP ID number, their MQSA certificate number, and, most importantly, their accreditation history.
900.12(a)(1)(ii)(A) Continuing experience and education for interpreting physicians	Following the second anniversary date ~~of the end of the calendar quarter~~in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the ~~24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24 month period~~**previous two calendar years. Continuing experience obtained outside of the U.S. is also acceptable.**	Following the second anniversary date in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the previous two calendar years. Continuing experience obtained outside of the U.S. is also acceptable.	(1) The current timeframe for counting this experience has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality. (2) There are a number of instances where physicians who initially qualified in the U.S. under MQSA practice temporarily outside the U.S. and then return. While at a foreign facility they continue to interpret mammograms using the skills they obtained while qualified in the U.S. They should not be prevented from using the examinations interpreted at a foreign site (as long as it is adequately documented) toward meeting the continuing experience requirements in the U.S. upon their return. Currently, FDA guidance prohibits the use of this foreign experience toward meeting MQSA requirements.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(a)(1)(ii)(B) Continuing experience and education for interpreting physicians	Following the third anniversary date ~~of the end of the calendar quarter~~in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the **previous three calendar years.** ~~36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36 month period~~. ~~This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.~~	Following the third anniversary date in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the previous three calendar years.	(1) The current timeframe for counting this education has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality. (2) Delete "six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice." The interpreting physician has already obtained the required initial 8 hours of training to begin interpreting from a new modality. It is more important to allow the physician to select CMEs for continuing experience to help improve breast disease interpretation skills. These do not change with the modality used.
900.12(a)(2)(iii)(A) Continuing education for radiologic technologists	Following the third anniversary date ~~of the end of the calendar quarter~~in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the ~~36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36 month period~~**previous three calendar years.**	Following the third anniversary date in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the previous three calendar years.	The current timeframe for counting this education has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(a)(2)(iii)(C) Continuing education for radiologic technologists	~~At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.~~**This continuing education shall include training appropriate to each mammographic modality used by the technologist.**	This continuing education shall include training appropriate to each mammographic modality used by the technologist.	The current requirement that technologists (and, in effect, continuing education-granting organizations) designate credits with the modality (i.e., screen-film or FFDM) is not reasonable. Most current existing credits are either on general breast disease or specific to screen-film mammography, thus, awarding 6 credits is excessive. They should just be required to include some (as with the original requirements for medical physicists).
900.12(a)(2)(iv)(A) Continuing experience for radiologic technologists	Following the second anniversary date~~ of the end of the calendar quarter~~in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the ~~24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period~~ **previous two calendar years.**	Following the second anniversary date in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the previous two calendar years.	The current timeframe for counting this experience has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(a)(3)(iii)(A) Continuing education for medical physicists	Following the third anniversary date ~~of the end of the calendar quarter~~in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the ~~36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36 month period~~**previous three calendar years**. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once toward the required 15 units in ~~a 36 month period~~ **three calendar years**, even if the course is taught multiple times during ~~the 36 months~~**this time period**.	Following the third anniversary date in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the previous three calendar years. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once toward the required 15 units in three calendar years, even if the course is taught multiple times during this time period.	The current timeframe for counting this education has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(a)(3)(iii)(B) Continuing experience for medical physicists	Following the second anniversary date ~~of the end of the calendar quarter~~in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least ~~two mammography facilities and a total of at least~~six mammography units during the ~~24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period~~**previous two calendar years.** No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.	Following the second anniversary date in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least six mammography units during the previous two calendar years. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.	(1) The current timeframe for counting this experience has been extremely confusing for personnel and even inspectors. Basing these numbers on calendar years will simplify compliance with no loss of quality. (2) Remove the requirement for two facilities every 24 months. It is becoming more difficult for medical physicists to provide services to more than one facility over a 24-month period. Some facilities do not allow employees to provide outside consulting. In addition, the ratio of units to facilities has increased significantly since MQSA went into effect (1.2 to 1.5). Many large facilities have over 10 units. Physicists have adequate experience surveying mammography units and evaluating QA at one place of employment.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(c)(1)(iv) Medical records and mammo reports—contents and terminology	Overall final assessment of findings, classified in one of the following categories: (A) "Negative:'' Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained); (B) "Benign **Finding(s)**:'' Also a negative assessment; (C) "Probably Benign **Finding—Initial Short-Term Follow-up Suggested**:'' Finding(s) has a high probability of being benign; (D) "Suspicious **Abnormality—Biopsy Should Be Considered**:'' Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant; (E) "Highly Suggestive of Malignancy—**Appropriate Action Should be Taken**:'' Finding(s) has a high probability of being malignant; **(F) "Known Biopsy—Proven Malignancy—Appropriate Action Should be Taken:" Reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.**	Overall final assessment of findings, classified in one of the following categories: (A) "Negative:'' Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained); (B) "Benign Finding(s):'' Also a negative assessment; (C) "Probably Benign Finding—Initial Short-Term Follow-up Suggested:'' Finding(s) has a high probability of being benign; (D) "Suspicious Abnormality—Biopsy Should Be Considered:'' Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant; (E) "Highly Suggestive of Malignancy—Appropriate Action Should be Taken:'' Finding(s) has a high probability of being malignant; (F) "Known Biopsy—Proven Malignancy—Appropriate Action Should be Taken:" Reserved for lesions identified on the imaging study with biopsy proof of malignancy prior to definitive therapy.	These changes will make the regulations more consistent with the 2003 BI-RADS categories and minimize confusion between the interpreting physician and the clinicians. The FDA has already approved these changes in an alternative standard.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(c)(1)(v) Medical records and mammo reports—contents and terminology	In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need Additional Imaging Evaluation **and/or Prior Mammograms for Comparison**'' shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician. **For cases rated 0 because of need for prior examinations, reassessment must be performed within 30 days to assign category.**	In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison'' shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician. For cases rated 0 because of need for prior examinations, reassessment must be performed within 30 days to assign category.	These changes will make the regulations more consistent with the 2003 BI-RADS category and minimize confusion between the interpreting physician and the clinicians. The FDA has already approved the change in an alternative standard.
900.12(d)(1)(i) Lead interpreting physician	The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate. **Lead interpreting physician must provide regular feedback to technologist on quality of images.**	The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate. Lead interpreting physician must provide regular feedback to technologist on quality of images.	Data from ACR SOSS surveys suggest 43.8 percent of facilities failing to pass accreditation after three consecutive attempts could benefit from improved physician-technologist communication. Requiring regular feedback may improve quality for facilities overall.
900.12(e)(2)(i) Weekly quality control tests	The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least ~~1.2~~ **1.40** when exposed under a typical clinical condition.	The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.40 when exposed under a typical clinical condition.	Higher contrast films that perform better at higher densities are standard since the final regulations were developed, improving the quality of mammography. The regulations should be changed to reflect this.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(e)(4)(i) Semiannual quality control tests	Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than ~~1.2~~**1.40** OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.	The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.40 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.	Consistent with 900.12(e)(2)(i).
900.12(e)(4)(ii) Semiannual quality control tests	Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested ~~semi-~~**annually. The test shall also be carried out initially for all new cassettes as they are placed in service, and whenever reduced image sharpness is suspected.**	Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested annually. The test shall also be carried out initially for all new cassettes as they are placed in service, and whenever reduced image sharpness is suspected.	This is a low-yield test that only needs to be performed annually, and when new cassettes are placed into service, as the majority of rejected cassettes are found upon initial placement into service.
900.12(e)(5)(i)(C) Annual quality control tests	Automatic exposure control performance. The optical density of the film in the center of the phantom image shall not be less than ~~1.2~~**1.40**.	The optical density of the film in the center of the phantom image shall not be less than 1.40.	Consistent with 900.12(e)(2)(i).

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(e)(5)(ii) Kilovoltage peak (kVp) accuracy and reproducibility	Facilities with **older three-phase** screen-film systems shall perform the following quality control tests at least annually: (ii) Kilovoltage peak (kVp) accuracy~~and reproducibility~~. ~~(A)~~ The kVp shall be accurate within +/- 5 percent of the indicated or selected kVp at: (1) The lowest clinical kVp that can be measured by a kVp test device; (2) The ~~most commonly used clinical~~kVp **that is obtained when the accrediting body phantom is imaged with the mammography X-ray unit set to the most commonly used clinical AEC mode; and** (3) The highest available clinical kVp~~, and~~. ~~(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.~~ **Newer units with medium- and high-frequency generators will not require this test.**	Facilities with older three-phase screen-film systems shall perform the following quality control tests at least annually: (ii) Kilovoltage peak (kVp) accuracy. The kVp shall be accurate within +/- 5 percent of the indicated or selected kVp at: (1) The lowest clinical kVp that can be measured by a kVp test device; (2) The kVp that is obtained when the accrediting body phantom is imaged with the mammography X-ray unit set to the most commonly used clinical AEC mode; and (3) The highest available clinical kVp. Newer units with medium- and high-frequency generators will not require this test.	(1) The phrase "most commonly used clinical kVp" often presents confusion because a different range of patient technique settings may be reviewed by the inspector than was examined by the medical physicist. (2) Data from DMIST trials show that this test rarely, if ever, fails during an annual survey. Modern equipment voltage regulation is extremely tight, making this test unnecessary on an annual basis. Reducing the scope of this test during annual surveys would allow the medical physicist to troubleshoot those productive tests that have a higher probability of failing. The test should be retained for equipment evaluations.
900.12(e)(5)(ix) Annual quality control tests	System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes~~and target-filter combinations~~**, targets, and filters** used clinically.	System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes, targets, and filters used clinically.	To assess for image quality and artifacts, only one test of target size, filter, and target is necessary, not combinations.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(e)(5)(xii) Annual quality control tests	**Viewboxes used for interpreting mammograms and clinical image quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter. The illumination levels must be less than or equal to 20 lux.**	Viewboxes used for interpreting mammograms and clinical image quality review by the technologist should be capable of producing a luminance of at least 3,000 candela per square meter. The illumination levels must be less than or equal to 20 lux.	Viewing conditions are critical in perceiving subtle contrast on film images. The 3,000 candela per square meter is consistent with the 1999 ACR mammography QC manual recommendations. Although the 20 lux value for illumination is lower than the 50 lux recommended in the ACR QC manual, more is known now about the importance of low ambient lighting than was known in 1999 when the manual was written.
900.12(f) Quality assurance-mammography medical outcomes audit	Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. **Facilities with the same interpreting physicians should combine medical audit data.** This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.	Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. Facilities with the same interpreting physicians should combine medical audit data. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.	(1) Medical audit data are more meaningful for a facility performing a larger number of examinations. Allowing facilities with the same interpreting physicians to combine their medical audit data across facilities will allow for more meaningful audit data and decrease the burden on individual facilities. (2) Using "should" instead of "may" suggests aggregate data are preferred, but will not result in noncompliance citations for those facilities submitting nonaggregate data.

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.12(f)(1) Quality assurance-mammography medical outcomes audit	General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians ~~at the facility~~for: **(i) Screening examinations, where a positive examination is defined as "Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison," "Suspicious Abnormality—Biopsy Should Be Considered," or "Highly Suggestive of Malignancy—Biopsy Should Be Considered," and** **(ii) Diagnostic examinations, where a positive examination is defined as "Suspicious Abnormality—Biopsy Should Be Considered," or "Highly Suggestive of Malignancy—Biopsy Should Be Considered."** (iii) In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.	General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians for: (i) Screening examinations, where a positive examination is defined as "Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison," "Suspicious Abnormality—Biopsy Should Be Considered," or "Highly Suggestive of Malignancy—Biopsy Should Be Considered," and (ii) Diagnostic examinations, where a positive examination is defined as "Suspicious Abnormality—Biopsy Should Be Considered," or "Highly Suggestive of Malignancy—Biopsy Should Be Considered." (iii) In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.	Combining medical audit data for screening with diagnostic examinations dilutes the meaning of the results and makes it impossible to compare facility/practice performance with current literature or established databases. Furthermore, the ACR BI-RADS Committee believes that a meaningful audit of screening examinations requires that the recommendation for recall imaging (BI-RADS Category 0) also be considered "positive." These changes will make the regulations more consistent with the BI-RADS follow-up and outcome monitoring guidance.

Continued

TABLE 3-1 Continued

Regulation	**Additions**/~~Deletions~~	Proposed Regulation	Rationale
900.13(a) FDA action following revocation of accreditation	If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks ~~reaccreditation~~**reinstatement**. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.	If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reinstatement. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.	After an AB revokes a facility's accreditation, the facility must take corrective action, have it approved by the AB and reinstate, not "reaccredit." "Reinstating" requires a facility to submit corrective action for review.

luminance of at least 3,000 candela per square meter, and should also require that illumination levels be less than or equal to 20 lux. Viewboxes used for clinical image quality review would not need to be inspected.

Personnel

Continuing Education and Experience

Quality standards for mammography personnel include specifications for continuing education and experience. Interpreting physicians are required to read a minimum of 960 mammographic examinations over a given 2-year period as evidence of this continuing experience. Increasing this volume requirement has been discussed as a potential way to improve interpretive quality, yet doing so may inadvertently jeopardize access to mammography services in some areas. Furthermore, current literature remains divided on whether volume alone has a positive effect on physician accuracy in detecting breast cancer (see Chapter 2). Until consensus is reached on the value of interpretive volume, this minimum requirement should remain unchanged.

MQSA-qualified physicians temporarily practicing mammography abroad are currently prohibited from using this foreign experience toward meeting the MQSA requirements. FDA and the ACR have reported requests for clarification on this policy, and, provided adequate documentation is available, such foreign practice should qualify as continuing experience and count toward the volume requirement.

The requirement for six category I continuing medical education (CME) credits in each mammographic modality used should be eliminated for interpreting physicians—only the more general requirement for 15 category I CME units in mammography should remain. Continuing education requirements for physicians should be broadened to allow physicians to select CME courses that help improve breast disease interpretation skills, rather than requiring specific courses in each mammographic modality (see Chapter 2 for more information on improving interpretive performance). However, the requirement for initial training in new mammographic modalities (regulation 900.12(a)(1)(ii)(C)) should remain unchanged.

Similarly, the requirement for modality-specific continuing education should be more flexible for radiologic technologists. The current regulations should be changed to eliminate the specific requirement for six continuing education units in each modality. Instead, regulations for radiologic technologists should more closely parallel those for medical physicists, which require only that "continuing education shall include hours of training appropriate to each mammographic modality." Because most existing credits are either on general breast disease or are specific to screen-film mammography, radiologic technologists and medical physicists should be required to specifically document only initial training in new modalities, as required in regulations 900.12(a)(2)(iii)(E) and 900.12(a)(3)(iii)(C), respectively. Finally, language describing the timeframe for completion of continuing education and experience should be based on calendar years, to improve clarity.

Continuing experience for medical physicists includes surveys of at least two mammography facilities during the previous 24 months. The number of mammography facilities in the United States has decreased by approximately 9.5 percent over the past 10

years. However, the number of mammography units has increased from 12,076 to 13,652, approximately a 13 percent increase, since 1998 (Destouet et al., in press). Thus the ratio of units to facilities has increased without clear indication of the impact on access, from 1.22 units to facilities in 1998 to 1.52 in 2004, and many large facilities are equipped with more than one unit. It has become increasingly difficult for medical physicists to meet the two-facility requirement, given the number of units at each facility. Sufficient experience is possible from quality control evaluations at one multiunit facility, and FDA regulations should be modified to reflect this.

Physician–Technologist Feedback

Regulation 900.12(d)(1)(ii) addresses the role of the interpreting physician in quality assurance procedures, specifically, taking corrective action when film images are of poor quality. Evidence from ACR site visits suggest radiologic technologists would benefit from improved feedback from physicians regarding image quality; in several instances, technologists have directly requested this feedback.[2] Furthermore, facilities with quality problems frequently lack regular communication between interpreting physicians and technologists. Facilities unable to pass ACR accreditation after three consecutive attempts participate in a Scheduled On-Site Survey (SOSS). The ACR team reviewing the facility in question recommends several areas for corrective action; improved communication between radiologists and technologists is suggested in 43.8 percent of SOSS cases (ACR, unpublished). Such improvements for all facilities, not only those under review, may positively impact quality overall.

Regulation 900.12(d)(1) should be expanded to require documentation of routine feedback to technologists from interpreting physicians; documentation of compliance could prove as simple as records of phone calls, e-mails, and quality control meeting minutes. Although a specific regulation requiring documentation may increase facility workload, the Committee agrees that strong communication between radiologists and technologists is an important factor in maintaining quality.

Foreign-Trained Radiologists

The quality of mammography programs abroad, including those in Canada and Europe, has been well documented (Dean and Pamilo, 1999; Hendrick et al., 2002; Elmore et al., 2003). While FDA currently accepts Canadian Board Certification and Canadian residency programs toward meeting initial requirements for interpreting physicians, interpreting physicians obtaining their initial qualifications in any other foreign country (e.g., the United Kingdom) remain effectively excluded from interpreting mammograms in U.S. facilities. FDA should further expand the initial qualification requirements to allow highly qualified interpreting physicians trained in foreign countries other than Canada to interpret mammograms under MQSA.

[2] Personal communication, P. Butler, Senior Director, Breast Imaging Accreditation Programs, American College of Radiology, October 15, 2004.

Ensuring Quality Personnel

Mandatory preceptorship training is typically recommended for mammography personnel deemed to be performing at a substandard level. However, such training can currently be avoided if the individual in question moves to a different facility. The state of Texas accreditation body has reported multiple instances of this, for both interpreting physicians and mammography technologists.[3] The initial qualification requirements for interpreting physicians and radiologic technologists should be modified to require documentation of employment history or radiology board qualifications prior to hiring. Individuals with incomplete training requirements should be required to continue and complete training at their new facility. Facilities should practice due diligence and verify employment history prior to hiring new personnel.

Technical Quality

Several quality control tests should be modified to better assess current mammography practice. Optical density (OD) of mammography films is evaluated through weekly quality control tests; FDA inspection data demonstrate few citations for below-threshold OD phantom scores (FDA, 2004a). Additionally, the high-contrast films currently in use require higher optical densities for optimal performance (Hendrick and Berns, 2000). Therefore, the minimum OD requirements should be increased from 1.2 to 1.4. Screen-film contact tests, previously performed semiannually, should be tested annually, given the low failure rate on inspection (National Mammography Quality Assurance Advisory Committee, 2004). Finally, Digital Mammographic Imaging Screening Trial (DMIST) data show that annual evaluations of kilovoltage peak (kVp) accuracy and reproducibility rarely fail for newer medium and high-frequency generators (Bloomquist et al., submitted). Older three-phase generators should still be tested annually, along with any new unit or equipment recently undergoing major repair.

Medical Audit

Facilities should be required to separate screening and diagnostic medical audit data. Combined screening and diagnostic examination data confound the meaning of the results and make it difficult to compare facility/practice performance with current literature or established databases. Further expansion of the medical audit is discussed at length in Chapter 2. Developing specific regulations to adopt the enhanced audit system recommended in Chapter 2 would be the responsibility of FDA.

The mammography medical outcomes audit currently requires data to be compiled for each radiologist practicing in each separate facility. Facilities with the same interpreting physicians should be allowed to merge the medical audit data for their interpreting physicians. Doing so will result in more meaningful physician data and reduce the burden on individual facilities. Although combined audits would be preferable, FDA inspectors should continue to accept nonaggregate data.

[3] Personal communication, K. Goss-Terry, Mammography Accreditation Program Manager, Texas Department of State Health Services, November 2004.

Reports

Mammography letters provided to patients are discussed in regulation 900.12(c)(1). FDA has approved an additional assessment category, "Known Biopsy-Proven Malignancy—Appropriate Action Should Be Taken," as an alternative standard. This revision should be incorporated into the final regulations because it ensures that the appropriate notification is sent to patients undergoing mammography examinations given that assessment. In addition, each assessment category should also be updated to be consistent with the 2003 Breast Imaging Reporting and Data System (BI-RADS) categories in order to reduce confusion between the clinician and interpreting radiologist.

Currently, cases where an incomplete workup prevents final assessment should be given a deadline for evaluation. The Committee discussed the possibility of requiring interpreting physicians to resolve all BI-RADS Category 0 assessments (incomplete—requires comparison with previous films)[4] within 30 days; however, such a requirement could prove problematic if a patient does not return for a complete workup within that time period. Thus resolution of Category 0 assessment should be required within 30 days for cases where full evaluation only depends on obtaining images from previous mammographic examinations.

According to FDA guidance, a lay summary must be sent to patients when images are compared with previous films, or when an addendum is added to the medical report, even if there is no change in the findings or recommended course of action (FDA, 2005b). Consequently, a lay summary must be sent even if the addendum merely states that the referring physician had been notified of the examination results. This requirement is burdensome on facilities, but more importantly, patients may be confused by receiving multiple letters that do not directly pertain to interpretation of their mammograms. Therefore, FDA guidance should be modified to require a patient letter only when images are reviewed and reinterpreted, even if there is no change in interpretation findings.

Interventional Procedures and New Technologies

Interventional Procedures

Standard mammography equipment is frequently used for interventional procedures, such as preoperative wire needle localization or ductograms. In addition, specialized mammography units can be used by physicians to guide minimally invasive tissue diagnosis procedures such as core needle biopsy. However, nationally recognized standards for such procedures were nonexistent at the time of MQSA implementation, and thus interventional mammographic procedures are currently exempted from regulation by FDA.

In 1997, the ACR and the American College of Surgery (ACoS) developed a joint set of qualifications for physicians performing stereotactic breast biopsy procedures, which included requirements for CME training and continuing experience. These standards became the basis for the ACR's and the ACoS's voluntary stereotactic biopsy ac-

[4] BI-RADS assessment Category 0 can also be assigned when additional imaging is required for accurate assessment. Resolving Category 0 assessments in such cases is not, and should not be, required within 30 days. Only those Category 0 assessment cases awaiting comparison with prior films should be resolved within the 30 days.

creditation programs (American College of Surgeons and American College of Radiology, 1998; ACR, 2004). However, in testimony to the Senate Committee on Health, Education, Labor, and Pensions on the reauthorization of MQSA, the American Cancer Society noted that of the 4,000 to 5,000 interventional mammography machines in use, fewer than 500 are accredited through the ACR program (American Cancer Society, 2003). Only 11 are accredited by the ACoS program. In similar testimonies, speakers on behalf of the Susan G. Komen Breast Cancer Foundation (Rowden, 2003) and the Society of Breast Imaging (Dershaw, 2003) advocated removing the exemption on interventional mammographic procedures from MQSA.

Furthermore, in the preamble to the final MQSA regulations, FDA noted that "although the agency has concluded that the final regulations should exclude coverage of interventional mammography, FDA expects to propose regulations covering all aspects of interventional mammography in the near future" (FDA, 1997). More than 7 years have passed, and in that time sufficient standards by which interventional breast imaging procedures can be measured have been developed. The Committee urges FDA to promptly remove the exemption of all interventional mammography from MQSA regulations. Specifically, all stereotactic breast biopsy procedures and equipment should be accredited by the appropriate accreditation body. Equipment used for other interventional procedures (e.g., needle localization) should also be regulated by FDA. (While there are accreditation programs for stereotactic biopsy, no programs exist for the other interventional procedures; the Committee believes mandatory accreditation of interventional equipment, not the interventional procedures themselves, is sufficient.) In addition, FDA inspectors should be trained to perform onsite inspections of stereotactic breast biopsy procedures and interventional equipment, as a paper review and review of films obtained by the site would be insufficient for ensuring quality.

Digital Mammography and CAD

The lack of specific regulation in MQSA for digital mammography is of particular concern because of the increasing prevalence of its use; the number of FFDM units has increased by 4 percent each month over the past year. The number of facilities offering FFDM rose from approximately 320 (approximately 4 percent of all facilities) in October 2003 to just over 500 (6 percent of all facilities) in October 2004 (Figure 3-1) (Destouet et al., in press). Since FDA regulations were enacted in 1999, little action has been taken to delineate oversight of digital mammography. Accrediting bodies are currently approved to accredit the General Electric 2000D, the General Electric DS, the Fischer Senoscan, and the Lorad Selenia FFDM units; other FDA-approved FFDM units (at the time of this writing, this only includes the Siemens Mammomat Novation) are permitted to operate under FDA's screen-film certification extension policy. Currently, facilities are instructed to adhere to the manufacturer's quality control manual when operating such devices. This can prove burdensome because the manuals are continually updated and there is little consistency between devices. Only the maximum 300 millirad dosage for a breast of average thickness and tissue composition is specifically covered in the regulations at this time. Regulation 900.12(b) should be expanded to include more specific regulation of digital mammography. Specifically, FDA should develop a uniform set of

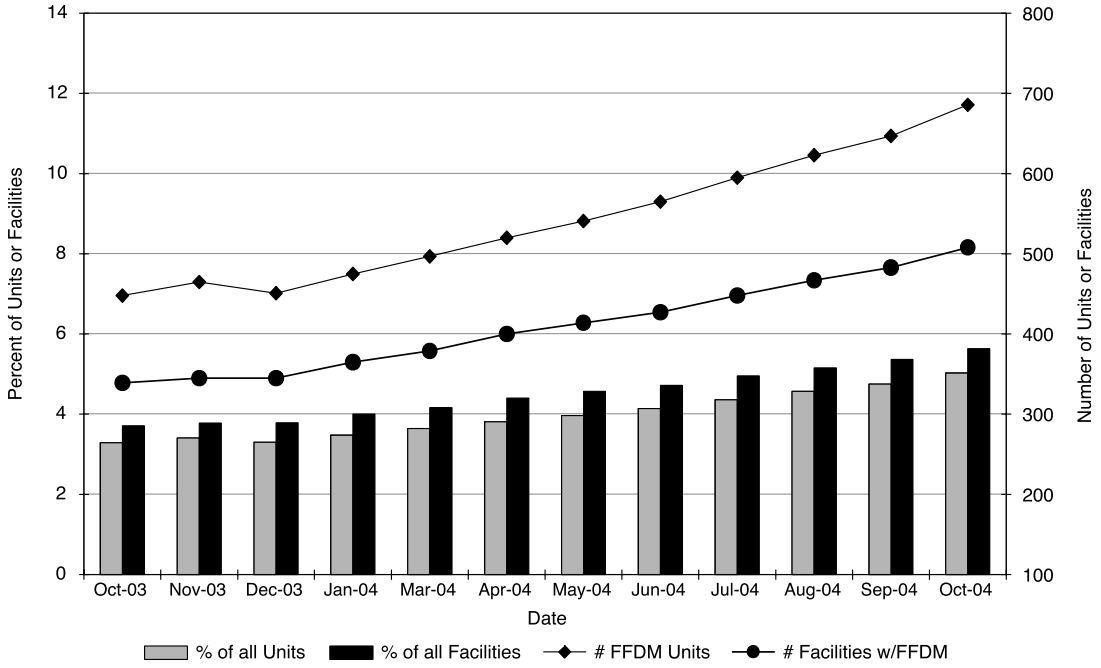

FIGURE 3-1 Full Field Digital Mammography (FFDM) growth. Data collected by the American College of Radiology and reported by Destouet et al. (in press) demonstrate an increase in both the number of FFDM units and the number of facilities with FFDM units since October 2003. The percentage of FFDM units and facilities with FFDM units is also represented graphically.
SOURCE: Destouet et al. (In press). Reprinted from the *Journal of the American College of Radiology*, In press, Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The American College of Radiology Mammography Accreditation Program—10 years of experience since MQSA, with permission from The American College of Radiology.

QC tests and test criteria across all digital systems. Uniform standards should not preclude performance of additional tests on some digital systems, as recommended by the equipment manufacturer. MQSA inspectors should be trained to perform onsite inspections of all digital equipment.

Computer-aided detection (CAD) is yet another emerging technology utilized in mammography to facilitate interpretation. However, CAD is software that physicians typically apply to FFDM or digitized film images after the images have been acquired, and may therefore be outside the purview of MQSA. FDA has considered this issue in the past in conjunction with issues surrounding double reading, and came to the conclusion that CAD was not a technology that could be readily dealt with through regulation.[5] The Committee concurs with this determination.

[5] Personal communication, C. Finder, M.D., Associate Director, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs (formerly the Office of Health and Industry Programs), CDRH, FDA, November 2004.

Facility Closures

The ACR has reported that between April 2001 and October 2004, approximately 19 percent (1,563 out of 8,325 fully accredited facilities) of their accredited mammography facilities have closed (Destouet et al., in press). Approximately one-third reportedly closed for financial reasons; movement to a sister site, equipment problems, and staffing shortages were also cited as reasons leading to closure. FDA has received a number of complaints from patients who were not informed when their mammography facility closed, and as a result were unable to or unsure of how to access their mammography records (FDA, 2003). Currently FDA guidelines suggest the "facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records [original mammography films and reports]," but no official patient notification is necessary (FDA, 2003). This reflects a serious lapse in patient care. Mammography facilities that close should be required to notify all patients and their doctors of the closure, and should be required to provide information regarding future access to mammography films and reports. However, in cases where facilities are unable to notify patients (e.g., facility bankruptcy), FDA should notify patients and referring physicians on that facility's behalf.

Enforcement of MQSA

Inspection Testing

Review of FDA inspection data from 2001 to 2003 revealed several inspection areas that could be streamlined, based on the low number of citations issued and the redundancy of the measurements by other entities. Radiation dose is currently measured by the accrediting body and annually by the medical physicist, and measurements rarely fail to meet MQSA regulation. Consequently, FDA should no longer measure radiation dose during inspection; analysis of dose measurements collected by the medical physicist will suffice. Additionally, inspectors should review and score phantom images taken previously by the facility; generation of new phantom images during the inspection is unnecessary. The exposure reproducibility coefficient of variation evaluation should be made only for three-phase units, as the medical physicist evaluates this annually. Half-value layer should no longer be evaluated for the same reason. Inspectors should continue the darkroom fog, collimator, and compression paddle tests due to the relatively larger number of FDA citations during annual inspections. Likewise, the inspectors should continue the processor tests primarily because these are not conducted by the medical physicists (FDA, 2004a).

Reducing the frequency of inspections for facilities with good performance records was considered as another way to reduce the burden of MQSA on mammography facilities. As part of the Mammography Quality Standards Reauthorization Act of 1997, Congress gave FDA the authority to organize an inspection demonstration program (IDP) to determine whether MQSA inspections could be conducted less frequently than annually (Mammography Quality Standards Reauthorization Act. Pub. L. No. 105–248 [1998]). Eligible facilities had undergone at least two annual inspections under the final regulations and had received no regulatory (i.e., compliance) actions. After 2 years,

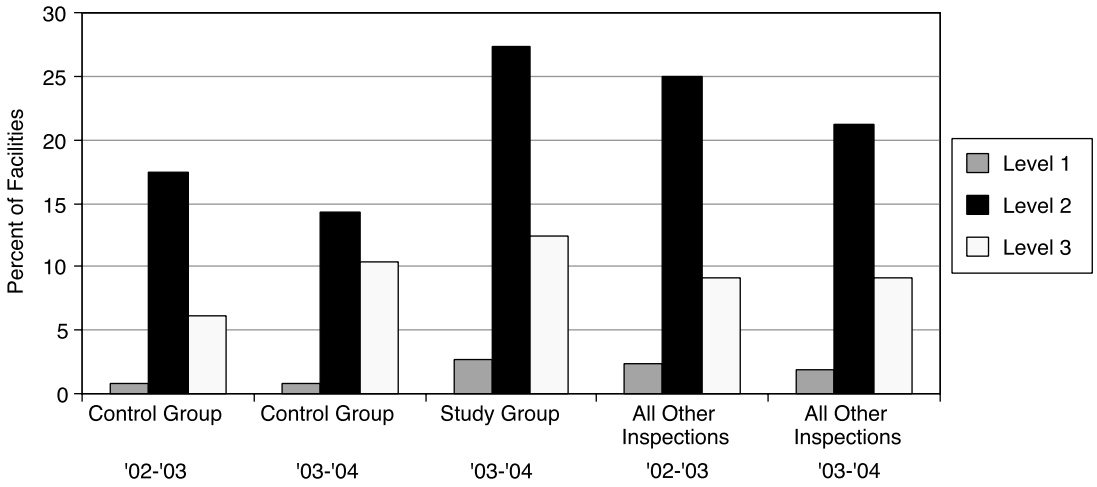

FIGURE 3-2 Percentage of facilities by highest violation level. Data collected from the FDA Inspection Demonstration Program suggest there are a higher percentage of Level 1, 2, and 3 violations at facilities undergoing biennial inspections as compared with facilities undergoing the currently mandated annual inspections.
SOURCE: Adapted from FDA (2005).

compliance data from the control (annual inspection) and study (biennial inspection) groups revealed more Level 1, 2, and 3 violations at facilities undergoing biennial inspections than at the facilities undergoing annual inspections. By percentage, there were more violations at each level for study facilities than there were at all facilities inspected nation-wide (Figure 3-2) (FDA, 2005a). Thus, current evidence suggests that reducing the frequency of inspections, even at historically compliant facilities, would negatively impact mammography quality.

Accreditation Failure

The inability of FDA to require facilities to cease performing mammography after two consecutive unsuccessful attempts at accreditation is another area of concern. The ACR has always strongly recommended that these facilities cease mammography, and has terminated accreditation until these facilities take corrective action and reinstate. Until 2003, FDA required facilities to cease in these cases. In 2003, FDA informed accrediting bodies that they can no longer require facilities to cease mammography if their MQSA certificate is still valid. However, FDA does tell these facilities they "should" cease mammography (FDA, 2004a). In the past year, the ACR has documented two cases in which a facility denied accreditation during the renewal process continued to practice mammography, one for 29 days and the other for 32 days, under a valid MQSA certificate.[6] Regardless of MQSA certificate status, facilities failing to reaccredit after two at-

[6] Personal communication, P. Butler, Senior Director, Breast Imaging Accreditation Programs, American College of Radiology, November 15, 2004.

tempts should be required to cease performing mammography until reinstated; FDA should have the authority to enforce this requirement.

Suspensions or Revocations of MQSA Certificates

Regulation 900.13 outlines the role of FDA following the revocation of a facility's accreditation. Currently, FDA can either declare a certificate "no longer in effect" under Section 900.13, or can fully revoke a certificate under Section 900.14, when a facility's accreditation is revoked or when the facility is deemed a serious risk to human health. Both regulations prevent the facility in question from performing mammography; as a result, FDA typically invokes 900.13 for timing and efficiency purposes.[7] Between 2001 and 2003, FDA declared a facility's certificate "no longer in effect" once for reasons of accreditation revocation (FDA, 2004b). Although FDA usually requires these facilities to notify their patients and referring physicians of such action (i.e., Patient/Physician Notification), there is currently no public notification system warning consumers in general about such facilities. FDA should require facilities to notify patients and their physicians if the MQSA certificate either is revoked or deemed no longer in effect.

NATIONAL QUALITY STANDARDS

Prior to the enactment of MQSA, the quality of mammography varied tremendously across the United States (U.S. Government Accountability Office, 1990; Galkin et al., 1988). Much of that variation stemmed from differences in the degree that states enacted legislation or regulations to ensure the quality of mammography within their borders. State legislation details requirements in four main areas: equipment specifications, equipment performance testing, facility quality assurance procedures, and personnel qualifications. More than 40 states enacted laws governing mammography quality in one or more areas, although how extensive these laws are varies from state to state. Required enforcement procedures were also variable from state to state (Fintor et al., 1995). MQSA was designed to foster uniform, high-quality mammography throughout the country by providing national standards that would eliminate the need for the patchwork of state regulations governing mammography standards. In recent years, this patchwork has begun to reemerge; vague regulations regarding requirements for accreditation bodies and the role of states has resulted in significant inconsistencies in the regulation of mammography in different states.

Inconsistencies Across Accreditation Bodies

MQSA provides a degree of decentralized oversight of mammography through the accreditation process. As discussed previously, a mammography facility must apply for reaccreditation through a qualified accreditation body every 3 years, once initial accreditation is granted. Currently, the American College of Radiology and the states of Texas, Iowa, and Arkansas have been approved by FDA to act as accreditation bodies. (California was also approved to accredit facilities, but the state's accreditation program

[7] Personal communication, C. Finder, M.D., Associate Director, Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs (formerly the Office of Health and Industry Programs), CDRH, FDA, October 2004.

was closed in late 2003.) However, MQSA sets standards only for the data that accreditation bodies must collect; specific requirements for accreditation vary across accreditation bodies. One particular area of issue is discussed below.

Qualifications for Review Physicians

Qualifications for physicians serving as image reviewers for accreditation bodies should be more comprehensive than the minimum required to interpret mammograms under MQSA. Accreditation body reviewers reviewing the performance quality of mammography facilities should have considerably more experience than the minimum established for physicians interpreting mammograms. The ACR currently requires review physicians to have 5 years of post residency experience in diagnostic radiology, with at least 50 percent of each year's practice in breast imaging, and be actively practicing in the modality reviewed. Increasing FDA standards to this level is not expected to cause a shortage of qualified review physicians for the state accreditation bodies of Iowa, Texas, or Arkansas. Texas already contracts with ACR-qualified reviewers, and the state of Iowa unofficially applies similar criteria to its own review physicians.[8,9,10] Thus, all accreditation bodies should require review physicians to match current ACR review physician criteria.

Inconsistencies Across States

Many states continue to impose regulations beyond those currently required by FDA, which can lead to confusion regarding state requirements for accreditation or certification that conflict with, or are in addition to, federal MQSA requirements. State requirements can also add to the cost of mammography because states that act as certifying bodies can require facilities to undergo additional inspections and can impose additional inspection fees and fines. For example, Missouri charges an additional per-unit fee at every facility in the state (Mo. Rev. Stat. § 192.764 [1992]; Mammography Authorization 19 C.S.R. 30-11.010 [1992]). Evidence is lacking to evaluate the effects of additional state requirements on facility practices, but these measures do not necessarily improve quality, and might detract from the time and resources devoted to breast imaging. The potential for conflict of interest is also a concern because reviewers for state programs generally reside in the same state they are inspecting. Because an increasing number of states are pursuing status as certification bodies, the Committee agreed that this trend warrants close observation.

MQSA regulations cannot supersede those of states; part (m) of the Act specifically states that "Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section." However, because MQSA regulations are so extensive, there may be a compelling reason to

[8] Personal communication, K. Kemp, Iowa Department of Public Health, November 2004.
[9] Personal communication, K. Goss-Terry, Mammography Accreditation Program Manager, Texas Department of State Health Services, October 2004.
[10] Personal communication, J. Bibb, Mammography Program Administrator, Arkansas Department of Health, November 2004.

BOX 3-2 Examples of Preemptive National Standards

Federal laws and regulations generally preempt state laws of the same scope if that is the expressly stated intent of the federal law or regulation. An example of such preemption is found in Section 521 [360k] of the Federal Food, Drug, and Cosmetic Act (FFDCA). This section specifies for devices intended for human use, that no states may establish, or continue to enforce, any requirement related to safety or effectiveness that is different from, or in addition to, those the federal act requires. Because the preemption clause in regard to the agency's regulation of devices was expressly stated, a case brought against the maker of a heart pump was denied. The claim stated that the device caused a death because it was defectively designed and manufactured, as well as inadequately labeled. The Food and Drug Administration considered the design, manufacturing process, and label of the heart pump before it approved the device for marketing; thus its regulation preempted state law tort claims, the court ruled.

When national laws or regulations do not specify a preemption clause, they can still preempt state laws if there is implied preemption. Such preemption presides when state law conflicts with federal law. For example, California passed a law called Proposition 65, which requires companies to include in the labeling of their products any chemicals that might cause cancer or reproductive toxicity. Armed with this law, a plaintiff sued the maker of nicotine gum and patches for failing to warn that its products were allegedly known to cause reproductive harm. The California Supreme Court ruled that the state law was preempted because it conflicted with the labeling requirements of the FFDCA.

Implied preemption also occurs when federal law is so extensive and pervasive that it can be assumed that Congress did not intend states to supplement it. But it can be waived if state rulings are more comprehensive and traditionally relied on, as was seen in a case regarding the labeling of wines in California. That case hinged on a California law that prohibits the use of the name "Napa" on the label of any wine not made with at least 75 percent of Napa County-grown grapes. This state law was not preempted by federal law because the protection of consumers from potentially misleading brand names and labels of wine is a subject that traditionally has been regulated by the states, the California Supreme Court stated in its ruling. Deference to state rules on wine labels is especially appropriate, the ruling added, considering the importance of the industry to California.

Both implied and expressly stated preemption will prevail only if courts find the state law in question governs the same area as the federal law presumed to preempt it.

SOURCES: High court (2004); Pitney Hardin LLP (2004); California court (2004); Drug and medical device cases (2002); California Office of Environmental Health Hazard Assessment (2003).

explicitly include a preemptive clause (Box 3-2) in the legislation.[11] Replacing part (m) with a reemption clause could help ensure that MQSA regulations are uniformly followed by facilities in all states, largely because these regulations would provide both minimum and maximum requirements for mammography facilities and personnel. An expressly stated preemption clause would also relieve mammography facilities and per-

[11] Personal communication, J.A. Levitt, Esq., Hogan & Hartson LLP, Washington, DC, October 2004.

TABLE 3-2 Self-Reported Estimate of the Cost of MQSA Compliance

MQSA Compliance Category	Cost per Procedure (in hospital, $)	Cost per Procedure (in office, $)
Continuing education/experience	0.90	1.93
Recordkeeping	0.10	0.19
Patient notification	4.84	4.15
Medical audit	7.54	5.78
Quality control tests	0.65	0.57
Annual physicist survey	1.00	0.35
Accreditation	0.31	0.39
MQSA inspection	0.45	0.65
Total	15.79	14.01

NOTES: Compliance with MQSA regulations presents a significant financial burden on mammography facilities. Recently, the American College of Radiology (ACR) conducted a cost survey of mammography practices. The ACR data, obtained from 15 hospital outpatient clinics and 22 office or freestanding practices, calculate the clinical staff, supplies, equipment, and indirect costs of performing screening mammography. To estimate the direct cost of MQSA compliance, the ACR survey data were sorted into eight categories devised by Farria and Feig (2000). Equipment costs, including upgrades to meet MQSA standards, are unknown and omitted from the cost total presented above.

SOURCES: Farria and Feig (2000); Personal communication, P. Kassing, Senior Director, Economics and Health Policy, American College of Radiology, January 5, 2005.

sonnel from the burden and confusion of trying to meet both MQSA and state certification and accreditation requirements.

The Committee believes that federal preemption of state standards is necessary. However, this national standard must be flexible in order to facilitate adoption of standards that may advance the quality of breast imaging. Similarly, if a preemption clause is enacted, provisions should be developed to foster the efforts of states that traditionally have been on the forefront of quality improvement initiatives, and to add such approaches to the national standard in a timely fashion.

THE COSTS AND BENEFITS OF MQSA

In 1997, FDA commissioned a study to assess the economic impact of compliance with MQSA Final Rules (Eastern Research Group and FDA, 1997). The Eastern Research Group (ERG) estimated that the average annualized total compliance cost at the time was $38.2 million by "identifying the most typical, least-cost methods of complying with each requirement," although the report likely underestimated the true cost of compliance. For example, ERG estimated no compliance costs for the medical audit and outcome analysis because project consultants indicated that outcomes analysis was already standard practice at most facilities. However, a recent cost survey conducted by the ACR

indicated that substantial costs are associated with medical audits.[12] The ACR collected self-reported cost data from 37 facilities and estimated that the cost of MQSA compliance was $14–$15.70 per mammogram, as shown in Table 3-2. At the time of their study, the FDA estimated that approximately 22.5 million mammograms were performed per year, which translates to $1.70 per mammogram ($2.00 in 2004 dollars). The true cost of MQSA compliance likely falls somewhere between the two estimates from FDA and the ACR. FDA also used a model to estimate health outcomes at various levels of mammography quality (measured by sensitivity and specificity). The report concluded that a 5 percent improvement in quality would have associated annual benefits of between $182 million and $263 million, with 75 fewer annual breast cancer deaths.

It is difficult to estimate the cost of the Committee's recommendations aimed at improving interpretive quality because costs will vary considerably depending on the current set up of a given facility. For example, facilities that already use software that separates screening and diagnostic exams may be able calculate the required measure with little change. Facilities that do all of their tracking and auditing on paper may find it more expensive to meet the new requirements. Similarly, some facilities already track patients with a BI-RADS 0 assessment, but most do not and thus will experience an additional compliance cost. The added cost of tracking women with 0 assessments will depend in part on the population being served and the recall rate for a particular facility.

Facilities that participate in the voluntary advanced medical audit procedures will likely incur additional costs for data entry, but they will save the time and costs that would be needed to organize and analyze the data (since that will be done by the statistical coordinating center). Also, some facilities may already have established methods of communication with pathologists, whereas others may need to devote considerable effort to establish and maintain adequate communication in order to meet the requirements of the advanced audit. The statistical coordinating center will require funds for staff and infrastructure, perhaps similar to the core costs of the Breast Cancer Surveillance Consortium, but ultimately the cost per mammogram will depend in part on how many providers participate in the advanced medical audit program.

It might be useful for FDA to survey all facilities regarding their intentions to participate in the voluntary advanced audits or to seek designation as a Center of Excellence prior to implementation. FDA could also commission another study on the economic impact of compliance with the new medical audit procedures, as they did in 1997.

SUMMARY AND CONCLUSIONS

The final FDA Mammography Quality Standards Act regulations, promulgated in 1999, understandably require revision given the development of mammography practice in recent years. Advancements in technology, particularly digital mammography, require expansion of the current regulations to ensure quality in each mammographic modality. The Committee specifically recommends removing the regulatory exemption on interventional mammographic procedures. The experience of facilities, personnel, and accreditation bodies with MQSA has revealed several areas of overlap that should be addressed; for example, inspection data have demonstrated that several quality control tests are un-

[12] Personal communication, P. Kassing, Senior Director, Economics and Health Policy, American College of Radiology, January 5, 2005.

necessary due to redundancy and exceptionally low rates of citation, and therefore could be removed. Regarding enforcement of MQSA regulations, FDA must have the authority to stop facilities from performing mammography following two unsuccessful attempts at reaccreditation, regardless of the validity of that facility's MQSA certificate. The Committee also recommends that patients and their referring physicians should be notified when a mammography facility either decides to close or has had its MQSA certificate revoked. Finally, the Committee believes that federal preemption of state standards is necessary to preserve the nature of MQSA as a single, unified set of mammography quality standards.

The Committee recognizes that the recommended revisions will require a substantial amount of work by FDA. The regulation revision process is staff-intensive; formal revisions would require solicitation of input from outside scientific and medical experts as well as mammography facilities and practitioners, followed by public hearings and a public comment period. Current guidance documents would also require revision. In addition to the staff costs associated with regulation revision, additional costs would be incurred by FDA following promulgation of the updated regulations. FDA would be responsible for educating facilities, providers, and inspectors about the revisions, and would also be responsible for strengthening enforcement. Therefore, sufficient funding should be made available to FDA for the additional resources and costs associated with revision of the current MQSA regulations.

In short, revision of the current FDA regulations is necessary to ensure that adequate enforcement of quality standards continues, to streamline the inspection process, and ultimately to reduce the burden of inspections on facilities without reducing mammography quality. Screening is only one stage in the process of breast care. Although the purview of MQSA is limited to breast imaging, other chapters in this report more fully discuss how the process of breast care can be improved.

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4

Ensuring an Adequate Workforce for Breast Cancer Screening and Diagnosis

Recent media reports suggest that shortages of radiologic technologists (RTs) and interpreting physicians (see Box 4-1) have contributed to the closure of some mammography facilities (Martinez, 2000; Gorman, 2001) and articles in trade publications refer to a current or looming "crisis" in access to mammography (Maguire, 2003; Brice, 2004; Hayes, 2004). Although these reports depict alarming situations, they are largely anecdotal or impressionistic; however, it is clear that demand for breast imaging services is increasing and is likely to continue to do so over the coming decades, while there is little to suggest that the numbers of interpreting physicians and RTs will rise accordingly. Although demand for mammography could potentially decrease in the future—for example, if longer screening intervals were recommended for some portion of the population—such changes are difficult to predict. These concerns serve to highlight the lack of data on the national mammography workforce, the volume of services it delivers, and its capacity for expansion—measures that are essential to determining whether, and where, workforce shortages occur and what impact such shortages have, or potentially could have, on the delivery of mammography and other breast imaging services.

In the absence of such data, the Committee relied on several sources of information in order to assess the current and future state of the mammography workforce. These included inspection reports to the Food and Drug Administration (FDA), as well as survey data from the American College of Radiology (ACR; see Appendix A), the Society of Breast Imaging (SBI; see Appendix B), and the American Society of Radiologic Technologists (ASRT). Although FDA does not collect data on individual practitioners, the Committee was able to estimate the total number of physicians who interpreted mammograms each year since 1997. However, it should be noted that these estimates are still likely to be inflated.[1]

It is also important to recognize the limitations of opinion surveys. Although they are helpful in gaining the perspective of current or potential members of the mammography workforce, survey methods are also prone to subject bias and error. Motivational factors may influence the results of surveys that address sensitive subjects such as employment; respondents may be unwilling to provide accurate information for reasons of self-protection or personal gain (Wentland, 1993). In addition, experiments in social psychology suggest that responses to survey questions regarding attitude are influenced by environment, survey type, and the context in which the question is presented (Tourangeau et al., 2000). The Committee's intention in presenting findings from opinion surveys, including those conducted by the ACR and SBI, is to shed light on a variety of attitudes

[1] Aggregate data obtained from FDA contained many duplicates because an interpreting physician is counted each time his or her name is recorded at a facility inspection, and many radiologists read at multiple facilities. A series of queries was used to remove most of the duplicate names, but approximately 10 percent of the entries are still likely to be duplicates, largely due to name misspellings or other variations in data entry.

BOX 4-1 The Mammography Workforce

Interpreting physician: Interprets mammograms. Initial training and qualifications: Must be a physician with a state license to practice medicine and must be board certified in diagnostic radiology by a Food and Drug Administration- (FDA-) approved body or have 3 months of formal training in mammography (although physicians who qualified under the interim regulations only needed two months). Must have a minimum of 60 hours of documented Continuing Medical Education (CME) in mammography (although physicians who qualified under the interim regulations only needed 40 hours), and have interpreted at least 240 mammograms under the direct supervision of an interpreting physician in the 6 months prior to qualifying. Continuing education: Must teach or complete at least 15 Category I CME hours in mammography every 36 months. Continuing experience: Must interpret a minimum of 960 mammograms every 24 months. The ***lead interpreting physician*** in a mammography facility has general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of Section 900.12(d) through (f). Each facility must also designate at least one ***audit interpreting physician*** to review and analyze the medical outcomes audit data. This individual is responsible for documenting the results, for notifying other interpreting physicians of their results and the facility aggregate results, and for documenting the nature of any follow-up actions.

Radiologic technologist (RT): Performs mammographic examinations and prepares films or digitized images for interpretation. Initial training and qualifications: Must be state licensed to perform general radiographic procedures, or have a general certification from an FDA-approved body to perform radiologic examinations. Must complete 40 hours of training specific to mammography, including performance of a minimum of 25 examinations under direct supervision (although technologists who qualified under the interim regulations did not need to perform 25 exams and the number of hours of mammography training was not specified). Continuing education: Must obtain 15 continuing education units every 36 months. Continuing experience: Must perform 200 mammograms every 24 months years.

Medical physicist: Surveys mammography equipment and oversees the equipment-related quality assurance practices of the facility. Initial training and qualifications: Must be board certified in an appropriate specialty area by an FDA-approved body, or be State licensed or approved for medical physics surveys of mammography facilities. Must have a master's degree or higher in physical science with no less than 20 semester hours or equivalent of college undergraduate- or graduate-level physics. Must complete 20 hours of specialized training in conducting surveys of mammographic facilities. Must survey at least 1 mammography facility and a total of 10 mammography units. (Medical physicists who qualified under the interim regulations could continue to perform surveys under the final regulations with a bachelor's degree in physical science and 10 semester hours of physics, provided they had 40 hours of training in surveys and had done surveys of at least one facility and 20 mammography units.) Continuing education: Must obtain 15 continuing education units every 36 months. Continuing experience: Must conduct surveys of two facilities and six units every 24 months.

Continued

BOX 4-1 *Continued*

Breast imaging specialist: Specializes in interpreting the results of mammographic and nonmammographic imaging examinations of the breast and performs interventional procedures, including image-guided biopsies of the breast. Training and qualifications are not defined by MQSA, but are generally considered to include some or all of the following: fellowship training in breast imaging, spending a majority of time on the interpretation of breast images, and conducting a high volume of breast imaging.

Radiologist assistant (RA): A recently created physician extender position, the RA is an advanced-level radiologic technologist who works under the supervision of a radiologist. Experience as an RT is a prerequisite for admission to ACR- and ASRT-approved RA training programs at four U.S. universities (additional programs are under development). The RA is an ARRT-certified radiographer who has successfully completed an advanced academic program encompassing a nationally recognized curriculum and a radiologist-directed clinical preceptorship. Under a radiologist's supervision, the RA performs patient assessment, patient management, and selected examinations. The roles and responsibilities of the RA, as agreed on by the ACR and ASRT, will not include interpretations (preliminary, final, or otherwise) of any radiological examination or the transmission of observations to anyone other than to the supervising radiologist. The RA may make initial observations of diagnostic images and forward them to the supervising radiologist.

SOURCES: 21 C.F.R. § 900.1 (2003); IOM (2004); Williams and Short (2004).

that may influence the present and future breast imaging workforce; it is not an attempt to determine or predict the magnitude of influence associated with a specific attitude or opinion.

Although predicting future workforce trends is fraught with uncertainty, the Committee commissioned Paul Wing, of the Center for Workforce Studies at the State University of New York School of Public Health in Albany, to model the possible effects of current trends and potential changes in regulations on the supply and demand for RTs who perform mammograms and the physicians who interpret them (see Appendix C). Key statistics, derived from the three surveys and the workforce modeling study, are summarized in Box 4-2.

The Committee examined a variety of factors that could limit the future supply of interpreting physicians, including concerns that reading mammograms, as compared with other areas of radiology, is less lucrative, more regulated, and carries greater medicolegal risk. It was also noted that the expanded use of nonmammographic imaging technologies for breast cancer detection and diagnosis are likely to increase future demand for breast imaging, and thereby the workload of some interpreting physicians. These issues are considered in proposing strategies to increase the number of new entrants to the field of breast imaging, retain the current mammography workforce, and enhance the productivity of new and existing practitioners.

BOX 4-2 Key U.S. Mammography Workforce Statistics

In 2003–2004:
Approximately 62 percent of all radiologists interpreted mammograms.

The supply of interpreting physicians was approximately 14,400 full-time equivalent (FTE) radiologists, which translates to approximately 2.4 FTE radiologists interpreting mammograms per 10,000 women aged 40 and older. However, an FTE radiologist is not an FTE interpreting physician, as most are general radiologists who spend a significant portion of their time interpreting other radiologic exams.

The average interpreting physician (50th percentile) read 1,670 mammograms per year.

Among interpreting physicians:

- The 25 percent who interpreted fewer than 1,000 mammograms per year account for 6 percent of all mammograms.
- The 54 percent who interpreted fewer than 2,000 mammograms per year read less than 25 percent of all mammograms.
- The 12 percent who interpreted 5,000 or more mammograms per year read more than 33 percent of all mammograms.

The effective workforce of radiologic technologists (RTs) in mammography is approximately 26,000 FTEs. Less than half of all members of the American Registry of Radiologic Technologists who are certified in mammography work primarily in mammography.

On an average hourly wage basis, RTs working primarily in mammography earned significantly less than those working primarily in nuclear medicine (26 percent), magnetic resonance imaging (12 percent), sonography (10 percent), and computerized tomography (6 percent).

Future projections based on current trends (assumes no change in the numbers of physicians or RTs entering or exiting the field):

The population of women over age 40 will increase by nearly 30 percent by 2025.

The number of interpreting physicians per 10,000 women over age 40 will decline by 14 percent by 2015 and by 23 percent by 2025. The shortfall could be overcome by increasing the number of interpreting physicians or by increasing the volume of mammograms read by the available pool of interpreting physicians.

The supply of RTs will decline by approximately 22 percent by 2025; the number of RTs per 10,000 women over age 40 will decline by 23 percent by 2015 and by 40 percent by 2025.

SOURCES: Wing (2005); American College of Radiology (2004); ASRT (2004a).

TABLE 4-1 Number of Interpreting Physicians by Year

Year (FY)	FDA Aggregate Number	Number of Individuals (most duplicates removed)
1997	56,421	20,604
1998	59,747	20,981
1999	61,225	21,636
2000	62,316	21,625
2001	61,971	21,562
2002	60,559	21,345
2003	59,265	21,029

NOTE: Food and Drug Administration (FDA) aggregate numbers include all interpreting physicians listed on all inspections for the year; hence there are many duplicates. Also, FDA does not inspect 100 percent of facilities during the course of each fiscal year (FY) because facilities can be inspected within a range of 10 to 14 months from their prior inspection date. FDA's actual FY inspection percentage is 98 percent.

FDA Database Deduplication Process

Two files obtained from FDA were first imported into a single Microsoft Access database. This database was then split by inspection year into separate tables, from 1996 to 2004. Each table went through the following steps.

Four new columns were added to the table to hold revised first and last name strings: Physician Last Name Fix, Physician First Name Fix, Physician Last Name Best, and Physician First Name Best.

Two queries targeted entries with contaminated Physician Last Name or Physician First Name data fields. These fields contained extraneous commas, spaces, and other values. The first query copied the Physician Last Name string preceding an embedded comma into the corresponding Physician Last Name Fix column field. The second copied the Physician First Name string following an embedded space into the corresponding Physician First Name Fix column field. This ensured that only the first and last name text strings, and not extraneous data, were copied into the Fix columns.

Data fields that did not require the above cleaning step were merged with the corresponding Fix column into a new Best column (e.g., Physician Last Name and Physician Last Name Fix into Physician Last Name Best). This merging process was carried out for first names as well. A final query appended the Physician Last Name Best and Physician First Name Best columns, removing any duplicates. The resulting nonduplicate entries were saved as a new table. The number of entries in this new table was assumed to equal the number of interpreting physicians for that particular year.

Approximately 10 percent of the entries are still likely to be duplicates, largely due to name misspellings or other variations in name entry during the data entry process. However, note that the percentage of duplication seems to be relatively consistent over time, suggesting that the trend in the number of interpreting physicians is real.

CURRENT STATUS: IS ACCESS TO MAMMOGRAPHY ENDANGERED?

As shown in Table 4-1, the number of interpreting physicians increased by 5 percent between 1997 and 1999, and then declined by about 3 percent by 2003. Although the absolute numbers are inflated due to redundancy in the data source, FDA estimates are

useful in that they reflect year-to-year trends. The ACR estimated a smaller number of interpreting physicians from the results of a 2003 survey[2] of radiologists and nuclear medicine specialists with major ties to radiology (for a detailed account of the ACR's survey methods, see Appendix A). The discrepancy between FDA and ACR estimates probably results from differences in the processes that produced them, and also is exacerbated by variability in name entry that eluded efforts to factor out redundancy.

As the data collection and analysis methods used to produce the ACR estimates were also used to address other questions about workforce, these results were used to model future workforce supply and demand for consistency (see below). In 2003, the ACR estimates that about 16,000 radiologists—60 percent of the U.S. total—interpreted mammograms, and that the equivalent of 2.4 full-time radiologists interpreted mammograms for every 10,000 women in the U.S. population aged 40 years and older. However, it is important to note that a full-time equivalent (FTE) radiologist is not necessarily an FTE interpreting physician. In fact, the vast majority of radiologists who interpret mammograms spend a significant portion of their time reading other types of images. The actual number of full-time equivalent interpreting physicians is thus much lower. As no attempt has been made to determine the optimal ratio of radiologists (or interpreting physicians) to women aged 40 and older, the ratio calculated by the ACR is meaningful only as a basis of comparison from year to year. Moreover, if such an optimal ratio could be determined, it would need to reflect technological innovation and screening intervals, and therefore would probably change over time. Although the volume of mammograms read by individual practitioners cannot be determined from FDA data, the ACR has collected such information. Figure 4-1, which classifies interpreting physicians in the United States according to the volume of mammograms they read during 2003, shows that 75 percent of the 16,000 estimated interpreting physicians read at least 1,000 of them, and 46 percent read at least 2,000. Seventy to 80 percent of radiologists in small and medium-sized practices (2 to 10 radiologists) interpreted mammograms, as compared with less than 40 percent in large, and apparently more specialized, practices (30 or more radiologists).

The ASRT's 2004 data indicate that approximately 26,000 full-time RTs work primarily in mammography in the United States (ASRT, 2004a). They comprise less than half of all technologists certified by the American Registry of Radiologic Technologists (ARRT) who are certified in mammography.

Unfilled Positions

One frequently cited indicator of workforce supply relative to demand in mammography is the number of unfilled job openings for interpreting physicians and RTs who perform mammography. In the SBI's October 2003 survey,[3] 29 percent of nearly 570 breast imaging practices reported unfilled positions for physicians. More than a third of

[2] The 2003 ACR survey (see Appendix A) was sent to a "stratified random sample" of 3,090 physicians derived primarily from the American Medical Association's Physician Masterfile, representing vascular/interventional radiologists, all other types of allopathic radiologists, osteopathic radiologists, and nuclear medicine specialists with major ties to radiology (e.g., those holding American Board of Radiology [ABR] certification and/or membership in the ACR). The sample included residents, fellows, and retirees; 1924 usable responses were received, yielding a response rate of 63 percent.

[3] The October 2003 SBI survey was sent to every breast imaging practice (one survey per practice) in the organization's database. Surveys were received from 575 practices (64 percent of study population).

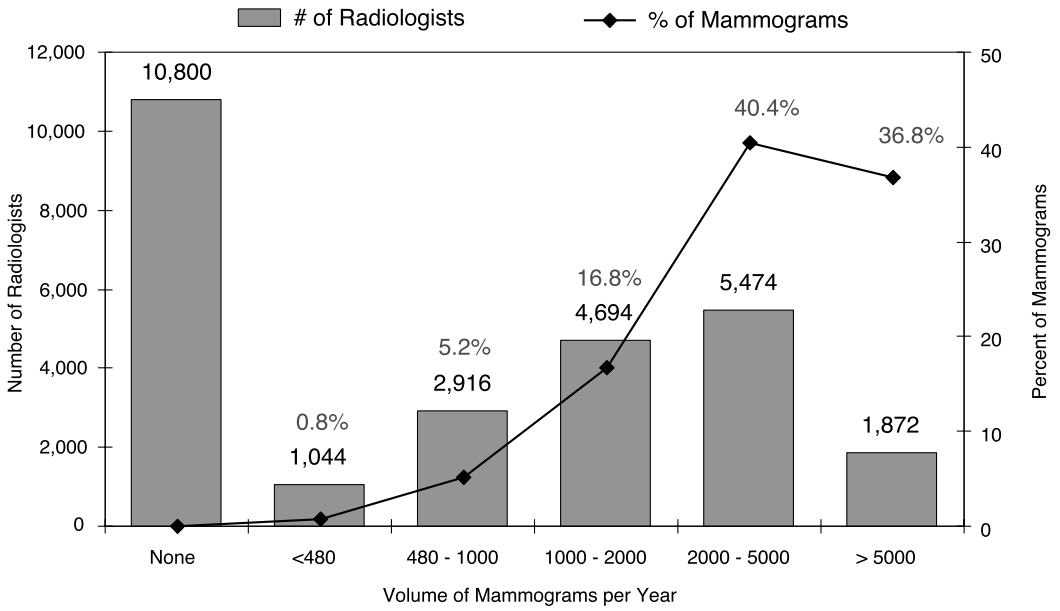

FIGURE 4-1 Estimated radiologists interpreting mammograms and percentage of total mammograms, by volume, United States, 2003. According to the figure, 5,474 radiologists read between 2,000 and 5,000 mammograms per year, accounting for 40.4 percent of all mammograms read each year.
SOURCE: Derived from Sunshine et al. (2004a) and Wing (2005).

these practices had two or more such openings, and nearly one-quarter had been attempting to hire an interpreting physician for more than 2 years (Farria et al., in press). There were many more interpreting physician and RT openings in academic practices than in private and government practices. Nearly two-thirds of the 12 percent of practices surveyed that offered breast imaging fellowships reported that these positions were unfilled. A survey of 53 community-based mammography facilities in three states (Washington, New Hampshire, and Colorado) conducted by D'Orsi and coworkers (2005) in 2001–2002 found shortages of interpreting physicians relative to mammography volume in 44 percent of these facilities.

Job vacancies in mammography do not appear to reflect an overall trend within radiology, which in 2003 saw multiple signs that a severe shortage of radiologists had eased (Sunshine et al., 2004b). Demand for all types of specialist physicians, and particularly for radiologists, rose between 2002 and 2003 (Merritt, Hawkins & Associates, 2003). The New York State Resident Exit Survey found that starting salaries for radiologists in general (both diagnostic and therapeutic) who had completed training within that state rose more than 37 percent between 1999 and 2003, and more than 45 percent between 1998 and 2003 (Center for Health Workforce Studies, 1999–2004). This survey indicates a slight drop (about a 2 percent change) in median salary between 2002 and 2003, but that came on the heels of a more than 17 percent in-crease between 2001 and 2002. Inasmuch as academic radiologists' salaries reflect general trends in the field, it can

also be noted that the median compensation[4] for a full-time assistant professor of diagnostic radiology rose by about 23 percent between 1999 and 2003, according to the Association of American Medical Colleges (1999–2003). This survey also reported a 9 percent median increase for assistant professors in all clinical departments and a 14 percent salary rise for those in therapeutic radiology over the same period. Year-to-year trends in these figures show a slight slowdown in annual salary increases for academic diagnostic radiologists after 2001–2002.

Trends in vacancies for mammography RT positions appear to mirror those for interpreting physicians. Thirty percent of the breast imaging practices that responded to the SBI survey reported unfilled mammography technologist positions; of these, 45 percent had two or more openings in 2003 (Farria et al., in press). Similarly, 20 percent of the community mammography facilities that responded to the aforementioned survey by D'Orsi and coworkers reported a shortage of MQSA-qualified RTs; 46 percent reported some difficulty in maintaining an adequate staff of qualified technologists (D'Orsi et al., 2005).

Data from the ARRT indicated a steady and substantial decline in examinees for certification in mammography between 1996 and 2000 (American Registry of Radiologic Technologists, 2001). However, since the exam was first offered in 1992, this decline may in part reflect the fact that many people taking the exam in its first few years were already working in the field (IOM, 2001). Since 2000, the total number of registrants has remained essentially flat, although 2003 showed the first increase in first-time examinees in recent years (a nearly 6 percent increase over the number of first-time examinees in 2002).

A key barrier to filling RT positions in mammography is their low pay in comparison to RT positions in other subspecialties. In the 2003 SBI survey, wages for RTs working primarily in mammography ranked third out of four radiology subspecialties (Farria et al., in press). On an average hourly wage basis, mammography RTs earned significantly less than those working primarily in nuclear medicine (26 percent), magnetic resonance imaging (MRI) (12 percent), sonography (10 percent), and computerized tomography (CT) (6 percent), according to the ASRT (2004b).[5] The average salaries of RTs who worked primarily in nuclear medicine in 2004 were 28 percent higher than those who worked primarily in mammography (ASRT, 2004b).

Medical physicists (see Box 4-1) also play an essential role in the breast imaging workforce, but supply/demand issues for these professionals are less well understood than those of interpreting physicians and RTs. A 1993 report written by the National Mammography Quality Assurance Advisory Committee showed that there were 511 medical physicists qualified under the interim rules to perform mammography surveys, and concluded that this number was sufficient to support mammography across the United States (National Mammography Quality Assurance Advisory Committee, 1996). However, concerns were subsequently raised that there would not be enough physicists to perform MQSA evaluations unless physicists substantially increased the number of mammography units they evaluated each year (Rothenberg et al., 1995). Moreover, a 2001 survey of

[4] Compensation includes salary, practice supplement, bonus/incentive pay, and uncontrolled outside earnings.

[5] Personal communication, R. Harris, ASRT Director of Research, November 10, 2004.

TABLE 4-2 American College of Radiology (ACR) Mammography Accreditation Program: Reason for Facility Closures Since April 2001 (as of October 2004)

Reason	Number of Facilities Closed	% of Total
Financial	523	33.5
Moved to sister site	370	23.7
Equipment	173	11.1
Staffing	161	10.3
Unknown	159	10.2
Other	84	5.4
Bankruptcy	34	2.2
Change in ownership	30	1.9
Mobile unit merged with another site	29	1.9
Total	1,563	—

SOURCE: Destouet et al. (In press). Reprinted from the *Journal of the American College of Radiology*, In press, Destouet JM, Bassett LW, Yaffe MJ, Butler PF, Wilcox PA. The American College of Radiology Mammography Accreditation Program—10 years of experience since MQSA, with permission from The American College of Radiology.

850 medical physicists revealed that clinical activities in breast imaging were among the most time-consuming activities they performed (Cypel and Sunshine, 2004). Due to the dearth of recent data in general—let alone among those who evaluate mammographic equipment—the possibility of a present or future shortage of medical physicists active in breast imaging cannot be determined. Nonetheless, the lack of even anecdotal reports on the supply of and demand for medical physicists suggests there is no shortage of these personnel.

Facility Closures

The ACR documented the closure of 1,563 (out of 8,325, or about 19 percent) facilities accredited by that organization between April 2001 and October 2004 (Destouet et al., in press). Although partially offset by the opening of hundreds of new facilities, these closures contributed to a net loss of 752, or more than 8 percent, of ACR-accredited facilities over that time period. Financial factors, cited by about one-third of respondents, were the most frequent reason for facility closures, as shown in Table 4-2. The second most common reason for the closure of ACR-accredited facilities, "moved to sister site," was cited in nearly one-quarter of these cases. This response may reflect consolidation that could provide more efficient delivery of services, but the prevalence of such closures suggests that access to mammography may have declined in many communities. According to FDA, the number of mammography units operated by hospitals and clinics rose 5.4 percent between 2000 and 2004.

As a result of concerns about the increasing number of mammography facility closures, the U.S. Government Accountability Office (GAO) is currently conducting a

study to evaluate the factors that contributed to the closing of facilities nationwide since 2001. The study, to be completed by July 2005, will attempt to determine whether these facilities closed due to consolidation, or whether they represent a true reduction in mammography availability. It will also explore the relationship between certified units and facility capacity, evaluate capacity issues, and determine the effect facility closings have had on public access (including underserved populations) to mammography services since the April 2002 GAO report on access to mammography.[6]

Wait Times for Screening and Diagnosis

A national survey of 9,908 mammogram facilities conducted in 1999–2000 found that 64 percent could schedule a patient for a screening mammogram within 7 days (IMV Medical Information Division, 2002). Similar results were obtained in a statewide survey representing 89 percent of licensed mammography practices that was conducted by the Florida Department of Health in July 2004, in conjunction with a study of the accessibility of mammography services in that state (The Workgroup on Mammography Accessibility, 2004). Survey results indicated that wait times for screening mammograms in the nation's fourth most populous state were highly variable, ranging from less than 24 hours to several months, but that 50 percent of appointment wait times were less than 3 days. The median wait time for a diagnostic mammogram scheduled by the patient was 2 days, and if scheduled by a physician, 1 day. Seventeen percent of mammography practices reported appointment wait times exceeding 28 days for screening mammograms (as compared with 8 percent in the national survey) (Eastern Research Group and U.S. Food and Drug Administration, 2001), 24 percent had patient-scheduled diagnostic appointment wait times longer than 7 days, and 21 percent had physician-scheduled appointment wait times longer than 7 days.

Reports of lengthy wait times for mammograms indicate that some breast cancer screening facilities are operating at or near full capacity (IOM, 2001). In New York City, patients waited an average of more than 40 days in 2003 for first-time screening mammograms, as compared with 14 days in 1998 (Maguire, 2003). In 2004, waits for screening mammograms in Jacksonville, Florida, where four breast imaging centers had closed within 2 years, reportedly ranged from 10 weeks to more than 5 months. The aforementioned three-state survey of community-based mammography facilities reported wait times for screening mammograms of up to 8 weeks (D'Orsi et al., 2005).

Mammography facilities with staff vacancies are likely to require longer wait times for appointments. The 2003 SBI survey found a strong association between the percentage of unfilled radiologist or RT positions in breast imaging practices and the length of time symptomatic women had to wait for a mammogram (Farria et al., in press). In facilities where at least 80 percent of either radiologist or RT positions were filled, average wait times for symptomatic women were less than 24 hours. Where only 40 percent of either radiologist or technologist positions were filled, symptomatic patients waited an average of at least 2 weeks.

The Florida accessibility study identified several additional factors contributing to longer wait times for mammography appointments. These included reports by

[6] Letter from Arlen Specter, Tom Harkin, and Barbara A. Mikulski, U.S. Senate, to David M. Walker, Comptroller General, GAO, June 15, 2004.

TABLE 4-3 Fees for Screening Mammograms Vary by Insured Status

Insurance Status	Amount (2004)
Private insurance[a]	$167.00
Uninsured[b]	$106.39
Medicare[c]	$88.54
Medicaid[d]	$45.48

[a] The amount reported for private insurance identifies the fee considered fair and reasonable as reported by the Florida Department of Health.

[b] Based on survey results from the American Cancer Society's *Mammography in Florida: A Consumer's Guide*, July 2004. This amount represents the average fee amount for a screening mammogram for the reporting facilities.

[c] For Medicare, the amount is the maximum authorized for screening mammograms. The reimbursement rate is 50 percent higher for screening mammograms when digital equipment is used. Medicare patients pay 20 percent of the Medicare-approved amount.

[d] Medicaid patients pay an additional $3 co-payment.

NOTE: Fees listed are from the state of Florida.

SOURCES: The Florida Legislature: Office of Program Policy Analysis & Government Accountability (2004); American Cancer Society (2004).

interpreting physicians at facilities with long wait times that they limited the number of mammograms they read in order to limit their exposure to medical malpractice lawsuits (The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). Women with private health insurance and/or who are members of health maintenance organizations may also face extended wait time because their primary physicians are contractually obliged to refer patients to designated—and therefore, high-volume—mammography facilities. Most importantly, however, the Florida study found that low-income women face a variety of barriers to access to mammography, as described below.

There is no consensus regarding optimal or acceptable wait times for screening or diagnostic appointments. Like other measures of workforce capacity, there are no national data to systematically assess wait times. There are different ways to measure this parameter, but consistently recording time to the third appointment (a standard measure for access in the health care industry; [National Quality Measures Clearinghouse, 2004]) for both screening and diagnostic exams would be a useful start.

Low-Income Limits Access

Many studies have identified a link between socioeconomic factors and limited access to mammography (reviewed by Lawson et al., 2000; Lannin et al., 2002; Ward et al., 2004). In Florida, the cost of services and the stipulation by most facilities that a woman must obtain a referral for a mammogram from a primary care provider were found to limit access to mammography for low-income women without insurance (The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). For women in Florida's Medicaid Program, reimbursement rates and facility admission criteria can serve as barriers to obtaining mammography services. More than 20

percent of the mammography facilities surveyed reported that they do not provide mammography services for Medicaid recipients; other facilities that accept Medicaid recipients limited the number of recipients served. Low reimbursement rates were cited as a primary reason for excluding or limiting the number of Medicaid patients (Table 4-3). In addition, Florida's Medicaid program does not currently reimburse for mammography at mobile facilities, although that restriction is currently under examination.

As a result of such barriers to mammography, while 65 percent of all Florida women aged 40 and older received annual mammograms in 2002, only 42 percent of Florida women over 40 without insurance, and a mere 4 percent of those on Medicaid, did so (The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). Nationally, 64 percent of insured women aged 40 and older received mammograms within the past 2 years (as of 2002), as compared with 38 percent of uninsured women aged 40 and older (Centers for Disease Control and Prevention, 2002).

Increasing Demand for Breast Imaging Services

In the absence of a comprehensive measurement of national mammography usage—and one that distinguishes between screening and diagnostic examinations—researchers have attempted to estimate mammography use through a variety of means. Most utilize self-report survey data, but a recently developed methodology uses disparate data sources, including screening registry data provided by the Breast Cancer Surveillance Consortium, to obtain a comprehensive model of screening use (Cronin et al., in press). As one might expect, the specific results of these exercises vary. However, similar trends in year-to-year increases in mammography usage emerge from these disparate estimates. According to GAO, mammography utilization rose 15 percent between 1998 and 2002 (U.S. Government Accountability Office, 2002). Between 2000 and 2003, mammography rates among privately insured women rose nearly 16 percent (Brice, 2004). The total number of mammography procedures (including an unknown proportion of diagnostic mammograms) reported to FDA has increased by more than 6 percent per year for the past 2 years (between December 2002 and January 2005).[7]

Accordingly, in 2003, 75 percent of breast imaging practices reported increased patient volume over the previous 2 years, according to the SBI (Farria et al., in press). Ninety-six percent of these practices attributed the upswing to "increased demand," interpreted as a combination of an increase in the number of women eligible for screening mammography, better compliance with examination guidelines by women over age 40, and greater use of a broadening spectrum of services offered by breast imaging practices, as described below.

FUTURE PROJECTIONS: WORKFORCE DEMAND OUTSTRIPS SUPPLY

In an effort to predict the future supply and demand of the mammography workforce, the Committee commissioned Paul Wing, of the Center for Workforce Studies at the State University of New York School of Public Health in Albany, to model the possi-

[7] Provided by T. Haran, Chief, Information Management Branch, Mammography Program Reporting and Information System Program Manager, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, FDA, October 2004.

ble effects of current trends and potential changes in regulations on the workforce. An age-cohort flow model (described in detail in Appendix C) was used to project the future supply of radiologists and radiologic technologists working in mammography (Wing, 2005). The current rates of entry into and departure from the field were estimated and predictions were made based on the assumption that these rates will remain essentially unchanged over the next 20 years. From this baseline model, predictions were made regarding the total number of specialists in the field; the ratio of specialists per 10,000 women over the age of 40, as predicted by the U.S. Census Bureau; and the workforce increases needed to implement potential new mandatory changes in mammography interpretation (e.g., double reading or an increase in the minimum reader volume).

The model of the projected supply of interpreting physicians depicted in Table 4-4 predicts that the number of radiologists interpreting mammograms will remain essentially flat through 2025. Thus, as the population of women over 40 increases by nearly 50 percent (U.S. Census Bureau, 2004), the number of practitioners per 10,000 women over age 40 is expected to decline by 14 percent by 2015, and by 23 percent by 2025. If the average volume of mammograms read by interpreting physicians remained constant, the number of new interpreting physicians would have to increase by 38 percent in order to maintain the current ratio of interpreting physicians to women 40 and over in future years.

Another way of increasing the effective supply of interpreting physicians would be to increase the volume of mammograms they read. Because the total number of interpreting physicians who spend more than 30 percent of their time interpreting mammograms is small, further increasing their volume would have a minimal impact on the workforce. Convincing radiologists who currently devote no time to mammography to begin reading mammograms appears also to offer only a marginal impact on the effective supply. To make a major impact, one would have to convince a large number of these radiologists (50 percent in Table 4-4b) to read 1,000 mammograms per year (Table 4-4b) in order to make a significant difference (the equivalent of approximately 1,080 radiologists who read 5,000 mammograms per year). That leaves the group currently devoting less than 30 percent of their time to mammography. If this group, which represents about half of all radiologists, could be convinced to increase their mammography volume by a third, it would increase the effective workforce supply by 34 percent (the equivalent of approximately 1,620 radiologists who read 5,000 mammograms per year). However, the capacity for increasing reading volume in the workforce is unknown, and would probably require radiologists to reduce their volume of nonmammographic interpretation.

Table 4-5 shows similar trends toward supply/demand imbalances for RTs who perform mammograms. In fact, if the current rates of entrants and departures from the field remain constant, their numbers are expected to decline by approximately 22 percent by 2025. Thus the decline in the number of mammography technologists per 10,000 women over age 40 is expected to drop even more than that predicted for radiologists—by 23 percent in 2015 and by 40 percent in 2025. If the number of RTs entering mammography increased from the actual 2000 to 2003 levels of approximately 1,150 per year, to 1,610 per year (a 40 percent increase), then the number of RTs performing mammography would remain approximately constant out to 2025 and beyond. If the number of RTs entering mammography increased to 2,235 per year (a 94 percent increase), then the

TABLE 4-4 Projected FTE Supply of Radiologists Performing Mammography. (A) Status quo projections for the United States, 2003–2005. Assumes constant introduction of new radiologists interpreting mammograms, constant rate of departure of radiologists interpreting mammograms, constant average interpretive volume, and increasing numbers of women 40 and older, per U.S. Census Bureau projections. (B) Impact on the effective supply of radiologists reading mammograms of increased interpretive volume.

A

1-Year Additions[a] 525 (%)	5-Year DDR[b] (%)	Age Group	Baseline 2003	Year 2005	2010	2015	2020	2025
17.1	0.0	<35	449	449	449	449	449	449
57.0	0.0	35–39	1,943	1,944	1,945	1,945	1,945	1,945
11.9	0.0	40–44	2,252	2,253	2,256	2,258	2,258	2,258
14.0	0.0	45–49	2,620	2,620	2,621	2,624	2,625	2,625
0.0	28.8	50–54	2,620	2,620	2,620	2,621	2,624	2,625
0.0	20.3	55–59	1,865	1,865	1,865	1,865	1,866	1,868
0.0	55.1	60–64	1,486	1,486	1,487	1,487	1,487	1,487
0.0	52.0	65–69	666	666	667	667	668	668
0.0	60.0	70–74	317	318	320	320	320	320
0.0	86.0	75+	194	194	195	195	196	196
100.0	—	Total	14,411	14,416	14,425	14,431	14,437	14,441
Women 40 + (000s)			68,357	70,197	75,265	79,633	83,888	88,583
Number / 100K Pop			21.1	20.5	19.2	18.1	17.2	16.3
Percent Change (%)			—	–2.6	–6.7	–5.4	–5.0	–5.3
Cumulative Percent Change (%)			—	–2.6	–9.1	–14.0	–18.4	–22.7

TABLE 4-4 Continued

B

Time Devoted to Mammography	Total Rads	Current Mammography Workload				Increased Mammography Workload			
		% Who Do Any	Avg. # per Rad	Total # (000s)	% of Total	% Who Do Any	Avg. # per Rad	Total # (000s)	% of Total
No time in breast imaging	10,800	0.0	0	0	0.0	50.0	1,000	5,400	—
Less than 30 percent of time in breast imaging	13,500	98.7	1,767	23,849	63.3	98.7	2,400	31,965	34.0
From 30 to 50 percent of time in breast imaging	1,000	98.7	5,213	5,143	13.7	98.7	5,500	5,426	5.5
At least 50 percent of time in breast imaging	1,500	98.9	5,834	8,655	23.0	98.9	5,834	8,655	0.0
Total	26,800	—	—	37,647	100.0	—	—	51,445	36.7

[a] New physicians added every year to maintain new entrant counts, estimated; percentages represent estimated allocation of new practitioners by age group.
[b] Rate of deaths, departures, and retirements (for 5-year groups), estimated; percentages represent estimated percentages of an age cohort that will retire, die, or otherwise depart from practice in a 5-year interval.
SOURCES: Derived from Sunshine et al. (2004a), Wing (2005), and U.S. Census Bureau (2004).

TABLE 4-5 Full-Time Equivalent (FTE)[a] Supply of Radiologic Technologists Performing Mammography: Status Quo Projections for the United States, 2004 to 2025

1-Year Additions[b] 938 (%)	5-Year DDR[c] (%)	Age Group	Baseline 2003	Year 2005	2010	2015	2020	2025
4.2	0.0	<25	196	196	197	197	197	197
25.0	0.0	25–29	1,368	1,368	1,369	1,369	1,369	1,369
40.3	0.0	30–34	3,256	3,256	3,258	3,259	3,260	3,260
11.2	0.0	35–39	3,782	3,781	3,781	3,783	3,784	3,785
16.2	0.0	40–44	4,544	4,543	4,541	4,541	4,543	4,544
3.1	11.5	45–49	4,689	4,689	4,688	4,687	4,686	4,688
0.0	36.5	50–54	4,150	4,150	4,150	4,149	4,148	4,147
0.0	56.2	55–59	2,633	2,633	2,635	2,635	2,635	2,634
0.0	74.0	60–64	1,153	1,153	1,153	1,154	1,154	1,154
0.0	82.5	65+	364	363	363	363	364	364
100.0		Total	26,132	26,132	26,136	26,138	26,139	26,142
Women 40 + (000s)			68,357	70,197	75,265	79,633	83,888	88,583
Number / 100K Pop			38.2	37.2	34.7	32.8	31.2	29.5
Percent Change (%)			—	–2.6	–6.7	–5.5	–5.1	–5.3
Cumulative Percent Change (%)			—	–2.6	–9.2	–14.1	–18.5	–22.8

[a] FTE = (mammography is 1st specialty)*1.0 + (mammography is 2nd specialty)*0.5.

[b] New RTs added ever year to maintain new entrant counts, estimated; percentages represent estimated allocation of new practitioners by age group.

[c] Rate of deaths, departures, and retirements (for 5-year groups), estimated; percentages represent estimated percentages of an age cohort that will retire, die, or otherwise depart from practice in a 5-year interval.

NOTE: Assumes constant introduction of new RTs performing mammography, constant rate of departure of RTs performing mammography, and increasing numbers of women 40 and older, per U.S. Census Bureau projections.

SOURCES: Derived from ASRT (2004a), Wing (2005), and U.S. Census Bureau (2004).

number of RTs performing mammography would increase at about the same rate as the number of women 40 and older.

Measures proposed later in this chapter intended to increase the number of new entrants to the field of breast imaging, to retain the current mammography workforce, and to increase productivity of new and existing practitioners could improve future access to mammography. However, a predicted impending shortage of all physicians and the nation's lack of capacity to expand medical class sizes may severely restrict growth in thenumber of interpreting physicians for several years to come (Cooper et al., 2003; RSNA, 2004b). Moreover, the field appears poised to experience a net loss of practitioners because more than half of radiologists interpreting mammograms are older than age 50 (Sunshine et al., 2004a; Smith-Bindman et al., 2005). This possibility is alarming, given simultaneous demographic trends that promise to increase demand for breast imaging over the next two decades.

The availability of sufficient mammography facilities and equipment to meet demand may also be a concern. In Florida, mammogram equipment capacity was estimated to be capable of serving 3.4 million women per year in 2004, but 3.3 million women were

expected to receive mammograms that year (The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). If demographic and compliance trends in that state continue, demand for mammograms is expected to exceed machine capacity by 2006.

Although a decline in mammography utilization rates over the next two decades appears unlikely, changes in recommended screening interval could reduce demand. Consensus does not exist as to the optimal screening interval (Smith et al., 2003). Several analyses indicate that shorter screening intervals for women aged 40 to 49 improve cancer detection at an earlier stage (which is associated with lower mortality), but offer no such advantage for older women (Jansen and Zoetelief, 1997; Duffy et al., 1997; White et al., 2004; Aiello et al., 2005).

If the hoped-for development of methods to predict breast cancer risk on an individual basis became reality, it could allow the relatively large number of women at low risk to be screened less frequently (IOM, 2005). On the other hand, several factors, discussed below, could raise future demand for mammography and associated breast imaging services. These include the increased use of additional breast imaging technologies, as well as potential changes in MQSA to increase continuing experience (minimum volume) requirements or to require double reading for all screening mammograms. These sorts of changes could move the current fragile stability of the breast imaging workforce toward a crisis.

Increasing Use of Additional Breast Imaging Technologies

If compliance rates for regular mammograms among women over age 40, estimated at 64 percent in 2002 (Centers for Disease Control and Prevention, 2002), increase, not only will demand for mammography rise accordingly, but also for other follow-up breast imaging services and interventional procedures. For example, about half of women recalled for additional imaging are examined by ultrasound. These trends are illustrated in workforce burden estimates, based on several outcome surveys of women with positive mammograms, as shown in Table 4-6 and Figure 4-2. According to the SBI survey, core biopsy and stereotactic core biopsy were offered, respectively, by 89 percent and 79 percent of responding breast imaging practices; 17 percent of practices stated they performed same-day core biopsies (Farria et al., in press).

In addition, a variety of other breast imaging technologies are increasingly employed to complement mammography. Some facilities are beginning to offer women at high risk other nonmammography screening tests for breast cancer, even though that is not currently recommended as the standard of care in any breast screening guidelines. Initial studies on these technologies are fueling demand. For example, 35 percent of the breast imaging practices that responded to the 2003 SBI survey reported that they offered screening ultrasound—more than twice as many as in 2000 (Farria et al., in press). Ultrasound imaging is offered in addition to a mammogram and must be correlated with it, and ultrasound images require more elaborate, real-time interpretation than a mammogram. Moreover, a small percentage of ultrasound results lead to additional, time-consuming procedures such as biopsies that might not have been suggested by mammography alone.

The SBI survey also found that 12 percent of breast imaging practices offered MRI screening, and 51 percent offered diagnostic MR (Farria et al., in press). Like ultrasound, MR images reportedly take significantly longer to interpret than a mammogram;

TABLE 4-6 Estimate of Workforce Burden Subsequent to Screening Mammography

Service	Percentage of Women Screened Ages 40–79 (%)	Procedures per 1,000 Screening Mammograms	Source[a]
Diagnostic mammography			
Call backs	7.2	72	Sickles et al. (in press)
Short-term follow-ups	5.0	50	Yasmeen et al. (2003)
Ultrasound			
Call backs	3.6	36	Sickles et al. (in press)
Short-term follow-ups	2.5	25	Yasmeen et al. (2003)
Biopsy			
Call backs	1.0	10	Sickles et al. (in press)
Short-term follow-ups	0.25	2.50	Yasmeen et al. (2003)

[a] Primary source: Personal communication, B. Monsees, M.D., Washington University in St. Louis, October 19, 2004.

MR also requires additional staffing and frequently leads to second-look ultrasound imaging. Demand for MR is likely to increase in response to recent reports of its superior sensitivity for detecting abnormalities that strengthened the case for its limited use in high-risk[8] populations of women (Liberman et al., 2003; Kriege et al., 2004; Warner et al., 2004).

Despite the fact that the value of these technologies for breast cancer screening has yet to be confirmed (Kopans, 2004; Lee, 2004; Irwig et al., 2004), demand for non-mammographic breast imaging services has driven insurance coverage in some cases, especially in the northeastern United States.[9] MR imaging is more costly than mammography (Table 4-7). Although data are currently limited on the number of facilities offering these services and the number of women receiving them, the Committee expects that increasingly significant downstream costs and workforce burden will result from MR false positives. For example, Liberman et al. (2003) found that 24 percent of the high-risk women[10] in their study received a "probably benign" interpretation at their first breast MR imaging screening exams. Of the nearly 80 percent of these women who underwent the recommended follow-up MRI (within an average of 11 months), only about 10 percent were found to have malignancy in the area initially judged to be "probably benign."

[8] Women with mutations in BRCA1 or BRCA2 (Warner et al., 2004) or women with a genetic or familial predisposition (a cumulative lifetime risk of breast cancer of 15 percent or more) to breast cancer (Kriege et al., 2004).

[9] Personal communication, B. Monsees, M.D., Professor and Chief of Breast Imaging, Mallinckrodt Institute of Radiology, Washington University Medical Center, February 14, 2005.

[10] Women with prior breast carcinoma, biopsy-proven lobular carcinoma in situ or atypia, or a family history of breast carcinoma.

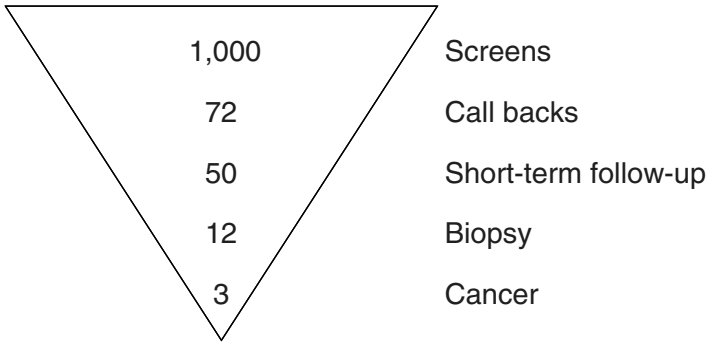

FIGURE 4-2 Simplified screening mammogram outcome pyramid. For every 1,000 mammograms, 72 individuals are recalled for additional imaging, 50 individuals are told to return in three months for a follow-up exam, 12 individuals are recommended for biopsy, and 3 individuals will be diagnosed with breast cancer.
SOURCES: Sickles et al. (in press); Personal communication, B. Monsees, M.D., Washington University in St. Louis, October 19, 2004. Adapted from Helvie (2004).

The Committee expressed concern that the publicity surrounding studies of MR use in high-risk women, as well as the relatively high rate of reimbursement for this procedure as compared with mammography, could lead to the inappropriate use of MR in breast imaging.

Even the hoped-for time savings conferred by digital mammography and computer-aided detection (CAD) appear to be elusive. A recent study conducted by researchers at Michigan State University found that on average, radiologists spent nearly twice as long interpreting a digital screening mammogram as compared with a film image; moreover, this difference persisted even after approximately 2 years of experience with digital mammography (Aben et al., 2004). Another recent study found that use of CAD did not shorten the amount of time required to read films (Taplin et al., submitted).

Potential Impact of Changes to MQSA Continuing Experience Requirements

The distribution of radiologists' volumes of mammogram interpretation in 2003, shown in Figure 4-1, was used to determine the effect of increasing the continuing experience (minimum volume) requirement from the current minimum of 960 mammograms every 24 months to either 1,000 or 2,000 mammograms per year. Raising the minimum interpretation volume to 1,000 mammograms per year would affect about 4,000 radiologists (25 percent of all practitioners) who interpreted approximately 6 percent of all mammograms performed in 2003 (Wing, 2005). If the minimum were raised to 2,000 mammograms per year, the change would affect about 8,700 radiologists (54 percent of all practitioners) who accounted for approximately 23 percent of all mammograms interpreted in 2003.

TABLE 4-7 Medicare Reimbursement for Selected Radiology Procedures, 2005

Procedure	CPT Code	Professional		Technical	
		RVU	Payment ($)	RVU	Payment ($)
Screening mammography (film)	76092	0.96	36.38	1.30	49.27
Screening mammography (digital)	G0202	0.96	36.38	2.61	98.91
Bilateral diagnostic mammography (film)	76091	1.19	45.10	1.38	52.30
Bilateral diagnostic mammography (digital)	G0204	1.19	45.10	2.57	97.40
Unilateral diagnostic mammography (film)	76090	0.96	36.38	1.11	42.07
Unilateral diagnostic mammography (digital)	G0206	0.96	36.38	2.08	78.83
CAD (screening mammography)	76083	0.09	3.41	0.43	16.30
CAD (diagnostic mammography)	76082	0.09	3.41	0.43	16.30
Breast sonography	76645	0.74	28.04	1.11	42.07
MRI, unilateral breast	76093	2.23	84.51	18.54	702.62
Stereotactic core breast biopsy	76095	2.20	83.37	7.53	285.37
Wire needle localization	76096	0.77	29.18	1.38	52.30
Contrast X-ray exam of aorta	75625	1.58	59.88	13.25	502.14
Chest radiograph, two views	71020	0.30	11.37	0.66	25.01
Foot radiograph, two views	73620	0.22	8.34	0.51	19.33
MRI of brain, with and without contrast	70553	3.25	123.17	26.19	992.54
CT of brain, with and without contrast	70470	1.75	66.32	7.44	281.96
CT of abdomen with and without contrast	74170	1.92	72.76	8.92	338.05
Three-phase bone scan	78315	1.40	53.06	5.03	190.62
Barium enema	G0106	1.35	51.16	2.36	89.44
Transvaginal echography	76830	0.95	36.00	1.62	61.39

NOTE: Reimbursement rates were calculated using the 2005 conversion factor of $37.897. Actual payment varies by geographic location.

SOURCE: CMS (2004a).

Because the percentages of radiologists interpreting high and low volumes of mammograms are not evenly distributed across the United States, these averages cannot reflect the potential local impacts of increasing the minimum volume requirement for mammogram interpretation. The data presented in Table 4-8, which displays radiologists' interpretation volumes according to their location in a large or small city, their respective suburbs, or in a nonmetropolitan area, was therefore used to predict the impact of increased interpretation volume requirements on different types of communities. These

TABLE 4-8 Percentages of Radiologists Interpreting Mammograms and Mammograms by Type of Location, 2003

	Percent of Radiologists Interpreting Different Volumes of Mammograms (%)					Percent of Mammograms Interpreted by Radiologists with Different Volumes of Mammograms (%)				
Type of Location	<480	480–1000	1000–2000	2000–5000	5000+	<480	480–1000	1000–2000	2000–5000	5000+
All Locations	6.5	18.2	29.3	34.2	11.7	0.8	5.2	16.8	40.4	36.8
Large Metro City	5.0	22.3	21.6	30.1	21.0	0.6	4.9	9.6	29.7	55.2
Large Metro Suburb	7.2	14.3	35.6	32.7	10.2	0.9	4.2	20.5	41.4	33.0
Small Metro City	5.9	15.3	26.2	37.7	14.9	0.8	3.8	13.4	40.3	41.7
Small Metro Suburb	14.1	22.7	23.8	32.0	7.4	1.9	7.6	16.4	42.9	31.2
Non-Metro	5.2	19.5	38.7	33.4	3.3	0.8	7.8	30.5	49.4	11.6

SOURCE: Derived from Sunshine et al. (2004a) and Wing (2005).

findings, and possible means to address the potential impacts they predict, are discussed in the next section of this chapter.

Potential Impact of Adding a Requirement for Double Reading

A model was also used to predict the effects of requiring every mammogram to be read by two different interpreting physicians. As shown in Table 4-9 (a, b), an increase in the current workforce of radiologists interpreting mammograms, or an increase in the number of mammograms read by interpreting physicians, or both, will be needed to implement double reading of mammograms in the United States. The magnitude of the need for an increased workforce or greater productivity will depend on the number of facilities currently performing double reads (a number that is not readily available) and the method of double reading used. If the second reading of a mammogram takes approximately half as long as the initial read, then the equivalent of as many as 7,000 interpreting physicians reading the current average volume of mammograms would be required to meet this demand. This increased demand could be met by greatly increasing the volume of mammograms read by the current pool of interpreting physicians and/or by recruiting a large number of new interpreting physicians. In any case, only large increases in the interpretive workforce or in physicians' productivity in reading mammograms could enable such a change to occur.

ADDRESSING UNDERSERVED COMMUNITIES

A nationwide shortfall in the mammography workforce is likely to further restrict low-income women's already limited access to mammography, particularly in under-served communities. Analysis of the distribution of interpreting physicians among dif-ferment types of communities identifies areas that are especially vulnerable to such ef-

TABLE 4-9 Estimated Numbers of New Radiologists Needed to Implement Double Reads on All Mammograms, Assuming Constant Average Volume for Interpreting Physicians: (A) Assuming Second Reads Are Blind and Thus Require Reading Time Equivalent to the First Read, and (B) For Different Assumptions About Time Required for Second Reads

A

	Mammograms Interpreted		Number of New Radiologists Needed for Double Reads, Assuming Current Percentage of Double-Reads Is:		
Annual Volume	Number	Percent (%)	0%	10%	20%
<480	307,066	0.8	130	119	100
480–1000	1,944,337	5.2	826	751	636
1000–2000	6,318,421	16.8	2,685	2,441	2,066
2000–5000	15,228,661	40.4	6,472	5,884	4,978
5000+	13,850,972	36.8	5,887	5,351	4,528
All	37,649,457	100	16,001	14,546	12,308

NOTE: Assumes that new radiologists interpret 2,353 mammograms per year, the 2003 average, and that the interpretation process requires the same amount of time per mammogram for first and second reads.
SOURCE: Derived from Sunshine et al. (2004a) and Wing (2005).

B

	Mammograms Interpreted		Number of New Radiologists Needed for Double Reads, Assuming That Time for Second Reads Is Percent of Time for First Reads:			
Annual Volume	Number	Percent (%)	100%	50%	25%	15%
<480	307,066	0.8	117	59	29	17
480–1000	1,944,337	5.2	744	372	186	105
1000–2000	6,318,421	16.8	2,417	1,208	604	342
2000–5000	15,228,661	40.4	5,825	2,912	1,456	825
5000+	13,850,972	36.8	5,298	2,649	1,324	751
All	37,649,457	100	14,401	7,200	3,600	2,040
Increase (%)	—	—	90	45	22	13

NOTE: Assumes that 10 percent of mammograms are already double read. The approximate second read times for the different percentages are: 50 percent is approximately 1 minute; 25 percent is approximately 20 seconds; 15 percent is approximately 18 seconds.
SOURCE: Derived from Sunshine et al. (2004a) and Wing (2005).

fects, and informs strategies, such as those described below, to improve access to mammography for underserved communities and individuals.

Distribution of Interpreting Physicians

Based on data obtained from the 2003 ACR survey, Sunshine and coworkers (2004a) examined the distribution of interpreting physicians among 5 different types of

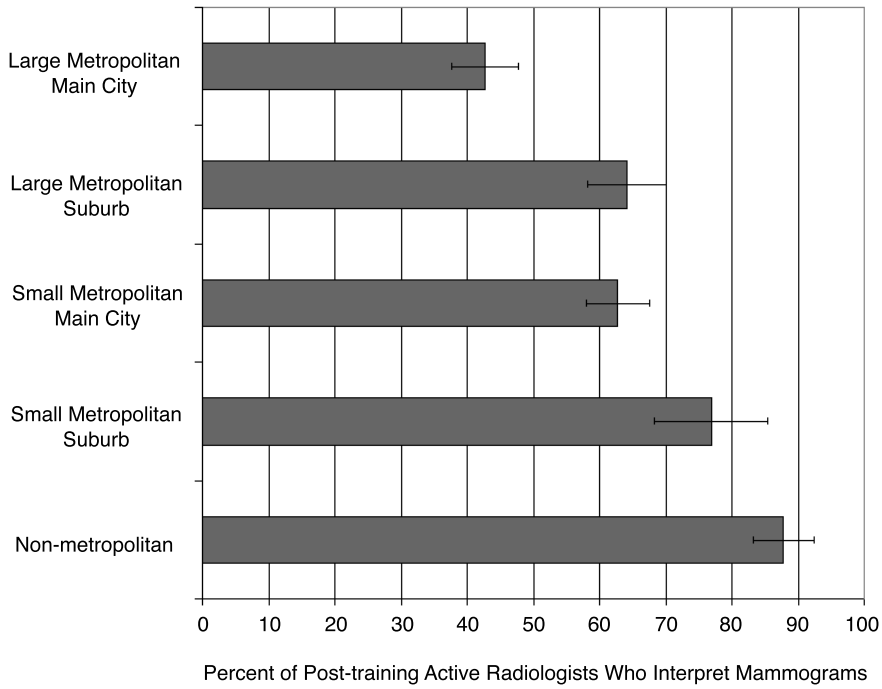

FIGURE 4-3 Percentage of radiologists who interpret mammograms in different community settings, by degree of urbanness. Figure demonstrates the percentage of all radiologists in a given geographic setting who interpret mammograms. For example, approximately 86 percent of all radiologists practicing in nonmetropolitan areas read mammograms, as compared with approximately 42 percent of all radiologists practicing in the main city of large metropolitan areas. NOTE: Error bars represent 95 percent confidence intervals.
SOURCE: Sunshine et al. (2004a).

communities: "large metropolitan main city" (total area population of 1 million or more), "large metropolitan suburb" (total area population of 1 million or more), "small metropolitan main city" (total area population greater than 50,000 but less than 1 million), "small metropolitan suburb" (total area population greater than 50,000 but less than 1 million), and "nonmetropolitan area" (total area population of 50,000 or less, and rural). Figure 4-3 shows the percentage of U.S. radiologists who interpret mammograms working in each of these community types. This analysis indicates that large metropolitan main cities have significantly fewer interpreting physicians per 1,000 women than do other types of communities, a finding that may reflect greater specialization among urban radiologists. Small metropolitan suburb and nonmetropolitan areas appear to have significantly higher percentages of interpreting physicians than do other types of communities.

Figure 4-4 shows the number of interpreting physicians in each community type per 10,000 women aged 40 and older. The authors (Sunshine et al., 2004a) suspect that the pronounced spike in this otherwise roughly equal distribution reflects a combination of confusion on the part of survey respondents regarding the definition of community types (i.e., the difference between a small metropolitan city and a suburb) and a pattern of residents of crossing boundaries to obtain services. Further refinement of these models

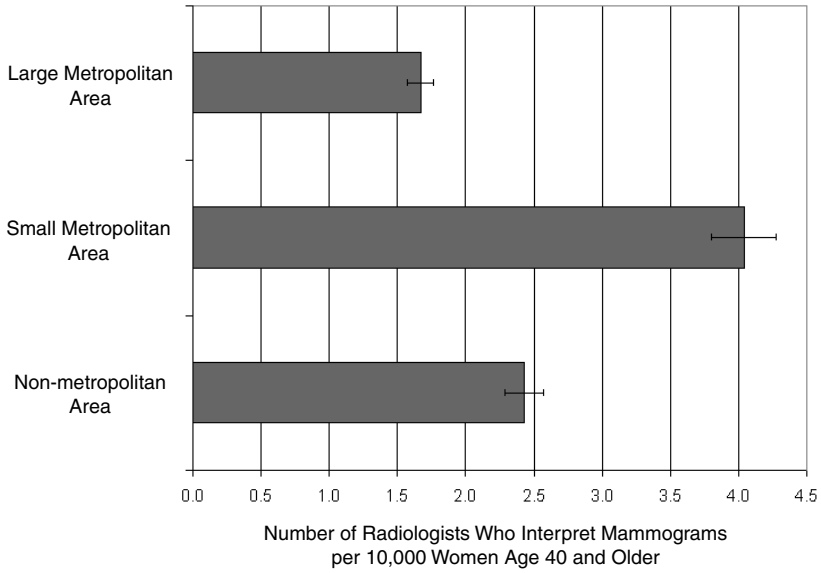

FIGURE 4-4 Number of radiologists who interpret mammograms per 10,000 women aged 40 and older in different communities, by degree of urbanness. In a large metropolitan setting, there are approximately 1.7 radiologists who interpret mammograms per 10,000 women. In small metropolitan and nonmetropolitan settings, there are 4.0 and 2.4 radiologists interpreting mammograms per 10,000 women, respectively.
NOTE: Error bars represent 95 percent confidence intervals.
SOURCE: Sunshine et al. (2004a).

will be necessary to gain a detailed picture of patterns of mammography service availability in U.S. communities.

The authors also examined access to mammography on a regional basis. In comparisons of three measures (percentages of total radiologists; number of radiologists interpreting mammograms per 10,000 women aged 40 and older; and average or median number of mammograms interpreted), no significant differences were found among four U.S. Census regions (Northeast, South, Midwest, West). This suggests that if there is indeed unequal access to mammography, it occurs within geographic regions, at the community level.

Effects of Increased Interpretation Volume on Access to Mammography

Any change in access resulting from an increase in MQSA-mandated continuing experience (minimum volume) requirement for interpreting physicians would be imposed upon the patterns of access to mammography identified above. To analyze such potential interactions, Wing (2005) combined the community-based data described above with the volume distribution data shown in Figure 4-1 to produce Table 4-8 (Wing, 2005).

The results of these calculations indicate that the impact of increasing the annual minimum volume to 1,000 would be greatest for radiologists in the suburbs of small met-

ropolitan areas. If such a change occurred, nearly 37 percent of the radiologists currently reading mammograms in these communities would have to increase their volume or stop interpreting mammograms. Under the same circumstances, 27 percent of mammography radiologists in large metropolitan cities would have to increase their volume or stop interpreting mammograms. These two groups of physicians respectively interpret about 10 and 6 percent of mammograms within their community types. Their current annual volume of mammograms could be interpreted by an additional 267 radiologists in small metropolitan suburbs and 478 radiologists in large metropolitan cities interpreting 1,000 mammograms per year, or by an increase in volume to 1,000 mammograms per year by about half of the 513 radiologists in small metropolitan suburbs and the 836 radiologists in large metropolitan cities who now interpret fewer than 1,000 mammograms per year.

By contrast, if the annual volume requirement were increased to 2,000 mammograms per year, the model predicts that the greatest impact would occur in nonmetropolitan areas, closely followed by the suburbs of small metropolitan areas (Wing, 2005). About 63 percent of radiologists in nonmetropolitan areas interpreting mammograms, and 61 percent in the suburbs of small metropolitan areas, would have to increase their volume to meet this requirement or stop interpreting mammograms. These two groups of physicians respectively interpret about 40 and 26 percent of mammograms within their community types. Their current annual volume of mammograms could be interpreted by an additional 1,166 radiologists in nonmetropolitan areas and 657 radiologists in small metropolitan suburbs interpreting 2,000 per year, or by an increase in volume to 2,000 mammograms per year by about half of the 2,118 radiologists in nonmetropolitan areas and the 846 radiologists in small metropolitan suburbs who now interpret fewer than 2,000 mammograms per year.

Strategies to Improve Mammography Access and Use

Telemammography, mobile mammography facilities, and centralized interpretation of mammograms have all been proposed as ways to increase access to screening mammography in remote or otherwise underserved communities. Existing examples of these models of mammography delivery can inform the design of national or regional programs to serve communities that may lose access. However, it is important to note that, unlike screening mammography, breast cancer diagnosis is not readily adaptable to remote exams. While the strategies described below offer greater access to screening mammograms, women may still have to travel long distances to a central facility for follow-up procedures, including biopsies, as well as for treatment. Moreover, access to mammography is not only a function of supply of facilities and physicians. As noted previously, lack of health coverage is a key factor in limiting access to mammography.

Telemammography

By the late 1990s, a variety of institutions, including teaching hospitals, medical schools, and the U.S. Army and Navy, had developed telemammography or teleradiology networks. In 1999, researchers at the National Cancer Institute (NCI) and the National Institutes of Health's Center for Information Technology launched a telemedicine system capable of transmitting diagnostic-quality radiology and pathology images (Michalowski, 2003). The system, called TELESYNERGY®, was subsequently expanded to 18 U.S. and

4 international sites. It was used for the first time in Belfast, Northern Ireland, in early 2003 to permit consultation with NCI physicians on a treatment plan for a patient with a rare form of leukemia. The U.S. Air Force, in anticipation of losing half of its radiology staff between 2002 and 2005, has developed a network that links radiologists at eight stateside hospitals operated by the U.S. military with eight overseas hospitals (as of April 2003) (Brewin, 2003). According to an Air Force spokesperson, teleradiology "will not fix the shortage, but it will make maximum use of the radiologists we currently have" (Trevino, 2003).

Mobile Mammography

Mobile mammography programs, some of which have existed for nearly two decades, serve women with limited mobility, including those living on farms and in small, remote communities. One such program, based in Rapid City, South Dakota, since 1985, provides screening mammograms for women in small towns and on Indian reservations throughout central and western South Dakota, and in some sites in Wyoming, Montana, and Nebraska.[11,12] A radiologic technologist, accompanied by an assistant who handles paperwork, drives the mammography machine in a converted minivan to sites such as community centers, houses of worship, and nursing homes, traveling an average of 32,000 miles per year. The machine is unloaded and mammograms are performed within the premises; afterward, the films are stored for the journey back to the Rapid City facility, where they are developed and interpreted. If additional views or diagnostic mammograms are indicated, patients must travel to Rapid City. This service, which generally operates 4 days per week, 51 weeks per year, provided screening mammograms for more than 3,400 women in 2003.

Mobile digital mammography programs are also underway, but presently cannot match the transportability and comparatively low cost of services based on film mammography. Until a truly portable digital mammography machine is developed—one that can withstand being driven over unpaved roads and repeated loading and unloading from a van—mobile digital mammography must be performed in comparatively large mobile clinics built from large recreational vehicles, buses, or trucks. A Canadian program that has provided both screening and diagnostic mammography to sparsely populated underserved areas in Northern Ontario for more than 10 years is attempting to fund a conversion to digital mammography.[13] The service presently operates aboard a converted bus. Films are returned to a central facility to be processed and interpreted—steps that could be eliminated by establishing a digital telemammography link on the bus.

Centralized and "Decentralized" Interpretation

Centralized facilities could permit expert interpretation, including second readings, of either films or digitized data collected at several remote locations (Shtern and Winfield, 1999; Michalowski, 2003). In France, for example, the Association pour le

[11] Personal communication, R. Belsaas, M.D., Radiology Associates, Rapid City Regional Hospital, November 10, 2004.
[12] Personal communication, J. Shaefer, M.D., Radiology Associates, Rapid City Regional Hospital, November 10, 2004.
[13] Personal communication, M. Yaffe, Professor, University of Toronto, November 11, 2004.

Dépistage des Maladies du Sein (ADEMAS) program has provided free mammography screening to women between the ages of 50 and 65 in the Strasbourg administrative regions and in surrounding small towns and rural areas since 1989 (Gairard et al., 1992; Renaud et al., 1994). This "decentralized" program was designed to accommodate existing patterns of service delivery predominated by private-practice radiologists, the lack of reliable population registries, and an apparent reluctance on the part of general practitioners to encourage women to obtain mammograms. Women aged 50 to 65 present themselves for testing every 2 years to an authorized radiologist, who performs a single external oblique mediolateral view of each entire breast (Gairard et al., 1992). After interpreting the mammogram, the radiologist sends it to a coordinating center, where it receives a second reading (and a third as well if the first two readings differ). The coordinating center also oversees regular quality control inspections of all participating mammography facilities (Maccia et al., 1995).

The success of the ADEMAS program led to the establishment of additional regional mammography programs and eventually to the creation of a national breast cancer screening protocol in France (Gairard et al., 1997). However, the cost-effectiveness of this decentralized program has been shown to be significantly less than of that of truly centralized breast cancer screening programs in other European countries (in which all screening and interpretation take place in centralized facilities) (Wait et al., 2000). A 1997 comparison of one of the French regional programs with a similar, but centralized, program in the United Kingdom also found lower compliance and cancer detection rates in the French program (McCann et al., 1997).

In some U.S. medical facilities, screening mammograms are performed by an RT who then sends the films by overnight delivery to a radiologist in another location for interpretation. Under current MQSA regulations, such remote facilities must be overseen by an offsite lead interpreting physician. In such cases, problems with quality should be readily apparent in the films, and can be corrected through clear communication with the RTs onsite.[14] Under such circumstances, the Committee notes, it might be feasible to allow a radiologist assistant (see Box 4-1) to take on this aspect of MQSA facility oversight.

FACTORS LIMITING THE SUPPLY OF INTERPRETING PHYSICIANS

Breast imaging specialists generally consider their chosen field to be challenging, diverse, and interesting, but they interpret less than 12 percent of mammograms in the United States; most are read by general radiologists.[15] FDA regulations do not require interpreting physicians to be radiologists, but most are. Generally the non-radiologists who read mammograms are breast surgeons or OB/GYNs. Other types of non-breast imaging data are often interpreted by orthopedic surgeons, cardiologists, and neurologists. Nevertheless, due to a combination of factors discussed below, the interpretation of mammograms is performed primarily by radiologists. These same factors influence radiologists in their choice of a specialty.

[14] Personal communication, R. Suberman, M.D., Chapel Hill Radiology, November 10, 2004.

[15] Personal communication, E. Pisano, M.D., Professor of Radiology and Biomedical Engineering, Chief of Breast Imaging, University of North Carolina, Chapel Hill, School of Medicine, February 10, 2005.

Few Residents Choose Breast Imaging

As trainees in radiology, residents spend 1 postgraduate year in clinical internships and 4 years in formal radiology training before they are Radiology Board eligible (American Board of Radiology, 2004). If a subspecialty is chosen, most train for an additional 1 to 2 years in that field. Radiology trainees who choose to subspecialize typically select their field during the course of their residency and pursue postresidency fellowships in order to train in that subspecialty. In addition to individual interests, market demands often influence the choice of a subspecialty, as residents tend to pursue fields that will allow them to obtain the best possible position.

A national radiology fellowship match program began in 2003 (Arenson, 2004). Most programs participated in a match for fellowships in July 2004, at which a total of 358 programs offered 769 positions in 9 categories. Fifty-three percent of these positions were filled in the match; however, in breast/women's imaging, only 12 of 48 positions (25 percent) were filled. A follow-up survey on the program conducted by the Society for the Chairmen of Academic Radiology Departments revealed that some positions for all categories were filled outside the match, and others went to inside candidates who did not participate in the match. After adjusting for these events, the success rate for breast/women's imaging in this initial match ranked eighth out of nine subspecialties, exceeding only pediatric radiology.

Several factors, some interrelated, have been noted by radiology residents as factors that dissuaded them from specializing in breast imaging, or even from choosing positions that will involve interpreting mammograms. A survey, conducted in 2000, of 211 radiology residents in 211 accredited radiology residencies in the United States and Canada found that although 65 percent of residents believed mammograms should be interpreted by breast imaging subspecialists, most wouldn't consider doing a fellowship in breast imaging (Bassett et al., 2003). Only 29 percent of residents agreed that they would like to spend at least 25 percent of their time interpreting mammograms when in practice. Those who said they wanted to spend little or no time interpreting mammograms chose the following explanations for their preference: that mammography was not an interesting enough field (45 percent); that they feared lawsuits (37 percent); and that interpreting mammograms was too stressful (19 percent). Twelve percent of respondents reported that they were disinclined to interpret mammograms because the field is "female dominated." This is in fact the case: Although radiology remains a male-dominated specialty, female radiologists—particularly among radiologists under age 45—are significantly more likely to interpret mammograms than their male counterparts. In addition, among radiologists who interpret mammograms, the median number of mammograms read by female radiologists is significantly higher than for male radiologists (Sunshine et al., 2004a).

When asked to compare interpreting a diagnostic mammogram with CT of the abdomen with contrast, 70 percent said they would be more concerned about missing a potentially important finding on a diagnostic mammogram than on a CT exam, and 93 percent said they would be more concerned about malpractice liability associated with diagnostic mammography as compared with other types of imaging examinations (Bassett et al., 2003). Eighty-two percent of residents rated stress associated with possible misdiagnosis as higher for diagnostic mammography as compared with interpreting other types of imaging examinations.

Factors That Deter Mammogram Interpretation by General Radiologists

According to the 2003 ACR survey, radiologists who interpret mammograms enjoy practicing medicine as much as radiologists who do not interpret mammograms (Sunshine et al., 2004a). Nevertheless, some general radiologists may find that reading large volumes of screening mammograms is tedious, especially when only a small fraction of screening mammograms identifies a woman with breast cancer. There is also the significant possibility that some cancers will be missed. As detailed in Chapter 2 (see section on "Factors Affecting Interpretive Performance"), mammograms are among the most challenging images to interpret. Abnormalities can be very subtle, and a missed cancer in a screening mammogram of an asymptomatic woman may not be clinically evident for several years. By contrast, most radiologic examinations of other areas of the body are ordered to evaluate symptomatic patients, so a false-negative result or an error in interpretation is more likely to be pursued.

A variety of factors raise public expectations for mammography as compared with other radiologic procedures. Although most imaging procedures are used for diagnosis, mammography is used to screen a large segment of the population. In addition, many women are especially fearful of breast cancer. Results of a recent survey by the American Heart Association found that women incorrectly perceive their risk of dying from breast cancer to be greater than their risk of dying from heart disease (American Heart Association, 2000; Mosca et al., 2004). In response to such concerns, 14 percent of breast imaging facilities offer online interpretation of mammograms (films are interpreted immediately, rather than batch read later), although it is not medically necessary (Farria et al., in press). A retrospective study of women who had received false-positive mammogram results found that those who obtained an immediate onsite diagnostic evaluation experienced less stress on average than those who received their results later and had to return for a diagnostic workup (Lindfors et al., 2001). However, it is also interesting to note that a similar survey-based study found that more women prefer to have their mammograms receive a double reading, despite a delay in receiving the result, than to have their films interpreted immediately, but only once, by an onsite physician (Hulka et al., 1997).

In the highly charged atmosphere surrounding mammography, it is perhaps not surprising that interpreting physicians are the most frequently named parties in lawsuits concerning missed breast cancer diagnoses (Physician Insurers Association of America, 2002). For example, 55 percent of breast imaging practices that responded to a 2003 Society of Breast Imaging survey of more than 550 U.S. practices reported involvement in at least one lawsuit during the previous 5 years (Farria et al., in press). National data indicate that the costs of settlements and judgments in mammography cases nearly doubled between 1995 and 2002, to reach an average of $346,000.[16]

Being found liable for misinterpreting a mammogram usually increases radiologists' malpractice insurance premiums. It can also limit the number of malpractice insurance companies willing to insure the radiologists to the point where some cannot afford or are able to acquire malpractice insurance. In addition, a previous malpractice claim against a radiologist can render the physician ineligible to contract with a managed care

[16] Personal communication, C.S. Bernstein, Research Associate, Physician Insurers Association of America, July 14, 2004.

organization or lead to severance of medical hospital staff credentialing (Berlin, 2003). A number of states also now post information regarding medical malpractice settlements and awards in publicly accessible Internet databases (Adams, 2003) (for more detail on medical malpractice issues, see Chapter 5).

Given the risk of missing a cancer and the possibility that such an oversight can lead to a lawsuit, it is perhaps not surprising that some radiologists and residents are reluctant to interpret mammograms. Twenty-seven percent of respondents to the 2003 SBI survey indicated that the threat of lawsuits decreased their willingness to do breast imaging, and 50 percent believed that this threat made staffing their practices more difficult (Farria et al., in press). Responding breast imagers ranked malpractice lawsuits the top factor deterring potential fellows from entering breast imaging, followed by stress, regulation, and low salary. Each of these factors was identified by more than 60 percent of respondents; malpractice was cited by 93 percent of respondents.

Another survey of practicing radiologists (Elmore et al., in press) also indicates that medicolegal liability is a common concern. This cross-sectional study found that approximately half (53 percent) of the radiologists reported a prior medical malpractice claim, with 18 out of 124 reporting mammography-related claims.[17] Radiologists who were older and those who had more years in clinical practice were both significantly more likely to report a prior medical malpractice claim, which may be due to the level of exposure over time to lawsuits. The majority of radiologists sued (81 percent) reported the experience to be very or extremely stressful. Three out of four radiologists (76 percent) either agreed or strongly agreed that they are concerned about the impact medical malpractice is having on their practice of mammography. In addition, about one-quarter of radiologists surveyed said they considered withdrawing from interpreting mammograms at least on a monthly basis, and 16 percent considered withdrawing weekly or daily because of concerns about malpractice (Elmore et al., in press). Among those thinking about leaving mammography on a daily, weekly, or monthly basis, there was no difference by age categories (35–44, 45–54, 55+). Radiologists more frequently considered withdrawing from mammography than from the practice of general radiology.

Nonetheless, radiologists' perceptions of malpractice risk appear to be somewhat inflated. Radiologists in the Elmore study reported that if in the next 5 years they were to interpret mammograms full-time, the majority (90 percent) estimated a probability of greater than 10 percent that they would be sued, with 56 percent estimating the probability as greater than 30 percent (Elmore et al., in press). In actuality, among radiologists who had been practicing for at least 5 years, only 9 percent reported a mammography-related claim filed against them from 1997 to 2001. The majority of radiologists with a previous mammography-related malpractice suit thought their probability of being sued in the next 5 years was 50 percent or higher. The majority of radiologists (61 percent) who consider leaving mammography on a monthly, weekly, or daily basis thought their probability of being sued in the next 5 years was 50 percent or higher.

[17] Among the 18 radiologists, a total of 24 prior mammography-related claims were noted (one prior claim n=13 radiologists, two claims n=4, three claims n=1). The reason for the claim was alleged misinterpretation of the mammogram in 20, alleged misinterpretation of a breast ultrasound in 1, another clinician (nonradiologist) missing a lesion on the X-ray in 1, and unknown in 2. The majority of claims were either withdrawn (n=11) or settled out of court (n=9), with one claim of unknown status and three going to trial (one trial completed and two in progress).

Federal regulation and state oversight of mammography services were also cited by 73 percent of respondents to the 2003 SBI survey as a disincentive to specialize in breast imaging (Farria et al., in press). Unlike other subspecialists in radiology, interpreting physicians must meet federal requirements, and they must regularly provide evidence of compliance. Financial and time considerations associated with that oversight historically have not been reimbursed.

Another factor commonly cited by radiologists as a disincentive to mammographic interpretation is the lower rate of reimbursement compared to rates for interpreting other images (see Box 4-3 and Table 4-7). Reimbursement for interpreting screening mammograms is lower than that for several other radiological procedures, the majority of which are diagnostic examinations. For example, a radiologist who receives a professional reimbursement of $36.38 from Medicare for interpreting screening mammography would receive the same amount for interpreting a unilateral diagnostic mammogram, $84.51 for interpreting a unilateral breast MRI, and $123.17 for interpreting a brain MRI with and without contrast. Interpreting physicians in hospital practices receive only this professional component of reimbursement; the hospital receives an additional sum, the technical component of reimbursement, to compensate for all other costs related to the procedure (see Table 4-7). Interpreting physicians in private practice receive both the professional and technical components of Medicare reimbursement, and may be able to retain some of the technical reimbursement after paying staff and overhead if their practice costs are lower than those of a hospital.[18]

In addition, hospitals typically see a larger proportion of Medicare recipients than do private practices, which may refuse or cap the number of such relatively unprofitable patients.[19] Teaching hospitals appear to be especially disadvantaged because they also tend to see a higher proportion of women seeking second opinions and those with difficult diagnoses, and are therefore likely to conduct a larger proportion of diagnostic mammograms as compared with community facilities (IOM, 2005). A financial analysis of seven university-based mammography programs conducted in 1997 and 1998 determined that all incurred financial losses, which were largely attributed to diagnostic mammography, in the professional component of reimbursement (Enzmann et al., 2001). Although Medicare only covers a portion of the women who undergo mammography, the above comparisons are informative because private insurers often use Medicare reimbursement rates as a reference when setting their own rates. However, reimbursement for mammography is far from uniform, and is most profoundly influenced by the patient's insurance status. Recent calculations performed for the Florida mammography accessibility study found that the average total fee for a screening mammogram in that state varies from $167 for women with private insurance, to $106 for uninsured women (out-of-pocket expense), to $89 for women on Medicare, to $46 for women on Medicaid (The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). Such disparities in reimbursement undoubtedly influence the accessibility of mammography for low-income women and the geographic accessibility of mammography to all women who live in communities with significant low-income populations.

[18] Personal communication, B. Monsees, M.D., Professor and Chief of Breast Imaging, Mallinckrodt Institute of Radiology, Washington University Medical Center, February 10, 2005.

[19] Personal communication, B. Monsees, M.D., Professor and Chief of Breast Imaging, Mallinckrodt Institute of Radiology, Washington University Medical Center, February 8, 2005.

BOX 4-3 Reimbursement

Medicare Physician Fee Schedule Overview

From the time of Medicare's implementation in 1966 until 1992, the reasonable charge payment method was used to reimburse physicians for services provided to Medicare recipients. In 1992, due to rising costs and wide variations in payments, the reasonable charge system was replaced by the physician fee schedule. The physician fee schedule consists of three parts: relative value, geographic adjustment, and conversion factor.

Relative Value: The Current Procedural Terminology (CPT) manual, published by the American Medical Association, assigns a code to every medical procedure performed by physicians. Medicare assigns each CPT code a numerical relative value unit (RVU). The RVU for a service compares the relative work for a physician performing that service to the work involved with providing other services. These comparisons are made through the use of the resource-based relative value scale (RBRVS).

The RVU for each service is divided into three components: physician work, practice expense, and malpractice expense. Each component is assigned a separate numerical RVU. The physician work component measures the time, mental and technical skill, and stress involved with performing a service. The practice expense component measures office expenses, and varies based on site of service; either a facility (inpatient or outpatient hospital settings, emergency rooms, skilled nursing facilities, or ambulatory surgical centers) or nonfacility setting payment applies. The malpractice expense component measures the average insurance costs for a service; estimates are derived from malpractice premiums data.

Radiology services are further divided into technical and professional components, enabling more accurate payment for each aspect of a service provided. For example, a screening mammogram performed in a hospital outpatient setting is billed separately by component: The hospital receives payment for the technical component of service, while the physician receives reimbursement for the professional component of service. The sum of the professional and technical components equals the global RVU, billed when one entity provides both components of a service.

The Relative Value Scale (RVS) Update Committee (RUC), composed of representatives from medical associations and specialty societies, advises the Centers for Medicare and Medicaid Services (CMS) annually on potential improvements to the RVS system. Although the RVS generally remains unchanged each year, CMS uses the RUC recommendations in its statutorily required comprehensive 5-year review.

Geographic Adjustment: To account for cost variations across geographic regions, CMS derived the geographic practice cost index (GPCI). There are currently 92 geographic regions defined by CMS. A separate GPCI is calculated for each component of the RVU; to obtain a single, geographically indexed RVU for a service, the three RVU components are multiplied by their respective GPCI values, and then summed.

Conversion Factor: Converting a geographically indexed RVU to a reimbursement dollar value requires use of a conversion factor. There is a single conversion factor for all ser-

Continued

BOX 4-3 *Continued*

vices. This dollar figure is adjusted annually by CMS to ensure that reimbursement levels match current market expenses; the conversion factor for 2005 is set at $37.897.

Mammography and Medicare

The history of reimbursement for mammography services through Medicare is complex, having undergone numerous revisions in the past decade. The most important changes that lead to the current reimbursement system are discussed below.

Screening Mammography: Reimbursement for screening mammography was initially set by congressional mandate. This flat reimbursement rate applied nationwide, regardless of site of service or geographic location. Passage of H.R. 4577 in December 2000 placed screening mammography within the purview of the Medicare physician fee schedule as of January 1, 2002.

The Hospital Outpatient Prospective Payment System (OPPS): Until recently, the technical component of screening and diagnostic mammography performed in a hospital outpatient department setting was paid under OPPS, not the Medicare physician fee schedule. OPPS was devised by CMS to standardize payment for the technical component of hospital outpatient services.

Reimbursement for the technical component of mammography under OPPS was seen as artificially low based on a cost survey conducted by the ACR. Legislation passed by the 108th Congress excluded mammography services from payment under OPPS, thereby placing such services under the physician fee schedule as of January 1, 2005. This statutory change is expected to increase the reimbursement rate for mammography procedures performed in the hospital outpatient setting.

Emerging Technologies: Digital screening and diagnostic mammography procedures have been reimbursed through Medicare since January 1, 2002. Historically, digital mammography has been reimbursed at a higher rate than its analog counterpart, largely due to higher associated operation costs. Computer-aided detection (CAD) technology is used on both film-screen and digital mammograms to facilitate interpretation. CAD has been reimbursed under the physician fee schedule as an add-on payment for screening and diagnostic mammography services since January 2004. In contrast, there is no add-on payment for double reading.

2005 Mammography Reimbursement: As of January 1, 2005, payment for both screening and diagnostic mammography services, regardless of practice setting, is provided through the physician fee schedule. The Medicare Physician Fee Schedule for 2005 was published in the *Federal Register* on November 15, 2004. Table 4-7 displays the most common mammography CPT codes, and associated reimbursement rates for 2005.

SOURCES: Odle (2003); Congressional Research Service (2003); Thorwarth and Borgstede (2001); Linver (2002); Pub. L. No. 106-554; CMS (2004a); Farria and Feig (2000).

Thus it is apparent that for some radiology and/or breast imaging practices, particularly hospital programs with a large proportion of patients without private insurance, mammograms may generate only marginal earnings. Under such circumstances, mammography may be regarded as a drain on a practice's profits; this negative perception may be exacerbated if obtaining malpractice insurance is difficult, or if premiums are increased because the practice provides mammography services. Among other issues related to malpractice insurance, which are discussed in detail in Chapter 5, tail coverage[20] for interpreting physicians may be especially expensive or hard to obtain because cancer occurrences may take years to become evident after a negative mammogram.

STRATEGIES TO ENSURE AN ADEQUATE MAMMOGRAPHY WORKFORCE

Improvements in breast imaging technology, as well as in the delivery of cancer screening services, could perhaps increase women's access to breast cancer screening in the future (IOM, 2005). Unfortunately, as indicated by the U.S. workforce projections described earlier in this chapter, it is unlikely that these benefits will arrive in time to prevent an impending shortage of interpreting physicians and mammography RTs who perform mammography. Three basic strategies could be used to ensure an adequate breast imaging workforce: increasing the number of new entrants to the field, retaining the current workforce, and increasing the productivity of new and existing practitioners.

Training More Interpreting Physicians

The Committee recognizes that efforts to reduce previously described disincentives for radiologists to specialize in breast imaging and for general radiologists to interpret mammograms are likely to strengthen the mammography workforce over the long term. Nevertheless, the Committee's recommendations focus on a variety of near-term incentives intended to increase access to mammography for underserved areas and populations and to enlarge the nation's aggregate supply of interpreting physicians—especially breast imaging specialists—and RTs.

The National Health Service Corps (NHSC) makes contract awards to clinicians for service in designated health professional shortage areas (U.S. Department of Health and Human Services, 2004a). In exchange for this service, NHSC participants receive funds for the repayment of their outstanding educational loans (up to $25,000 for each year of service), plus tax assistance (equal to 39 percent of the total amount of loan repayments received during a tax year) (U.S. Department of Health and Human Services, 2004b). Expanding this program to provide loan repayment awards to appropriately qualified radiologists who work in underserved areas, and who spend at least half of their professional time in breast imaging, could improve access to mammography. This designation would also serve to emphasize the national importance of breast imaging specialists to medical students and physicians in training and would further the goals of Breast Imaging Centers of Excellence, as discussed in Chapter 2.

[20] Tail coverage is malpractice insurance that can be purchased after the expiration of a claims-made liability policy to cover claims made during an extended reporting or discovery period. Such insurance covers radiologists who retire (or move) who are later sued for missed diagnoses made at facilities at which they were formerly employed.

Another established means of bolstering the supply of in-demand physician specialists is by waiving the requirement that non-U.S. resident physicians return to their country of origin for 2 years following training as part of the U.S. Department of State J-1 visa program (U.S. Department of State, 2004). Such waivers, which can be requested from the Department of State on a participant's behalf by either federal or state agencies (such as health departments), currently bring physicians to underserved areas throughout the country (Wisconsin Department of Health and Family Services, 2003; Hagopian et al., 2003; California Department of Health Services, 2004). The Committee recommends that J-1 visa waivers, when authorized, also be extended to appropriately qualified breast imaging radiologists who work in underserved areas and who spend at least half of their professional time in breast imaging. In order to target breast imagers to the highest need areas, the Health Resources and Services Administration should establish a process to identify and designate shortage areas for breast imaging specialists.

The Committee also notes educational incentives such as proposals to sequence residency training that would expose radiology residents to breast imaging earlier in their education and training (Bassett et al., 2003). The SBI has developed a curriculum for resident education in breast imaging intended to provide guidance to academic chairpersons, list key topics for residents, and specify critical material that practicing radiologists need to know (The Society of Breast Imaging, 1999–2005; Feig et al., 2000); these guidelines could provide the basis for a more specialized "fast track" for breast imaging that could be created within existing radiology fellowship programs, similar to existing combined training programs for nuclear medicine and diagnostic radiology (American Board of Nuclear Medicine, 2004). Alternatively, a new breast imaging subspecialty could be developed. For example, a breast imaging specialty with a 3-year residency independent of the general radiology track could attract physicians to the field, as does the breast surgery subspecialty recently launched by the Society of Surgical Oncology. However, establishing a breast imaging subspecialty would require the creation of a new credentialing organization. Moreover, the new subspecialty could face underpopulation if medical students are reluctant to commit to such a narrow (and presently unpopular) area of specialization.

Finally, the Committee notes that breast imaging specialists must make an effort to promote their field if it is to grow. They need to share their enthusiasm for the specialty with medical students and radiology residents, and explain their reasons for choosing and remaining in their field.

Retaining Skilled Practitioners

The existing supply of radiologists who read mammograms at a high level of interpretive performance is a valuable resource. To invest in efforts to increase the number of entrants into this specialty without also addressing early departures from the existing workforce would be counterproductive.

Efforts directed at retaining already highly skilled practitioners, even for part-time work, may represent a cost-effective means to maintaining access to high-quality breast imaging services. For example, radiologists who wish to work part-time may find it difficult to choose breast imaging as a specialty because malpractice costs are not adjusted for less than full-time work. When such personnel approach retirement, encouraging them to continue reading mammograms part-time could ease the projected workforce shortage.

Possible incentives, described in Chapter 5, could include providing pro-rated malpractice and reduced-rate malpractice tail coverage (see footnote 20) insurance for such practitioners, who currently pay as much for these policies as their full-time counterparts. In recognition of the significant workload for mammography staff associated with MQSA compliance, as well as the heretofore uncompensated expense of compliance for mammography facilities, the Committee also recommends that reimbursement rates for mammography be increased to reflect these costs. Historically the costs of regulatory compliance have not been factored into reimbursement, placing a considerable financial burden on mammography facilities; however, successful programs in other countries such as the United Kingdom depend on funding to cover quality assurance activities (Perry, 2004). Moreover, the new audit procedures proposed earlier in this report (Chapter 2) will further increase the workload and costs associated with MQSA compliance.

Increasing Workforce Productivity

As an additional balance to its recommended expansion of the medical audit requirement for mammography interpretation, and in order to make the most effective use of the existing supply of well-trained breast imaging specialists, the Committee also recommends the development and expansion of roles for other members of the mammography workforce. This includes support for the training of radiologist assistants (RAs; see Box 4-1) and the exploration of possible new roles for these professionals in breast imaging; it also includes innovative staffing configurations in breast imaging facilities that could enable nontechnical personnel to take on appropriate responsibilities in quality control and administration. As a first step, demonstration projects could test the performance of both RAs and nontechnical personnel in a variety of responsibilities and tasks.

Integrating Radiologist Assistants into Breast Imaging

Increasing demands on radiologists—as well as the need to establish a career path by which to attract and retain RTs—have been recognized by the American College of Radiology and American Society of Radiologic Technologists, which recently collaborated to develop training and practice guidelines for a new type of physician extender, the radiologist assistant (Advanced Practice Advisory Panel, 2002; Williams and Short, 2004; RSNA, 2004a). Similar professionals such as physician assistants (PAs) and nurse practitioners have come to play key roles in other medical specialties, but this trend has largely bypassed radiology, which employs less than 0.5 percent of all PAs (Dunnick, 2004). Training programs, for which experience as an RT is a prerequisite, were recently initiated at Loma Linda University, Midwestern State University, the University of North Carolina, and the University of Medicine and Dentistry in New Jersey; eight additional institutions are also developing RA programs (Williams and Short, 2004; Dunnick, 2004).

The RA's duties will include patient management; assisting radiologists with invasive procedures; conducting, monitoring, and tailoring certain routine procedures under direct supervision by a radiologist; and communicating results to referring physicians. They are not allowed to perform interpretations (preliminary, final, or otherwise) (Williams and Short, 2004). Maximizing the potential role of RAs in breast imaging could improve the quality of services as well as facility productivity and efficiency. In addition,

should MQSA eventually be amended to require double reading for mammograms, the resulting increase in workload for radiologists could potentially be eased, and the cost-effectiveness of double reading increased, by permitting nonphysician clinicians (e.g., radiologist assistants, radiologic technologists, nurse practitioners, physician assistants, etc.) to serve as second readers under the direct supervision of interpreting physicians. Based on evidence from several studies evaluating the interpretation of screening mammograms by RTs working under the supervision of board-certified radiologists (Sumkin et al., 2003; Wivell et al., 2003; Casey, 2003), the IOM report *Saving Women's Lives* (2005) recommended that mammography facilities "enlist specially trained non-physician personnel to prescreen mammograms for abnormalities or double-read mammograms to expand the capacity of breast imaging specialists." Immediately following the June 2004 release of *Saving Women's Lives*, the ACR expressed strong opposition to technologists reading screening mammograms (Brice and Kaiser, 2004). However, it should be stressed that the previous IOM Committee did not recommend that technologists serve as the sole readers of any mammograms, but rather as second readers—thus all mammograms would still be read by a physician.

The existence of a precedent for according comparable responsibility to non-physicians in the United States should also be noted: the routine interpretation of cervical cancer screening tests. Papanicolaou slide interpretation is carried out largely by non-physician cytotechnologists under the supervision of a physician. Physicians are required to be onsite to provide technical oversight of the testing staff, and all gynecologic slide preparations positive for cell abnormalities must be confirmed by physicians before patient results are released (42 C.F.R. § 493). Analogous to mammography facilities, laboratories and personnel that perform Pap tests must adhere to quality assurance regulations stipulated by The Clinical Laboratory Improvement Amendments (CLIA), passed by Congress in 1988. CLIA established standards for all clinical laboratories to "ensure the accuracy, reliability, and timeliness" of clinical test results (Box 4-4). CLIA is user-fee funded; laboratories are responsible for the cost of registration, compliance, and surveys. The Centers for Medicare and Medicaid Services oversees registration, fee collection, surveys, enforcement, accreditation, and proficiency testing for all laboratories under CLIA (CMS, 2004b).

The current IOM Committee concurs that the potential benefits provided by a second reading of screening mammograms by an experienced and well-trained nonphysician clinician, supervised by a licensed, MQSA-qualified interpreting physician, could be significant. In order to better characterize potential benefits and risks, the Committee recommends the implementation of demonstration programs to evaluate the potential contribution of nonphysicians to the double reading of screening mammograms. These programs will require careful design in order to ensure women's participation.

Improving Workplace Design and Organization

The incorporation of key elements of successful breast cancer screening programs in other countries, including centralized expert interpretation of all breast imaging modalities and a thorough quality assurance process, could increase the quality and effectiveness of breast cancer detection in the United States. Such improvements are discussed throughout this report, and are collected in the description of Breast Imaging Centers of

BOX 4-4 CLIA Regulation of Pap Testing

The Clinical Laboratory Improvement Amendments (CLIA) regulations define standards for laboratories performing clinical tests. Quality standards for cytology laboratories performing Pap testing are described below.

I. Certificates
- a. *Registration Certificate:* Required initially for all laboratories performing nonwaived tests, requires paid fee, and is valid for 2 years, or until the Department of Health and Human Services (HHS) compliance inspection, whichever is shorter.
- b. *Certificate of Compliance:* Issued after successful completion of HHS compliance inspection. Certification requires a paid fee, is valid for 2 years, and can be renewed. Laboratories undergo announced or unannounced inspections by HHS biannually to ensure compliance.
- c. *Certificate of Accreditation:* Issued in lieu of a Certificate of Compliance to laboratories certified through a private, not for-profit accrediting program approved by HHS. Laboratories undergo random sample validation inspections, conducted randomly by HHS to validate the accrediting process. HHS monitors inspection and proficiency testing data from accredited labs. Certificate is valid for 2 years, requires paid fee, and is renewable. Failure to meet accreditation standards results in full compliance review by HHS.

II. Proficiency testing
- a. *Overview:* A laboratory must enroll in HHS-approved proficiency testing (PT) programs for each specialty for which it seeks certification. HHS uses PT data to measure laboratory compliance; PT data are available to the public.
- b. *General requirements:* PT samples must be tested in the same manner by the same personnel as patient samples. Communication between laboratories on PT samples is forbidden.
- c. *Pap cytology:* Personnel (cytotechnologists and technical supervisors) are tested once per year via announced or unannounced testing events.
    - i. Test overview: Sample slides provided by the PT program are distributed to cytology laboratories. Individual responses are collected and compared with the predetermined consensus agreement from at least three physicians certified in anatomic pathology.
    - ii. Scoring: Slides are graded individually. Scoring rewards or penalizes participants in proportion to the distance of their answers from the correct response, and is weighted in proportion to severity of sample lesion. Personnel must achieve a PT score of 90+ to pass.
    - iii. Compliance: Two hours to complete the basic 10-slide proficiency test.
    - iv. Failure.
        1. First failure: Retested with an additional 10 slides.
        2. Second failure: Mandatory remedial training and education followed by a 4-hour, 20-slide test. All gynecologic slides evaluated subsequent to notice of failure must be reviewed and documented until the 20-slide retest is taken.
        3. Third failure: Personnel must cease examination of gynecologic slides, and must complete 35 hours of formal continuing education until effective completion of 20-slide test.

Continued

BOX 4-4 *Continued*

III. Quality systems
- a. *Preanalytic, analytic, and postanalytic systems:* Laboratories must adhere to standards for all phases of the testing process.
- b. *Cytology analytic systems:*
  - i. Written policies: Laboratories must establish written policies for detecting errors in performance, including review of slides determined to be negative for cell abnormalities, comparison of clinical information with prior cytology reports, statistical laboratory evaluation, and evaluation of each individual interpreting slides against the laboratory's overall performance.
  - ii. Workload limits: Technical supervisors establish limits for laboratory personnel, not to exceed examination of 100 slides in 24 hours.
  - iii. Oversight: Technical supervisors must confirm each gynecological examination interpreted to exhibit cell abnormalities (e.g., malignancy).

IV. Personnel
- a. *Laboratory director:* Must be a doctor of medicine, osteopathy, or podiatry, licensed in the state, with certification in anatomic or clinical pathology and significant laboratory experience. Responsible for overall operation and administration of the laboratory.
- b. *Technical supervisor:* Must be a doctor of medicine or osteopathy licensed by the state. Responsible for technical and scientific oversight of the laboratory.
- c. *Clinical consultant:* Must qualify as a laboratory director. Provides consultation on appropriateness of tests ordered and interpretation of results.
- d. *Cytology general supervisor:* Must be qualified as a technical supervisor or have 3 years of full-time experience in the preceding 10 years. Responsible for daily oversight of laboratory operation; must be accessible to provide onsite assistance. Must document all cytology cases he or she examines or reviews.
- e. *Cytotechnologist*: Must be state licensed. Responsible for interpretation results of each gynecologic cytology case examined or reviewed.
- f. *Testing personnel*: Must be state licensed. Responsible for specimen processing, test performance, and reporting test results.

V. Inspection
- a. *Basic inspections:* The Centers for Medicare and Medicaid Services (CMS) or a CMS agent may interview personnel, require the facility to analyze test samples, observe personnel performing all phases of the testing process, or examine records and data.
- b. *Compliance inspections:* Laboratories issued a Certificate of Registration are subject to initial compliance inspections. Subsequent inspections are conducted on a biennial or more frequent basis as necessary to ensure compliance.
- c. *Certificate of Accreditation inspections:* CMS conducts validation and complaint inspections at labs operating under a Certificate of Accreditation. CMS may conduct a full review if there is evidence of noncompliance.

VI. Enforcement/sanctions

Sanctions against laboratories with noncompliance violations include suspension, limitation, or revocation of CLIA certificate; Medicare payment approval cancellation; directed plans of correction; civil money penalties; and onsite monitoring.

SOURCE: 42 C.F.R. § 493 (2003).

Excellence in Chapter 2; similar recommendations were also made in *Saving Women's Lives*. These same attributes—centralized, high-volume interpretation and ex-parties in nonmammographic imaging—may also make Breast Imaging Centers of Excellence attractive places to work.

Such centers could offer breast imagers the opportunity to use diverse skills, rather than focusing solely on mammography. These multidisciplinary environments should foster networking and feedback among practitioners with a common interest in breast health—practices that are not only likely to increase job satisfaction for radiologists and radiologic technologists, but which also appear to encourage accuracy in mammogram interpretation (Beam et al., 2003; Maguire, 2003). The continuity among screening, diagnosis, and treatment at breast health centers could also facilitate quality assurance, allowing it to become a more natural part of workflow and less of a burden.

A structure for organizing such multidisciplinary breast units throughout Europe was proposed in a 2000 position paper by the European Society of Mastology (European Society of Mastology (EUSOMA), 2000). This document established guidelines intended to convert existing, heterogeneous practices into a unified system with strong standards for the diagnosis and treatment of breast cancer (Mansel, 2000). While breast cancer experts in both Europe and the United States applauded the proposal's overall aims—ensuring prompt and efficient diagnosis of breast cancer by specialists—they also expressed concern with the inflexibility of the proposed requirements, including the roles and protocols prescribed for the core members of the breast care teams (Silverstein, 2000; Mansel, 2000). These objections make clear that specialization in and of itself is not a prescription for job satisfaction, particularly in the United States, where physicians highly prize their right to individual judgment (Silverstein, 2000).

Increasing Administrative Efficiency

If RTs and interpreting physicians are to maximize their productivity, they should be able to focus their efforts on image interpretation and performing interventional breast imaging procedures, undistracted by administrative tasks. Administrative personnel, data entry personnel, and others could make an important contribution by taking on nontechnical responsibilities in quality control and administration. The Committee therefore recommends support for demonstrations to evaluate the roles of such nontechnical personnel in mammography, and to assess the costs and benefits of alternative staffing configurations on the efficiency, productivity, and quality of breast imaging services.

SUMMARY AND CONCLUSIONS

Because early detection of occult breast cancer is a key element for reducing breast cancer morbidity and mortality, it is important to accurately monitor the capacity of mammography services and to ensure adequate access for women. The paucity of robust national and regional data on the supply of and demand for mammography services necessitated an assessment of the mammography workforce based on estimates and projections and informed by anecdotal and regional reports of unfilled positions, facility closures, wait times, and barriers to access. Barring changes that would decrease demand, demographic projections predict that access to mammography is likely to become in-

creasingly limited, particularly in light of trends in training and employment for both interpreting physicians and RTs. The most severe restrictions in access will probably occur among currently underserved populations, including low-income women.

Clearly, data on the national mammography workforce, volume of services, and capacity should be routinely collected and analyzed, both in order to determine the status quo and to plan for the future. The Committee recommends that FDA address this need by collecting the relevant data during the annual inspection and using unique identifiers for all certified physicians, technologists, and medical physicists. The Health Resources and Service Administration should analyze this data to produce routine reports on the volume of mammography services by region, state, and type of service.

There is an urgent need to begin data collection immediately because it will take several years to identify trends. If the fragile stability of the breast imaging workforce moves toward crisis, data will be needed to react swiftly and effectively. Tracking mammography capacity will also be very important to monitor the impact of the new regulations and voluntary programs recommended in this report. There is always potential for unintended consequences of changes designed to improve quality. For example, it is possible that mammography facilities that lack the resources to participate in the voluntary advanced audit program or to seek designation as a Center of Excellence, as described in Chapter 2, might unfairly be viewed as providing substandard care by patients and insurers, and thus could see their patient base and income decrease This could lead to facility closures and reduce access, especially among women who lack the means to travel and pay for services. Likewise, the added costs of the proposed new medical audit procedures, whether covered by increased reimbursements or not, could disproportionately affect access by low income women.

Initiatives to expand the mammography workforce face a spectrum of factors that discourage today's radiology residents from choosing breast imaging as a subspecialization in radiology and general radiologists from interpreting mammograms. Strategies proposed here to ease these problems focus on increasing the number of entrants to the field of breast imaging and their employment in underserved communities and on retaining skilled breast imagers. The first of these aims could be advanced through existing loan repayment and J-1 visa waiver programs. The second could be achieved by encouraging federal and state agencies and health care payers to develop incentives to recruit and retain skilled breast imagers, for example through support for part-time interpretation of mammograms. Establishing reimbursement rates for mammography that reflect the workload and expense of adhering to requirements of MQSA, as recommended in Chapter 2, would also have a positive impact on the workforce.

Improvements in workplace organization and effectiveness could act in a variety of ways to increase access to mammography, by simultaneously boosting recruitment, retention, and productivity in the breast imaging workforce.

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5

Beyond MQSA

Although much of this report has focused on improving the quality of breast cancer detection as implemented through the Mammography Quality Standards Act (MQSA), this goal can be further advanced through additional measures that extend beyond the current purview of MQSA. Mammography is only one component of a multistep process in breast health care—quality care is thus dependent on performance standards across the cancer care continuum (IOM, 1999). As noted in Chapter 2, the best possible care will result from effective communication and coordination among breast imagers, surgeons, pathologists, and primary and other care providers.

This chapter examines broader approaches to optimizing breast cancer detection through an exploration of the context in which mammography is performed, including challenges associated with broad implementation of reminder systems, the complex issue of medicolegal liability, and the growth of breast imaging technologies that complement mammography, but for which there are no equivalent mandated quality assurance standards.

REMINDER SYSTEMS

Considerable research indicates that adherence to recommended screening intervals is important to maximizing the life-saving potential of screening mammography (Hunt et al., 1999; Tabar et al., 1999; Michaelson et al., 2000; Blanchard et al., 2004). Several studies, including meta-analyses of randomized controlled trials, have demonstrated that the use of patient reminders is associated with an increase in screening mammography and other preventive health measures, although the reported magnitude of this effect is variable (Balas et al., 1996; Shea et al., 1996; Mandelblatt and Yabroff, 1999; Stone et al., 2002; Gimotty et al., 2002; Blanchard et al., 2004; Quinley et al., 2004). However, the Task Force on Community Preventative Services recently conducted a systematic review of studies on reminder systems and concluded that there is strong evidence for the effectiveness of patient reminders to increase breast cancer screening (Task Force on Community Preventative Services, 2005). Thus there is ongoing interest in determining which types of reminders are most effective and cost-effective in increasing mammography use and frequency in different practice settings, particularly among eligible women who have never had a screening mammogram and those who are overdue for a repeat mammogram.

Mammography in the United States has been described as opportunistic, meaning that a woman generally requests a mammogram on her own initiative and/or as a result of a recommendation by her physician. Perhaps not surprisingly, many American women do not receive mammograms at recommended intervals, as illustrated by a multiyear study of mammography utilization in a large screening center at Massachusetts General Hospital (Blanchard et al., 2004). It showed that more than half of women who received a mammogram in 1992 had fewer than five mammograms during the subsequent 10 years (the expected number if following a 2-year screening interval), and that only 6 percent

received annual mammograms during the entire 10 years. Similarly, data from the New Mexico Mammography Project revealed that between 1994 and 1997, 30 percent or fewer women had adhered to the Project's established annual screening recommendations (Gilliland et al., 2000). On the other hand, researchers who examined one of the few examples of organized breast cancer screening in the United States—a not-for-profit managed health care plan serving more than 350,000 people in the state of Washington—found that women who were enrolled in the plan's screening program had a 61 percent lower risk of late-stage breast cancer, compared with women who were not enrolled in the program, using primarily a 2-year interval of screening (Taplin et al., 2004).

Unlike organized breast cancer screening programs in European countries, the United States has not established centralized registers or reminder systems to alert women when they are due for a mammogram. While there are many obstacles to the development of European-style systematized screening in the United States, a variety of reminder systems (see Box 5-1) that have been implemented in both opportunistic and organized screening programs could be further expanded. However, as the findings in Box 5-1 indicate, no single type of mammography reminder system has been found to be superior to others in all populations and situations.

It would also seem that a reminder system that monitors multiple diseases and health risks would be better—from the point of view of both patient and health care provider—than the sort of single-disease intervention typified by mammogram reminders. Related needs such as screening for breast and cervical cancers may be more effectively addressed in combination than through approaches that target single interventions (Valanis et al., 2003). Because many health organizations are committed to increasing rates of preventive care, there is significant potential for developing reminder systems to coordinate multiple prevention activities. For example, an evolving collaboration among the American Cancer Society, the American Heart Association, and the American Diabetes Association could lead to the development of systems that integrate preventive care and testing for each of these diseases (Eyre et al., 2004).

The Committee concluded that patient reminder systems are an important and effective tool to encourage women to undergo breast cancer screening at recommended intervals, and that broader use should be encouraged. However, the variability of practice settings in the United States makes it difficult to recommend any one particular type of reminder system, or to mandate their use under MQSA.

MEDICOLEGAL LIABILITY AND THE QUALITY OF CARE

As noted in Chapter 4, concerns about the likelihood and consequences of malpractice liability may discourage radiologists from interpreting mammograms. Malpractice lawsuits (described in Box 5-2) have become increasingly common, costly, and time-consuming. Malpractice liability insurance rates have also risen. Physicians interpreting mammograms are particularly concerned about the high frequency of malpractice lawsuits involving delayed diagnosis of breast cancer and the expense of paid claims for such suits.

The escalation of medicolegal costs could perhaps be contained through medical liability reform. However, this is a complex topic of considerable controversy. Many approaches to reform have been proposed, but there is widespread disagreement in the

BOX 5-1 Reminder System Models and Comparisons

Some women use electronic or paper-based calendar tools to alert them when it is time to schedule their mammogram. Certain primary care practices and mammography programs notify women that they are due for screening by letter (an "outreach" reminder system); others insert a notice into a woman's medical chart instructing her primary care physician to advise her to schedule a mammogram at her next visit (a "provider-based" reminder system). Either type of reminder system can be readily automated for use, particularly if electronic medical records are used.

However, simply constructing such a reminder system does not guarantee its effective use. Several studies have attempted to determine and compare the effectiveness of various reminder systems for a variety of preventive health measures, and to assess the reasons why such systems often fail. Reminders that depend on regular encounters between patient and health care provider are inherently limited. Even women with consistent access to medical care switch health plans and, as they age, tend to see their physicians more for chronic health problems than for preventive care. Moreover, research indicates that physicians frequently ignore or neglect to mention chart reminders, often due to lack of time.

Evidence indicates that outreach reminders to patients are more effective than provider-based reminders in increasing rates for preventive care procedures, including mammography. A 1998 meta-analysis of 16 U.S. studies in which controls did not receive any type of reminder found that women who received a mailed reminder were approximately 50 percent more likely to get a mammogram, and that letters tailored to the health risks faced by individual women were even more effective; more recent studies add to the support for such outreach reminders. The combined weight of this research suggests that mammography rates could be increased if mammography facilities, as well as primary care providers, implemented a routine outreach reminder system for eligible women.

Comparisons of the cost-effectiveness of various mammogram reminder systems have favored postcards and telephone-plus-letter interventions. However, Vogt and colleagues argue that "to be maximally effective, reminder systems need to concentrate on the rarely screened." These researchers examined the cost-effectiveness of letter and phone outreach interventions to deliver breast and cervical cancer screening to approximately 41,000 women who had been unscreened for at least 3 years. A combination of letter plus follow-up phone call, the most cost-effective option, led to mammography screening in about half of women who received the intervention; this was more than twice the rate of compliance among women who received the letter alone, and five times the rate of compliance among women who were reminded only by routine system and environmental prompts. "An initial letter gets the motivated people in cheaply . . . [while] a personal phone call in which the appointment can be scheduled motivates those who are more reluctant," the researchers conclude. Unscreened and underscreened women tend to be older. Lower mammography rates have also been found for women living in rural areas, those with low incomes and/or socioeconomic status, and minority women.

Reminder letters were found to increase mammography among long-term noncompliant older women, and were associated with a higher rate of repeat mammography among women Medicare members (predominantly age 65 and older), particularly those aged 75 and older. A comparative study of reminder systems used by primary care pra-

Continued

BOX 5-1 *Continued*

ctices in Kansas found that significantly fewer rural practices employed such systems, a difference that apparently contributed to (but did not entirely explain) disparities in rural–urban mammography rates.

By contrast, letter reminders were found to be ineffective in prompting predominantly low-income, black members of a Detroit health maintenance organization to schedule mammograms. Although a study of low-income women in Colorado found that phone outreach intervention involving multiple reminder calls significantly increased mammography among previously nonadherent women, it is important to note that the subjects in this study were chosen based on their ability to receive phone calls. Researchers in the Detroit study found that nearly half of its potential participants had either unlisted or absent telephone numbers; under such circumstances, provider-based reminder systems may have the best chance of improving mammography rates. Taken as a whole, these findings indicate that a "one size fits all" approach to mammography reminders is unlikely to be effective. In much the same way that tailoring reminders to individual women improves their impact, so may reminder systems need to be designed to reach specific populations.

SOURCES: Yarnall et al. (1998); Schellhase et al. (2003); Bankhead et al. (2001); Somkin et al. (1997); Wagner (1998); Mayer et al. (2000); Rakowski et al. (2003); Fishman et al. (2000); Valanis et al. (2003); Saywell et al. (1999); Vogt et al. (2003); Simon et al. (1998); Engleman et al. (2004); Harrison et al. (2003); Quinley et al. (2004); Crane et al. (2000).

United States on what reforms, if any, would be beneficial for improving the delivery of quality health care, in part because the full effects of reforms are difficult to predict. In order to explore the potential of one approach—a no-fault liability system linked with high performance requirements—to simultaneously improve the quality of breast imaging, reduce the burden of lawsuits, and ensure fair and timely compensation in the event of a misdiagnosis, the Committee recommends that the feasibility of such a system be tested within breast imaging Centers of Excellence, as described in Chapter 2. The following section provides the context and justification for rewarding and promoting high-quality care with protection from claims of negligence.

The Costs and Consequences of Malpractice Litigation

Although malpractice liability may make a modest positive contribution to patient safety in some areas of medicine (Hyman and Silver, 2004), there is a lack of consistency underlying which cases of medical negligence are argued in court, and the amount of damages awarded in these cases. The degree of negligence does not appear to be rationally linked to either of these outcomes (Studdert et al., 2004). A research team at Harvard University reviewed the medical records from more than 30,000 hospital discharges and 3,500 malpractice claims in the state of New York. The authors reported that only 2 percent of negligent injuries resulted in claims, and only 17 percent of claims seemed to involve a negligent injury (Localio et al., 1991). A follow-up study found that the severity of the patient's injury, not the doctor's negligence, was predictive of the amount of dam-

BOX 5-2 The Malpractice Claims Process

The majority of medical malpractice claims are taken to civil courts, where the plaintiff's attorney (for the patient) argues that the defendant (physician) has harmed a patient through professional negligence (tort). To prove the claim of negligence, the attorney must show that the physician failed to fulfill his or her duty to the patient and that this failure resulted in injury and damage to the patient. The duty a doctor has to a patient is generally defined as adhering to a "standard of care," which, in turn, is vaguely defined by the courts as being "reasonable" or "ordinary" medical treatment. Often a physician with the same expertise as the defendant serves as a witness for the prosecution to claim that the standard of care was not followed by the defendant. Increasingly, published medical standards or guidelines written by medical professional societies or hospitals, or discussed in medical textbooks and monographs, are used to establish the standard of care.

Once a physician has been found negligent, the jury then decides how much monetary compensation the doctor should provide the patient. Such "damages" usually include "general or noneconomic damages" for the pain and suffering that resulted from the injury in question, and "special or economic damages" that are designed to cover the medical expenses, lost income, funeral expenses, or other miscellaneous costs associated with the injury incurred. If an attorney is able to show that a physician's negligence was reckless or willful, then an additional amount of "punitive damages" are awarded to the patient or the patient's family, although this rarely occurs. Attorneys usually charge their clients a percentage of the damages awarded as their fee for arguing the case. These fees can be as much as 40 percent of the total damages awarded. In addition, it can take years to resolve a claim through the court system.

SOURCES: Congressional Research Service (2004); Posner et al. (1996).

ages paid to the patient (Brennan et al., 1996). Similar results were found in another study conducted in Utah and Colorado in the late 1990s (Thomas et al., 2000).

An increasing number of medical malpractice cases and rising amounts of damages awarded by juries or through negotiated settlements may have helped fuel a dramatic increase in medical malpractice insurance rates (Studdert et al., 2004; Vidmar et al., 2005). The current high cost of such insurance is also likely due, in part, to other factors such as insurance market dynamics, a downturn in the economy that lowered the interest rates paid in bonds invested by insurance companies, and the rising cost of medical care (Public Citizen, 2004; Thorpe, 2004; Black et al., 2005). But a U.S. Government Accountability Office (GAO) report concludes that these are lesser factors than rising claim costs (U.S. Government Accountability Office, 2003). Between 1994 and 2001, the average medical liability award increased 176 percent. In 2002, medical malpractice insurers paid more in claims, with a median of $30,000,[1] than they received in premiums (Jury Verdict Research, 2002). A Medical Group Management Association (MGMA)

[1] The average was $3.9 million due to a small number of very high claims.

survey[2] found physician groups faced an average rate hike of 53 percent in malpractice premiums between 2002 and 2003 (MGMA Center for Research, 2003).

Comprehensive data to establish direct links among malpractice costs, provider actions, and access to health care is lacking (U.S. Government Accountability Office, 2003; Public Citizen, 2004). Nonetheless, concerns about malpractice liability could potentially lead some physicians to limit services, retire early, move to other states where liability premiums are stable, or choose less litigious specialties. The American Medical Association (AMA) asserts that such choices have resulted in serious patient access problems in 20 states (AMA, 2004). A recent Harris poll[3] suggests that the growing threat of medical liability might influence a doctor's choice of specialty. Nearly a third of doctors surveyed indicated that they chose a specialty they thought was less likely to be affected by legal claims. Another 43 percent of respondents said they have considered leaving medicine because of concerns about medical malpractice. Three-quarters of those surveyed said the threat of litigation affects their ability to provide quality medical care (Harris Interactive Inc., 2002). Ninety-four percent of respondents claimed unnecessary or excessive care is often given to avoid medical malpractice lawsuits, even though GAO and the Congressional Budget Office (CBO) have reported that there is no empirical evidence to document the practice of defensive medicine (U.S. Government Accountability Office, 2003; CBO, 2004). An AMA survey[4] of medical students found that about half said that medical liability was a factor in their choice of specialty (AMA, 2003).

Medical Liability and Mammography

The delay in diagnosing breast cancer in women leads to more malpractice claims than any other medical condition and is second only to the neurological impairment of newborns in the expense of paid claims, according to a 2002 Physician Insurers Association of America (PIAA) report. The settlements and judgments in mammography cases nearly doubled from 1992 to 2002 (PIAA, 2002).

The large number of malpractice suits stemming from mammography is partly due to the high volume of screening mammograms conducted each year in this country (Brenner, 2000). But many of these malpractice cases may be rooted in the misguided public perception that mammograms are infallible and provide clear-cut evidence of any cancer that might be present in the breast (Lerner, 2001; Kopans, 2004; IOM, 2005). Fifteen to 20 percent of breast cancers are not visualized on mammograms, and approximately 30 percent of breast cancers can, only in retrospect, be seen on previous mammo-

[2] MGMA's questionnaire was made available to a convenience sample of members on the association's website. Thus, the results may not be scientifically valid or representative of all medical groups. MGMA collected responses from 700 group practices that employ more than 16,000 physicians (mean group size was 9 physicians). MGMA has 19,000 members who manage more than 11,000 organizations, which employ nearly 240,000 physicians.

[3] Three hundred physicians were interviewed online using Harris Interactive's Physician Panel. One hundred hospital-based nurses and 100 hospital administrators were interviewed by telephone. The three sample groups were selected because they were thought to make up the key constituents in the delivery of medical care, and also were thought to potentially have different views on the subject matter and perhaps even different abilities or incentives to be either forthcoming or reserved on the subject matter.

[4] In August 2003, an e-mail with a hyperlink to the online survey was sent to 20,976 medical students for whom the AMA had e-mail addresses. A total of 3,952 surveys were completed and returned, for a response rate of 19 percent. The stated purpose of the survey was to examine medical students' awareness of the medical liability situation, concerns related to the current medical liability environment, and the impact of those concerns on choice of specialty and state of practice.

grams interpreted as normal (Martin et al., 1979; Bird et al., 1992; van Dijck et al., 1993; Reintgen et al., 1993; Harvey et al., 1993; Burhenne et al., 1994; Duncan and Wallis, 1995; Ganott et al., 1999; Warren-Burhenne et al., 2000; Saarenmaa et al., 2001). Even experienced radiologists specializing in breast imaging will prospectively miss cancers that are evident in retrospect.

In mammograms, cancers are often obscured by normal glandular and connective tissue in the breast, are located in areas difficult to visualize, or mimic benign structures (Brenner, 2000; IOM, 2001, 2005). The dense, obscuring breast tissue common in younger women makes mammograms particularly difficult to interpret. This is, in part, reflected in the fact that more than one-third of paid claims for delayed diagnosis of breast cancer involved women under the age of 40, who comprise less than 5 percent of invasive breast cancer cases (PIAA, 2002).

A 2002 PIAA study found that in nearly 80 percent of the lawsuits for failure to diagnose breast cancer, the results of the first mammogram were reported as negative or equivocal (PIAA, 2002). Testimony by an expert radiologist that conflicts with that of the defendant is often used to support a medical malpractice claim related to a missed breast cancer diagnosis after interpreting a mammogram. But expert witnesses often misstate to juries what the standard of care is (Homer, 2004; Berlin, 2004), and radiologists often vary in their interpretation of subtle findings in a mammogram. One study of the "normal" mammograms of women who were diagnosed with breast cancer shortly after the mammograms were taken found 80 percent of them had subtle, nonspecific findings in the area of the breast where the cancer was found. When two expert radiologists reviewed these negative mammograms, they concurred that most of the subtle findings were below the threshold for intervention (Ikeda et al., 2003a). The author of this study concluded, in a response to a letter to the editor, that "just because 'something' is visible where cancer develops subsequently does not mean that a defendant radiologist was negligent in choosing not to recommend recall for additional imaging. Our results show that failure to act on every subtle mammographic finding at a site where cancer develops later does not necessarily imply failure to conform to the standard of care" (Ikeda et al., 2003b). Nonetheless, unrealistic public expectations for mammography may deter radiologists from contesting even seemingly frivolous cases (Berlin, 2003).

There also is debate in the medical literature over whether delays of less than a year in the diagnosis of breast cancer significantly alter prognosis (Berlin, 2001). Most breast cancers are slow-growing tumors whose spread would not be affected significantly by such delays. Others have such aggressive tendencies that an earlier diagnosis would not necessarily improve outcome. Despite this debate, the average amount paid for breast cancer diagnosis delays of less than 6 months was $227,000 in 2002 (PIAA, 2002).

As noted in Chapter 2, fear of litigation could potentially affect the way radiologists interpret mammograms, with "defensive medicine"[5] becoming more common. Mammography screening programs in North America have a higher percentage of false-positive readings than similar programs in other countries (Smith-Bindman et al., 2003; Yankaskas et al., 2004). Although this difference could be due to differences in the population of women screened, in how they are screened, or in how abnormal mammograms are defined, it could also be due to the risk of being sued for malpractice being of higher

[5] Defensive medicine is defined as medical actions undertaken to avoid liability rather than to benefit the patient.

concern to American doctors (Elmore et al., 2003). No causal relationship can be definitively shown, but the near doubling of the false-positive rate in the United States from 1985 to 1993 closely paralleled the increasing rates of mammography-related malpractice suits (Elmore et al., 2002). In addition, one survey of U.S. radiologists found nearly three-quarters of them believed concerns about malpractice moderately or greatly increased their recommendations for diagnostic mammography and ultrasounds, and more than half (59 percent) believed this concern moderately or greatly increased their recommendations for breast biopsies (Elmore et al., in press).

Reforming the Medical Liability System

In response to the recent medical malpractice trends, many states, as well as the U.S. Congress, have introduced tort reform bills (see Box 5-3). Recently proposed legislation in Florida targeted medical malpractice suits directed at radiologists who perform mammograms (H.B. 1087, S.B. 2306).[6] The original Radiologists Performing Mammograms bill would have provided Florida-licensed radiologists performing mammography with immunity from tort liability unless they were found to be grossly negligent or failed to adhere to practice criteria the bill establishes. These criteria included adhering to MQSA standards and American College of Radiology (ACR) guidelines for mammography procedures, participating in a facility's quality improvement program, and communicating any unexpected findings on a mammogram to the referring physician or other appropriate individuals, even if the findings do not warrant immediate treatment.

The bill underwent extensive revision in committee. The final version, signed into law, omitted the malpractice immunity clause and created in its place a Workgroup on Mammography Accessibility to study the availability, quality of care, and accessibility of mammography in Florida (Florida House of Representatives Staff, 2004). However, the state could not conclusively determine whether malpractice claims were having a detrimental effect on access to mammography services due to a lack of comprehensive and accurate medical liability insurance and claims data specific to Florida (The Workgroup on Mammography Accessibility, 2004; The Florida Legislature: Office of Program Policy Analysis & Government Accountability, 2004). Nonetheless, based on the available national data and recognition that mammography is not a perfect test, the Workgroup recommended medical malpractice reform measures, including a limit on noneconomic damage awards, establishment of an expert panel to review presuit images for "probable cause" before advancing the case for further legal action, and a change in the burden of proof for alleged medical liability cases involving breast cancer, from the greater weight or preponderance-of-the-evidence standard to the clear-and-convincing standard (The Workgroup on Mammography Accessibility, 2004).

In recent years, the U.S. House of Representatives has passed several national tort reform bills, but none have been passed by the Senate. In 2004, the Senate debated S. 11, Patients First Act of 2003. This bill would have imposed caps on noneconomic damages and punitive damages, permitted defendants to be held liable for no more than their share of responsibility for a plaintiff's injuries, and required that damage awards be reduced by the amounts plaintiffs receive from collateral sources. The bill also would have limited

[6] Radiologists Performing Mammograms Act. H.B. 1087/S.B. 2306, Florida State Legislature, Regular Sess. (2004).

BOX 5-3 Tort Reform Legislation

Most tort reform focuses on limiting access to court, modifying liability, and/or capping the size of awards granted. Limiting access to court is accomplished by requiring screening panels to determine whether the merits of claims are worthy enough to go to court, or by creating a statute of limitations—a specified period within which a plaintiff is permitted to sue after experiencing or discovering the injury. Liability is modified by passing laws that set standards for expert witnesses and/or medical practices, or by making each defendant in multidefendant cases liable only for his or her share of responsibility for the plaintiff's injury. This elimination of the standard "joint and several liability" common law rule may only apply to noneconomic damages or to defendants responsible for less than a specified percentage of the plaintiff's harm.

The size of awards granted can be limited by specifying a cap on the amount of damages allowed. Usually this cap only applies to noneconomic (pain and suffering) damages, but it can also be applied to economic or punitive damages. Alternatively, the size of awards granted can be indirectly lowered by other rulings that regulate attorneys' fees, often reducing the maximum percentage of attorneys' contingency fees. Another tactic is to have rules mandating "collateral source offsets" and "periodic payments." Collateral source rules deter plaintiffs from double dipping—receiving monetary compensation for losses that can be recouped from other sources, such as an insurance company, an employer, or the government. Periodic payments enable defendants to pay plaintiffs in installments, usually done annually, rather than paying a lump-sum award. The costs of periodic payments tend to be less than conventional lump-sum settlements.

California was one of the first states to enact tort reform measures. Its Medical Injury Compensation Reform Act (MICRA), which was enacted in 1975, has served as a model for many state and federal efforts at tort reform. This Act puts a $250,000 limit on noneconomic damages, limits attorneys' contingency fees, creates a statute of limitations, provides for periodic payments of future damages, and limits double dipping by enabling a defendant to introduce evidence of collateral source payments as they relate to damages sought by the plaintiff. More than half of the states similarly cap noneconomic damages in medical malpractice suits, with ceilings ranging from $250,000 to $700,000, and about one-third of the states regulate attorneys' fees.

Studies are beginning to reveal the effects of state tort reform measures. Most studies show that caps on damages significantly reduce payouts in medical malpractice cases, but their effect on medical malpractice insurance premiums is less clear. Since MICRA was enacted, the increase in medical liability premiums in California is one-third of what it has been for the rest of the nation, although additional state legislation to reform the insurance industry also likely had an impact on premium increases. Collateral source offsets appear to reduce payouts and the frequency of claims, but not the cost of malpractice insurance premiums. Other studies show inconsistent results or a lack of effects from creating a statute of limitations, regulating attorneys' fees, or establishing pretrial screening panels. One study linked state legislation capping damages to higher growth over time in the supply of physicians in the state.

SOURCES: Congressional Research Service (2004); Public Citizen (2004); Studdert et al. (2004); Thorpe (2004); California Physician (2003); CBO (2003); U.S. Government Accountability Office (2003); Hellinger and Encinosa (2003); Kessler and McClellan (2000).

attorneys' contingent fees, created a statute of limitations, and enabled periodic payment of future damages. In addition, S. 11 would have required expert witnesses in health care lawsuits to meet specific qualifications (Congressional Research Service, 2004).

When the Senate failed to pass S. 11, a similar bill was introduced in March 2004. This bill, S. 2207, the Pregnancy and Traumatic Care Access Protection Act of 2004, had the same stipulations as S. 11, except it limited their application only to cases involving obstetric, gynecological, emergency, or trauma care. This bill targeted medical specialties most affected by rising malpractice insurance premiums, but also failed passage in the Senate, as did a similar bill, S. 2061, Healthy Mothers and Healthy Babies Access to Care Act (Congressional Research Service, 2004; Heil et al., 2004a, 2004b). More recently, Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan indicated that the Bush Administration would consider a range of options to reform the medical liability system, including requirements to report medical errors, to set up expert review panels, and to establish early offer programs. He noted that there is growing evidence that a set of changes is needed to ensure justice for all parties in the medical malpractice system. Senate Majority Leader Bill Frist also has indicated that he favors more comprehensive changes (Health Care Information Center, 2005).

No-Fault Systems for Medical Liability

Although state and national efforts at tort reform might eventually succeed in stemming the number of malpractice cases and in lowering malpractice insurance premiums, critics point out that these efforts are not likely to improve the quality of patient care or make compensation for injuries more accurate or fair (Thorpe, 2004; Studdert et al., 2004; Hyman and Silver, 2004). These critics call for more sweeping malpractice reforms, including those that offer mechanisms other than civil tort suits to resolve disputes. Options include private settlements, structured mediation, or the hearing of cases in front of a medical court. Responsibility for malpractice situations could also be placed at the institutional level (enterprise liability), such that hospitals or other medical facilities would assume primary responsibility for any claim brought against an affiliated clinician and would cover their physicians' liability costs at rates that vary according to the institution's overall injury experience (Studdert et al., 2004). Both an Institute of Medicine report and the Florida Governor's Select Task Force on Healthcare Professional Liability Insurance have endorsed pilot projects that explore such institutional liability as well as administrative compensation schemes akin to workers compensation (IOM, 2003; Studdert et al., 2004).

In the latter case, "no-fault" standards would replace negligence as the basis for compensation and give an administrative body the power to determine compensation for medical injury claims without the need to prove negligence, as is done for workers compensation for injuries sustained at the workplace. No-fault systems already exist in other countries such as Sweden and New Zealand (Studdert and Brennan, 2001). Sweden's system has been in place for 30 years, and physicians are actively involved in filing claims in the majority of cases (Espersson, 1992). When a claim is made, the physician files a report and an adjuster makes an initial determination of eligibility before forwarding the case for final determination to one or more specialists retained to help judge compensability. About 40 percent of claims receive compensation that addresses both economic and noneconomic losses within 6 months of initiation, on average. Patients who are dis-

satisfied with the outcome may pursue a two-step appeals process that consists of review by a panel followed by an arbitration procedure (Espersson, 1992). The concept of avoidability is central to the compensation criteria. In short, the reviewers must determine whether an injury resulted from treatment, whether the treatment was medically justified, and whether the outcome was unavoidable (Studdert and Brennan, 2001).

In the United States, the no-fault approach is rarely used. Florida and Virginia have each used a small-scale, no-fault system since the late 1980s for newborns with severe, birth-related neurological impairment. Studies indicate that these programs have been effective in providing consistent and timely compensation, and have also reduced administrative costs (Horwitz and Brennan, 1995; Sloan et al., 1997; Studdert et al., 2000). Doctors are charged varying annual fees to pay for these two programs, but other entities, including hospitals, health plans, and taxpayers, could also theoretically bear some of the cost. It is difficult to estimate the cost of a large-scale program in other areas of medicine, but one study suggests that the cost of a no-fault system in Utah and Colorado would be nearly equivalent to malpractice premiums paid in those states even though four times as many people would receive compensation (Studdert et al., 1997; Thomas et al., 1999).

Critics have noted that no-fault systems may not provide feedback to educate physicians about errors, and lack incentives to improve the quality of care. These factors would be addressed in the design of breast imaging Centers of Excellence by incorporating high performance standards, advanced medical audits with feedback, and the financial incentives for quality improvement, such as scaling of insurance premiums based on performance measures (as well as participation in the no-fault system itself). Indeed, by removing the fear of litigation, such systems would create a safe harbor in which physicians could more easily reveal mistakes and learn from them.

Adopting a no-fault system in exchange for this highest level of quality assurance could also benefit patients. The goal of a no-fault system would be to provide access to higher quality mammography services, while also consistently and fairly compensating women in the event of a misdiagnosis without having to endure a long, difficult lawsuit with uncertain outcome. As a result, women would be empowered to make informed choices about where to seek breast imaging services, and would benefit from more open and honest dialogue with physicians. Furthermore, patients who are dissatisfied with the outcome of a case review could appeal the decision and seek arbitration. Even under the ideal conditions within Centers of Excellence, some cancers will be missed because of the inherent limitations of mammography. However, women who experience a misdiagnosis would be more likely to be compensated, and in a shorter period of time, than with the current medical liability system. Under the current system, many women with a misdiagnosis are not compensated at all, and for those who are, compensation varies enormously. In addition, lawsuits often take many years to resolve, and can be difficult, stressful, and costly for the patient.

OVERSIGHT OF OTHER BREAST IMAGING MODALITIES

Mammography currently is the principal screening modality for breast cancer. But other imaging techniques are routinely used for diagnosing breast cancer, and researchers continue to explore new and existing imaging technologies for breast cancer screening and diagnosis, as noted in Chapter 4 (IOM, 2001, 2005). For example, studies suggest

ultrasound or magnetic resonance imaging (MRI) may be useful for screening select populations, such as women at high risk for breast cancer and women with breast implants. In addition, physicians are increasingly using image-guided biopsy procedures to aid in the localization and excision of breast lesions.

Thus, the Committee considered whether there is a need for national standards and quality assurance programs for other breast imaging modalities and for image-guided biopsy techniques, which are not now governed by any national mandates. Currently there is no standardization of quality assurance for other breast imaging procedures, although accreditation programs do exist for breast ultrasound, stereotactic breast biopsy, and general MRI, as described below. These programs are offered by the American College of Radiology and the American Institute of Ultrasound in Medicine (Dershaw, 2000; ACR, 2004a).

Ultrasound Accreditation

Several studies have demonstrated that the effectiveness of ultrasound at detecting abnormalities depends on the expertise of the operator (Abuhamad et al., 2004). Diagnostic errors made by radiologists are the main cause of obstetric ultrasound malpractice cases, according to one study (PIAA and ACR, 1997). The Routine Antenatal Diagnostic Imaging with Ultrasound (RADIUS) trial found the detection of fetal abnormalities was nearly three-fold higher when the sonographer was highly trained in ultrasonography (Ewigman et al., 1993).

Prompted by these findings, the American Institute of Ultrasound in Medicine (AIUM) established a program for voluntary accreditation of ultrasound practices in the United States and Canada in 1996. This accreditation is provided for practices that show evidence of physicians' training in ultrasonography, credentialing of sonographers, Continuing Medical Education (CME) for both physicians and sonographers, and protocols and quality assurance procedures that ensure proper and safe practice of ultrasonography. In addition, practices applying for AIUM accreditation must submit four case studies for each specified area of accreditation—obstetrics, gynecology, breast, and/or abdomen/general ultrasound. These case studies are scored by independent reviewers according to minimum criteria for ultrasound practices set by AIUM (Abuhamad et al., 2004).

AIUM's accreditation program was followed in 1998 by one for breast ultrasound by the ACR (ACR, 2004c). A facility may apply for breast ultrasound accreditation, or for breast ultrasound plus biopsy accreditation. The facility must submit sets of clinical ultrasound images that demonstrate breast lesions and/or breast lesions with accurate needle placement. The images are scored by a review panel of qualified radiologists. Physicians must have sufficient training in ultrasound, meet the ACR qualifications for screening and diagnostic mammography, conduct a recommended minimum number of ultrasound-guided breast biopsies and/or ultrasound exams per year, and have sufficient CME in breast ultrasound or ultrasound-guided breast biopsies. Sonographers must be certified by the American Registry of Diagnostic Medical Sonographers, or have post-primary certification ("advanced registry") in breast sonography by the American Registry of Radiologic Technologists. Sonographers also must attend a minimum number of CME programs and regularly perform breast ultrasound exams. In addition, each facility must submit outcomes data on the number of procedures done, cancers found, benign lesions identified, and ultrasound-guided biopsies needing repeat biopsy or causing com-

plications. Facilities also must meet equipment specifications and provide documentation of a quality control program (ACR, 2004c). As of January 2005, 435 facilities had obtained accreditation in breast ultrasound, up from 337 in March 2002.

Although obtaining accreditation in ultrasound is voluntary, some state Medicare programs and private insurers are starting to require facility accreditation and/or sonographer certification for reimbursement for ultrasound exams (Krotz, 1998). Some experts estimate that about half of sonographers in the United States lack certification (Krotz, 1998). It is not documented what proportion of facilities performing breast ultrasound exams or guided biopsies are accredited, nor is there firm evidence that voluntary accreditation programs in ultrasound have improved the quality of ultrasound exams and interpretations. One study found that facilities applying for reaccreditation by AIUM had significantly improved scores for their obstetric and gynecologic case studies compared to their scores when they first applied for accreditation (Abuhamad et al., 2004). This improvement could be due to more experience, however, and not due to the accreditation process itself.

Stereotactic Breast Biopsy Accreditation

Stereotactic breast biopsy, which entails removal of breast tissue with a needle under mammographic guidance for proper placement, is currently exempt from MQSA regulations. However, since 1996, the ACR has offered an accreditation program in the procedure, with quality standards that are consistent with those of MQSA. By January 2005, this voluntary program had accredited 430 units at 423 facilities. An accreditation program offered by the American College of Surgeons with the assistance of the ACR also accredits stereotactic breast biopsy, but only seven surgical facilities currently participate. Among those facilities seeking ACR accreditation for stereotactic biopsy, the initial pass rate is 68 percent, roughly equivalent to the 70 percent pass rate for mammography when MQSA was first enacted (the mammography accreditation initial pass rate is now 88.3 percent) (Destouet et al., in press). Although exact numbers are not available, the ACR estimates that several thousand facilities perform this procedure without accreditation. In such facilities, mammography units that have not been accredited under MQSA can be used for stereotactic biopsies.

In order to become accredited, facilities must submit clinical images that demonstrate accurate needle placement for a suspicious lesion, as well as phantom images, to the ACR for expert review. Physicians must have adequate training and CME attendance, as well as initial and continuing experience conducting stereotactic breast biopsies and managing patients recovering from biopsies. Radiologic technologists must be certified; receive training in breast radiology, radiation safety and protection, and quality control; and perform mammography on a regular basis. Radiologic technologists also must have initial and continuing experience in stereotactic biopsies and mammography, and must attend a minimum number of relevant CME programs (ACR, 2004e).

The ACR accreditation program for stereotactic breast biopsy also specifies requirements for the medical physicist and the equipment at a facility, and requires documentation of quality control, including conducting specific annual tests. Facilities must also conduct ongoing medical audits of their stereotactic breast biopsy procedures to evaluate and improve performance, including noting the numbers of procedures done, cancers diagnosed, benign lesions identified, lesions needing repeat biopsy, and biopsy

complications requiring treatment (ACR, 2004e). But the use of these results to improve performance is not overseen by the ACR and ultimately is the responsibility of the physician in charge of the facility. Appropriate benchmarks for each of these outcomes measures have not yet been established in peer-reviewed literature (Dershaw, 2000).

Most states do not require accreditation to perform stereotactic breast biopsies. But the Food and Drug Administration has stated in the past that unless nearly all facilities performing stereotactic breast biopsies become voluntarily accredited, a mandatory program would be instituted under MQSA (Dershaw, 2000). As noted in Chapter 3, the Committee recommends that these interventional mammographic procedures, as well as standard presurgery wire localization procedures, be included now under MQSA regulations.

MRI Accreditation

There are no breast-specific MRI accreditation programs, although the ACR has begun a dialogue to examine the possibility of establishing such a program.[7] Since 1996, the ACR has offered a whole-body MRI accreditation program. This program specifies a minimum amount of training, experience, and CME attendance for physicians, technologists, and medical physicists or MRI scientists at facilities conducting MRI. It also requires MRI equipment to meet all state and federal specifications and performance requirements, as well as to perform adequately in quality control tests conducted regularly at the facility. MRI safe practice guidelines must also be written, enforced, reviewed, and documented at least annually by the MRI supervising physician. Facilities must submit clinical images of specific sites in the body to the ACR for evaluation by MRI experts, but the breast is not one of the body sites specified (ACR, 2004d). Although some general MRI machines are being used for breast imaging, use of a dedicated breast coil is imperative for obtaining high-quality images (Schnall, 2003; Lee, 2004).

Time to Mandate Accreditation of Breast Ultrasound and MRI

As noted in Chapter 4, several recent reports have suggested that ultrasound and MRI may be useful for breast cancer screening among high-risk women. These data are not yet definitive, but the publicity accorded these studies is leading to increased use of the technologies, whether warranted or not. These two imaging technologies are also commonly used for the diagnosis of breast cancer. However, concerns have been raised regarding variability in breast MRI image quality because imaging methods have not been standardized for this procedure, but different approaches can affect the quality of the image produced (Bosmans et al., 2000; Orel and Schnall, 2001; Schnall, 2003; ACR, 2003). In addition, although the ACR has developed assessment categories for breast ultrasound and MRI similar to those for mammography, interpretation of images generated by these methods is quite variable (Goscin et al., 2001; Baker and Soo, 2002; Flobbe et al., 2002; ACR, 2003).

In the past voluntary accreditation programs have not been widely adopted, including voluntary programs for mammography accreditation prior to MQSA. Given the small proportion of facilities undergoing voluntary accreditation, it may now be advisable to mandate accreditation of some other commonly used breast imaging methods like MRI

[7] Personal communication, P. Butler, Senior Director, Breast Imaging Accreditation Programs, American College of Radiology, January 2005.

and ultrasound. Among those facilities currently choosing to undergo voluntary accreditation for breast ultrasound, the initial pass rate is now 80 percent, compared to 66 percent in 1998 when the program began. The average proficiency of facilities that currently choose not to undergo voluntary breast ultrasound accreditation is likely to be lower, similar to the mammography experience prior to MQSA. Expansion of accreditation requirements to these breast imaging methods is likely to result in significant improvement in quality of practice, similar to what has been observed for mammography.

Some large health care insurers are encouraging providers to participate in voluntary accreditation programs. For example, United Healthcare, the nation's largest health insurer, plans to label ACR-accredited radiology facilities with an "Excellence in Radiology" moniker in their provider directories with the intent of compelling patients to seek accredited facilities (Thompson, 2004). United Healthcare will also disseminate the ACR Appropriateness Criteria (ACR, 2004b), which provide consensus guidelines on imaging utilization in various clinical scenarios, with the goal of curbing improper use of imaging procedures.

Such tactics are commendable, but making accreditation mandatory would likely have a broader impact. As long as the number of facilities participating in voluntary programs is small, a large number of women will undergo imaging procedures that may be of questionable quality and utility. By making accreditation mandatory for commonly used breast imaging procedures, all patients would be assured that providers meet minimum standards for competence and quality. Although such a move may reduce the number of facilities or physicians offering the procedures, presumably those that were committed to quality and accuracy would seek accreditation and continue to provide services. The burden on facilities could be minimized initially by forgoing onsite inspections as is currently required for mammography under MQSA. Ideally, a panel of experts and patient advocates would routinely review the status and use of various breast imaging procedures to update the requirements for accreditation or inspections as needed.

Proposals for mandatory accreditation of other medical imaging procedures have been raised recently as well. The Medicare Payment Advisory Commission has proposed setting national standards of expertise for providers who bill Medicare for performing and interpreting diagnostic imaging, due to evidence of varying quality and because diagnostic imaging is the fastest growing category of physician services covered by Medicare (Miller, 2005). Concerned about potential cuts to Medicare reimbursement rates, the ACR is also lobbying Congress to support legislation that would limit Medicare reimbursement for MRI, computed tomography (CT), and positron emission tomography (PET) procedures to facilities and physicians with defined qualifications (Brice, 2005). Such legislation would likely include mandatory federal accreditation for MRI, CT and PET, and would set minimum standards for training, CME, and interpretive volume.

Medical technology is constantly evolving, and much has changed since MQSA was originally enacted. The intent of MQSA to ensure quality breast cancer screening and diagnosis could be undermined if it continues to focus solely on mammography without recognizing that high-quality screening mammography cannot reduce breast cancer morbidity and mortality in the absence of accurate pathologic interpretation and appropriate treatment. Although the latter was beyond the scope of the study charge, the Committee stresses that ensuring high-quality treatment is equally as important to reducing the bur-

den of breast cancer as ensuring high-quality screening and diagnosis (IOM, 1999; Zapka et al., 2003), as discussed in Chapter 2.

Breast Biopsy Options

Women who are referred for breast biopsy have a number of options available to them, in addition to the traditional open surgical biopsy. Several forms of minimally invasive needle biopsies, which are performed under image guidance (either mammography or ultrasound), can provide accurate diagnosis (Verkooijen and Core Biopsy After Radiological Localisation [COBRA] Study Group, 2002; Collins et al., 2004). Such procedures are generally better tolerated and are less costly than surgery (Rubin et al., 2001; Verkooijen et al., 2002). This has led to a shift of biopsy procedures from surgery to radiology, as well as an increase in the number of surgeons performing interventional imaging procedures.

However, not all women may be aware of these alternatives, and the choice of procedure may depend on what is offered to them by a particular health care provider. Although variability in the quality of biopsy services among providers or facilities has not been studied, the lack of standards and oversight could potentially result in significant differences.

Although stereotactic breast biopsies should be regulated under MQSA as noted above and in Chapter 3, ultrasound-guided biopsies do not fall under the purview of MQSA. Furthermore, health care providers may be more inclined to perform ultrasound-guided biopsies if stereotactic methods were to be regulated. Mandatory accreditation for other breast imaging techniques such as ultrasound could remove the incentive to provide one procedure over another, and the variability in physician recommendations and performance of these procedures might be reduced. However, another useful approach might be to include a requirement that women be given patient education materials prior to undergoing a breast biopsy. These materials would delineate the limitations, advantages, and disadvantages of different breast biopsy procedures and systems, and could prompt women to ask providers and facilities questions, such as whether they are accredited or certified for particular procedures. California has established a precedent for this with their state law, which requires that any woman about to have a breast biopsy be given a pamphlet on breast cancer diagnosis and treatment (California Department of Health Services, 2004). Michigan law also requires that all women diagnosed with breast cancer receive a copy of a similar booklet prior to choosing a treatment plan (Michigan Department of Community Health, 2003). The National Cancer Institute (NCI) might be the appropriate institution to develop such a product because it has recently developed an informational brochure for women who are trying to decide whether to undergo lumpectomy or mastectomy (National Cancer Institute, 2004). This sort of patient education has been shown in a randomized trial to significantly affect women's choices (Whelan et al., 2004), and the NCI brochure has been well received by some patient advocates (Ready, 2004).

SUMMARY AND CONCLUSIONS

In considering the broader context and intent of MQSA, the Committee studied a variety of measures that could extend and reinforce the Act's success to date in improv-

ing access to quality services for the early detection of breast cancer. The breast imaging Centers of Excellence described in Chapter 2 could test the feasibility of replacing a complex, costly, and punitive medicolegal system with one that rewards and encourages quality care and continuous improvement. In recognition of the importance of a multidisciplinary approach to breast cancer detection, the Committee stresses the need to extend quality assurance, as embodied by MQSA, to stereotactic breast biopsy and standard presurgery wire localization procedures, breast ultrasound and ultrasound-guided biopsy, and breast MRI under the next MQSA reauthorization. This will entail a name change to the Breast Imaging Quality Standards Act (BIQSA). Although quality assurance standards are not currently mandated for these technologies, current accreditation programs could provide the basis for national standards and could greatly improve the overall quality of breast cancer detection, diagnosis, and treatment. However, in the case of MRI, accreditation programs specific for breast imaging will need to be developed and established before accreditation can be mandated. Finally, in order to continue to build on the success of MQSA, a panel of experts and patient advocates should be established to review the need for accreditation or certification of future breast imaging technologies. Achieving the overarching goal of reducing the burden of breast cancer depends on the performance of multiple steps that include screening, diagnosis, and treatment—delivering high-quality care at each of those steps is essential to reduce breast cancer morbidity and mortality.

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Appendix A

ACR SURVEY METHODS AND ANALYSIS

The 2003 Survey was similar to its predecessor, the American College of Radiology's (ACR's) 1995 Survey of Radiologists and Radiation Oncologists (Deitch et al., 1997), but incorporated important improvements throughout the survey process. These ranged from more thorough canvassing of all ACR leadership in order to identify issues of importance and ascertain priorities among them, through use of a multifaceted "tailored design method" (Dillman, 2000) to maximize the response rate, to use of an expanded and more intensive array of steps to improve data quality.

The questionnaire for the 2003 Survey consisted of 36 items; many items in turn consisted of multiple subitems. Questionnaire items and topics were elicited from two rounds of canvassing ACR physician leaders and staff leaders, winnowed according to priorities indicated by top leadership, and pretested in two large pretests conducted in autumn 2002, with refinements made after each pretest.

The survey sample, a stratified random sample composed of four strata, was taken primarily from the American Medical Association's (AMA's) Physician Masterfile, a reasonably complete listing of all allopathic physicians in the United States, whether or not AMA members. The sample from the Masterfile consisted of a 16 percent sample of all those self-designated in the Masterfile as vascular/interventional radiologists, an 8 percent sample of all other radiologists, and an 8 percent sample of nuclear medicine specialists. The sample included residents, fellows, and retirees, not merely posttraining professionally active physicians, and it included physicians whether or not the Masterfile had usable addresses for them. The Masterfile sample was obtained from Medical Marketing Service, Inc. (Wood Dale, IL), the commercial firm designated by the AMA to provide Masterfile data, in January 2003. In addition, the sample included 92 osteopathic radiologists, selected at random by the American Osteopathic College of Radiology (AOCR) from its membership. Based on information supplied by the AOCR, this was an approximately 6.7 percent sample of all osteopathic radiologists in the United States, including non-AOCR members.

In March 2003, the ACR contractor, the Center for Survey Research (CSR) of the University of Virginia, mailed the survey. Nonrespondents were sent up to four remailings as necessary, at approximately monthly intervals. In addition, to boost the response rate: first-class stamps (not metered postage) were used on all outgoing and return envelopes; the survey was publicized in ACR hard-copy and electronic newsletters and those of other radiology organizations; the third remailing was conducted by U.S. Postal Service Priority Mail, which uses a large, attention-getting red, white, and blue envelope; nonrespondents for whom we had telephone numbers were telephoned after the third remailing (with a message left if not reachable after two calls) to urge them to complete the survey; and the third and fourth remailing had a handwritten note urging completion of the survey. The last remailing took place in mid-July; acceptance of responses ended a month later.

As in previous ACR surveys, among nuclear medicine specialists, the ACR was interested only in those who had major ties to radiology; this concept of a major tie to radiology was operationalized as holding American Board of Radiology (ABR) certification and/or being a member of the ACR (Sunshine et al., 2002). On this basis, approximately two-thirds of the original sample of nuclear medicine specialists were omitted from consideration.

The total sample of interest, which was composed of the four strata of interventionalists, all other allopathic radiologists, osteopathic radiologists, and nuclear medicine specialists of interest, consisted of 3,090 physicians. From these, 1,924 usably complete responses were received. In addition, not in the form of completed questionnaires, the ACR received information that 21 addressees were deceased, 6 were no longer practicing in the United States, and 6 were not radiologists. The response rate was thus (1,924 + 6) / (3,090 – 21 – 6) = 63 percent.

Responses were weighted so that the weighted statistics would be representative of the answers that would have been received if all physicians in the United States in the four strata had been surveyed and had responded. The weighting process has been described previously (Sunshine et al., 2002). To begin, logistic regression analysis was employed to determine how many different sets of weights were to be used in each of the four strata. For the 2,743 physicians in the "all other allopathic radiologists" stratum, the analysis showed that ACR membership and age had statistically significant effects on the response rate, while sex, geographic region, and listing in the Masterfile as a "radiologist," "diagnostic radiologist," or "radiology subspecialist" did not. Accordingly, 10 weighting categories, based on whether or not a physician was an ACR member and his/her age, were used, and responses in each category were weighted by the reciprocal of the category's response rate. A similar logistic analysis of the 202 interventionalists in the sample resulted in two weighting categories, based on whether or not the physician was an ACR member. Because logistic regression showed no statistically significant effect, only one weighting category was used for the nuclear medicine specialists of interest and one for the osteopathic radiologists. After all responses in each weighting category were given a weight equal to the reciprocal of the response rate for that category, these weights were multiplied by the reciprocal of the sampling rate to complete the process of making responses representative of the entire U.S. population of radiologists. For example, if a weighting category had a response rate of 65 percent and it was part of a stratum that had been sampled at the general 8 percent sampling rate, then all responses in that weighting category were given a weight of (1/0.65) x (1/0.08) = 19.23.

Data Quality Improvement

Every survey has some deficient data—that is, missing items, responses not in accordance with directions given by the questionnaire, and responses that are inconsistent or have other problems. The leading tool to minimize data deficiencies in this survey was the designation of the 12 items on the questionnaire judged most crucial as "core questions." When questionnaires were returned, CSR checked that these 12 items were indeed answered, and made three designated consistency checks involving them. If there were any problems with the core items, CSR telephoned the respondent to obtain the missing response(s) and/or resolve the consistency problems.

During the data entry process, CSR spot checked entries against the paper questionnaires and found an error rate of less than 0.1 percent. Judging this error rate satisfactory, the data were not double entered.

Data used in this report have been additionally cleaned and edited to further minimize deficiencies. An example of items with relatively extensive cleaning and editing is as follows: For two questions about how radiologists spend their time, answers to subparts were supposed to total to 100 percent. Actual totals were computed, and it was found that in the vast majority of cases in which the entries did not total to 100 percent, the total was slightly below 100 percent. Consequently, if the recorded percentages totaled 95 to 99, all recorded percentages were checked against the paper questionnaire and any errors corrected. The data for all respondents were then edited using an algorithm the ACR has long used with items that are supposed to sum to 100 percent: recorded percentages are summed. If the sum is 80 percent to 125 percent, each percentage is divided by the sum, which makes the revised percentages total to 100 percent. If the sum is <80 percent or >125 percent, the responses are deemed too deficient to use and all responses are set to missing.

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ANALYSES AND REPORTS ON RADIOLOGISTS PERFORMING MAMMOGRAPHY

The American College of Radiology provided the following tables to the Institute of Medicine Committee on Improving Mammography Quality Standards. The following list of column and row headings for each table reflects the type of information provided to the Committee. Actual data is omitted, but is available on request.

TABLE I Number of Radiologists with Various Breast-Imaging-Related Characteristics

Rows:

A. All posttraining professionally active radiologists
B. Radiologists who interpret any mammograms (number of mammograms >0)
C. Radiologists with a fellowship in breast imaging
D. Radiologists who designated breast imaging as their primary subspecialty (on the ACR's 2003 Survey of Radiologists)
E. Radiologists who designated breast imaging as their secondary subspecialty
F. Radiologists who spend more than 30 percent of time in breast imaging
G. Radiologists who spend more than 50 percent of time in breast imaging
H. Radiologists who interpret less than 480 mammograms per year
I. Radiologists who interpret at least 480 mammograms per year
J. Radiologists who interpret at least 1,000 mammograms per year
K. Radiologists who interpret at least 2,000 mammograms per year
L. Radiologists who interpret at least 5,000 mammograms per year
M. Radiologists who do any nonmammo breast imaging (ultrasound biopsy, etc.)
N. Radiologists who do any other breast imaging, but no mammograms

Columns:

1. Unweighted number of responses
2. Weighted number = number of radiologists in the United States who meet the definition, with standard deviation
3. Weighted percentage of all radiologists, with standard error

TABLE II Combinations of Breast-Imaging-Related Characteristics

Rows: Same as Table I

Columns: Same as B through N

Note: Each cell indicates the percentage (and standard error) of those in the row who also meet the column definition. For example, this table will give the percentage of those who say breast imaging is their primary specialty who interpreted 2,000 mammograms a year, the percentage of those who did a breast imaging fellowship that now spend at least 30 percent of their clinical work time doing breast imaging, etc.

TABLE III Further Information About the Breast Imaging Activity of Those in Each Category, A Through N

TABLE IIIa Further Information on Mammography Activity and Other Breast Imaging Activity, by Radiologists' Breast-Imaging-Related Characteristics

Rows: Same as Table I, definitions A through N

Columns:

1. Unweighted number of responses (Repeat from Table I)
2. Weighted number of radiologists (Repeat from Table I)
3. Weighted percentage of all radiologists (Repeat from Table I)
4. Percentage who interpret any mammograms
5. Weighted average number of mammograms for those who interpret any
6. 25th percentile, 50th percentile, and 75th percentile of number of mammograms for those who interpret any
7. Overall average number of mammograms (not only for those who interpret any)

TABLE IIIb Further Information on Nonmammography Breast Imaging Activity, by Radiologists' Breast-Imaging-Related Characteristics

Rows: Same as Table I, definitions A through N

Columns:

1. Percentage doing any nonmammography breast imaging
2. Average number of types (of the ones listed below) of nonmammography breast imaging done
3. Percentage who do each of the following types of nonmammography breast imaging, with standard error
    a. ultrasound-guided breast biopsy
    b. stereotactic breast biopsy
    c. localizations for surgical breast biopsy
    d. fine needle aspiration (FNAC)
    e. computer aided detection (CAD)
    f. full-field digital mammography
    g. breast magnetic resonance imaging (MRI)

TABLE IV Geographic Variation

Rows:

National total
4 Census regions
    1 = Northeast
    2 = Midwest
    3 = South
    4 = West

9 Census divisions
- 1 = New England
- 2 = Mid-Atlantic
- 3 = East North Central
- 4 = West North Central
- 5 = South Atlantic
- 6 = East South Central
- 7 = West South Central
- 8 = Mountain
- 9 = Pacific

Columns:

1. Percentage of all radiologists in the area who interpret any mammograms, with standard error
2. For those who interpret any mammograms, average number of mammograms
3. 25th, 50th, and 75th percentiles of number of mammograms, for those who interpret any
4. Overall average number of mammograms (not only for those who interpret any)
5. Number of radiologists interpreting mammograms per 10,000 women age 40 and older in area
6. Percentage of all radiologists in the area who do any nonmammography breast imaging

TABLE V Information by Degree of Urbanness of Location

Rows: Same as Table I, definitions A through N

Columns:

For each of the following degrees of urbanness:
- *All locations*
- *Large metro main city*
- *Large metro suburb*
- *Small metro main city*
- *Small metro suburb*
- *Nonmetro*

Each of the following columns:

1. Percentage of radiologists who interpret any mammograms in each location type, with standard error
2. Average number of mammograms for those who interpret any mammograms, with standard error
3. Number of radiologists who interpret mammograms, per 10,000 women age 40 or older

TABLE VI Age Distribution

TABLE VIa Information by Age

Rows: Same as Table I, definitions A through N

Columns:

For each of the following age categories:

- *All ages*
- *Ages <45*
- *Ages 45–54*
- *Ages 55–64*
- *Ages 65+*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error
3. Average number of mammograms for those who interpret any mammograms, with standard error

TABLE VIb Number and Percentage of Radiologists Who Interpret Mammograms and Mammography Volume, by Age

Rows:

Each of the following age categories:

- *All ages*
- *Ages <45*
- *Ages 45–54*
- *Ages 55–64*
- *Ages 65+*

Columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error
3. Average mammograms by those who interpret any mammograms, with standard error
4. 25th, 50th, and 75th percentile of number of mammograms, for those who interpret any

TABLE VII Demographics

TABLE VIIa Number and Percentage of Radiologists Who Interpret Mammograms, by Practice Type

Rows: Same as Table I, definitions A through N

Columns:

For each practice type:

- *All practice types*
- *Academic practice*
- *Nonacademic multispecialty practice*
- *Nonacademic private radiology practice*
- *Solo practice*
- *Nonacademic government practice*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error

TABLE VIIb Number and Percentage of Radiologists Who Interpret Mammograms, by Site(s) Served by Practice

Rows: Same as Table I, definitions A through N

Columns:

For each type of practice setting in which radiologist works, or types of settings the radiologist's practice serves:

- *All settings*
- *Hospitals only*
- *Nonhospital sites only*
- *Both*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error

TABLE VIIc Number and Percentage of Radiologists Who Interpret Mammograms Overall, for Females, for Those Who Work Full-Time, and for Those Who Are Board Certified

Rows: Same as Table I, definitions A through N

Columns:

For each of the following:

- *All radiologists*
- *Male versus female radiologists*
- *Full-time versus part-time radiologists*
- *Radiologist board certified or not*

Each of the following columns:

1. Number of radiologists who interpret any mammograms

2. Percentage of radiologists who interpret any mammograms, with standard error

TABLE VIId Number and Percentage of Radiologists Interpreting Mammograms, by Practice Size

Rows: Same as Table I, definitions A through N

Columns:

For each of the following practice size categories:

- *All sizes*
- *2 to 4*
- *5 to 7*
- *8 to 10*
- *11 to 14*
- *15 to 29*
- *30 and more*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error

TABLE VIIe Number and Percentage of Radiologists Interpreting Mammograms, by Self-Reported Enjoyment of Working as a Radiologist

Rows: Same as Table I, definitions A through N

Columns:

1. Average (mean) enjoyment score (Scores are: enjoy very much = 2; enjoy somewhat = 1; etc.), with standard error

For each of the following enjoyment scores in Q9:

- *All scores*
- *Enjoy very much*
- *Enjoy somewhat*
- *Neither like nor dislike*
- *Dislike somewhat or very much*

Each of the following columns:

2. Number of radiologists who interpret any mammograms
3. Percentage of radiologists who interpret any mammograms, with standard error

TABLE VIII Percentage Performing Mammograms and Number of Mammograms Performed, by Gender

Rows: Same as Table I, definitions A through N

Columns:

For each of the following categories:

- *All*
- *Male*
- *Female*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error
3. Average mammograms by those who interpret any mammograms, with standard error
4. Estimated total number of mammograms

TABLE IX Number and Percentage of Radiologists Who Want More or Fewer Hours of Work and Amount of Increase/Decrease in Hours Desired

Rows: Same as Table I, definitions A through N

Columns:

For each of the following categories:

- *Those who want their work and income increased*
- *Those who want their work and income decreased*

Each of the following columns:

1. Number of radiologists who interpret any mammograms
2. Percentage of radiologists who interpret any mammograms, with standard error
3. Average desired percentage change in workload

TABLE X Work Status by Gender and 5-Year Age Group

Rows:

Each of the following age categories:

- *<35*
- *35–39*
- *40–44*
- *45–49*
- *50–54*
- *55–59*
- *60–64*
- *65–69*
- *70–74*
- *75+*

Columns:

For each gender category:

- *All*
- *Male*
- *Female*

And for each of the following work status categories:

- *In residency training*
- *In fellowship training*
- *Working full-time in radiology*
- *Working part-time in radiology*
- *Not working in radiology*

The following column:

1. Estimated number (weighted count) of U.S. radiologists in this category

NOTE: This is the only table that uses all survey responses, including trainees and retirees.

Appendix B

SOCIETY OF BREAST IMAGING SURVEY

To gain insight into the practice patterns, use of emerging technologies, and concerns of breast imagers in current practice, a survey was undertaken with support from the Society of Breast Imaging (SBI) (Farria et al., submitted). SBI staff and representatives participated in the design and conduct of the study and in the collection, analysis, and interpretation of the data.

From October 2003 to April 2004, the SBI conducted a survey of breast imaging practices in the United States, using the SBI membership database. The SBI has 1,684 general members. Membership in the SBI indicates an interest in breast imaging and requires board certification in diagnostic radiology.

The survey tool was developed by Dione M. Farria, M.D., M.P.H.; Maria E. Schmidt, M.D.; Barbara S. Monsees, M.D.; Robert A. Smith, Ph.D.; Debra L. Monticciolo, M.D.; and Stephen A. Feig, M.D. Five of these authors actively practice breast imaging in academic or private practice settings. The sixth individual has expertise in survey design. One survey was requested per breast imaging practice. Duplicate surveys from the same practice were not included in the analysis. Each respondent was asked to give the names of other breast imagers in their practice, which enabled the tracking of duplicate surveys. In addition, the authors cross-referenced business addresses, business phone numbers, and practice names to identify duplicate surveys. If more than one survey from the same practice was received, the respondents were contacted by phone to determine which survey was most representative of their practice.

Retired individuals, nonpracticing physicians, foreign members, and nonphysicians were excluded from the database, resulting in 1,572 practicing breast imaging radiologists in the study sample. The survey was distributed via e-mail. Respondents could submit their responses online, by fax, or by postal mail. If an individual from a practice did not respond after three e-mail requests, one final request was sent via postal mail. Those individuals who did not supply an e-mail address received the survey by postal mail. If these radiologists did not respond, the survey was remailed, for a total of three attempts via postal mail.

The survey included 57 items covering general practice characteristics and trends, such as the type of practice, practice setting (rural versus urban versus suburban), practice location, patient population, case volume, and the spectrum of imaging and interventional services. Annual volumes of procedures refer to volume in 2002. Other questions focused on workload, staff shortages, appointment waiting times, and financial status. Questions on malpractice concerns and morale were also included.

Geographic regions were based on the classification used by the U.S. Census Bureau. Data for the questionnaire responses were either nominal or ordinal. Frequency and relative frequency distributions were calculated for the responses. Statistical tests were used to determine if associations existed between selected responses. If the responses were nominal, chi-square tests were used. If one of the responses was ordinal, Kruskal-Wallis tests for singly ordered R x C tables were used. If both responses were ordinal,

Jonckheere-Terpstra tests for doubly ordered R x C tables were used. If 20 percent of cells had expected counts of less than 5, exact p values were calculated by means of data permutation. If the calculation took longer than the StatXact software's default limit of 30 seconds, Monte Carlo sampling (10,000 samples) was used to estimate the exact p values.

For this study, alpha was set at 0.05. A Bonferroni corrected alpha value to adjust for the family-wise error rate of performing the 15 statistical tests of this study results in an alpha of 0.003. The use of the Bonferroni adjusted alpha value decreases the potential for Type I errors, but increases the potential for Type II errors. Unadjusted p values are reported in this article. Statistical analyses were performed with JMP Statistical Software (Release 5.0.1.2, SAS Institute, Inc., Cary, NC) and StatXact Statistical Software for Exact Nonparametric Inference (Version 6, Cytel Software Corp., Cambridge, MA).

Ethics approval was obtained from the Washington University Medical School Human Studies Committee.

The authors received surveys from 575 practices, which represent 1,006 radiologists or 64 percent of 1,572 actively practicing breast imagers in the SBI. This return rate provided a 99 percent level of confidence for report responses, with a confidence interval of ± 3 percentage points (Rea and Parker, 1997). The sample included practices with a broad range of case volumes and serving a diverse population. The number of responses varied with each item.

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Appendix C

WORKFORCE PROJECTION METHODS

This appendix provides additional details about the computations and data sources used in developing the projections of radiologists and radiologic technologists (RTs) performing mammography presented in the body of this report.

Supply Projections

Generally speaking, reliable projections of the supply of a particular health profession require an accurate, up-to-date dataset containing information about the profession. Projections based on a comprehensive age-cohort flow model require at a minimum:

- A baseline supply profile of the profession that includes the age distribution of active professionals for a recent year. Typically, the age profile is provided in 10-year (or preferably 5-year) age groups. Additional information about full-time/part-time/inactive status, hours of work, productivity, and other work-related characteristics by age group can improve the realism and accuracy of the projections.
- A profile of the entrants to the profession tabulated by the same age groups as the baseline age profile. Ideally, this entrant profile will include any additional work-related characteristics for the new entrants by age group (e.g., full-time or part-time status). To the extent that the counts of new entrants are linked to factors such as graduations from professional education programs, license exam passers, new licensee counts, etc., the possibilities for exploring alternative "what if" scenarios are increased.
- A profile of practitioners leaving the profession due to death, retirement, or other reasons, tabulated by the same age groups as the baseline supply profile. To the extent that the counts of those leaving a profession are linked to factors such as transitions to part-time work, the state of the economy, etc., the possibilities for exploring alternative "what if" scenarios are increased.

If projections are required for alternative scenarios of the future, such as increasing educational program production, then estimates of future changes in the factors represented in the scenarios must also be provided.

If an alternate model is used, then different datasets may be required. For example, the American Society of Radiologic Technologists (ASRT) produces short-term supply projections of RTs performing mammography based on time-in-profession statistics, rather than age. This type of model requires estimates of the percentages of different groups of new entrants/licensees that remain active in the profession for different lengths of time. By aggregating new entrants into (say) 5-year cohorts, it is possible to develop estimates of the numbers of practitioners that will remain active at different points in time in the future. This method appears to be especially useful for short-term projections for professions that typically do not retain practitioners for a full lifetime of service (e.g., RTs in other specialties practicing mammography).

Unfortunately, even though considerable data are available for both radiologists and RTs performing mammography, all the data needed for comprehensive projection models are not available. Estimates of the age distributions of practitioners are available, but because formal certification is not a requirement for the practice of mammography in all states, complete data on all new entrants to mammography practice are not available. In addition, reliable data on departures from practice are vague at best. However, it is clear from the basic age distribution data that the proportion of RTs performing mammography past the age of 65 is much lower than comparable proportions for most health professions.

The Supply Projection Models

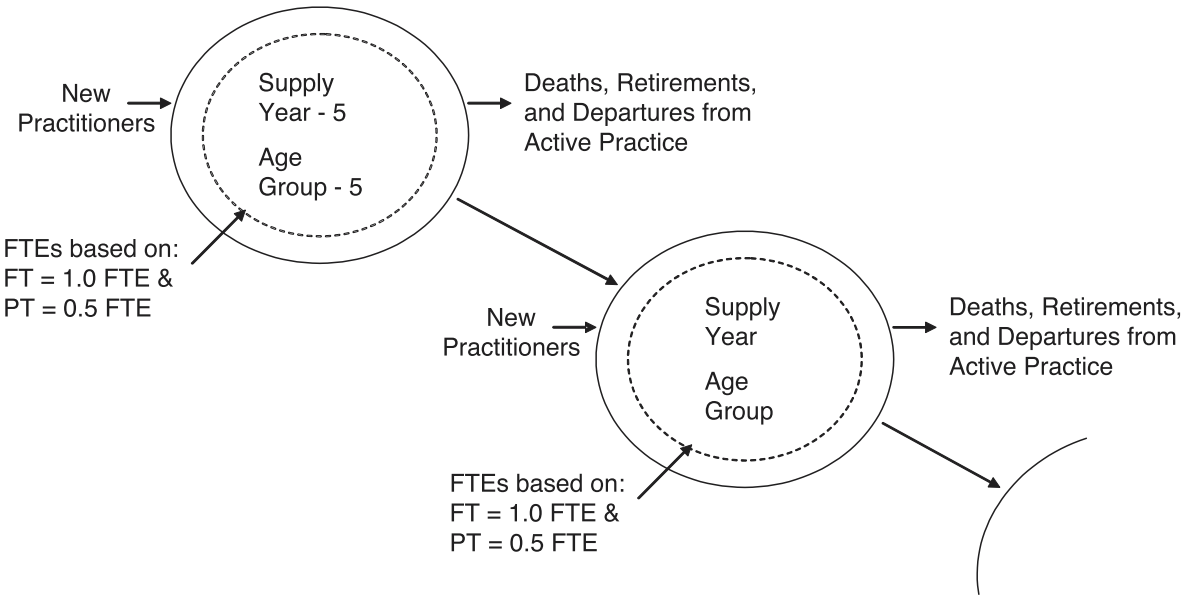
Both the radiologist and technologist projections provided in this study are based on an age-cohort flow model. Typical calculations are described in the diagram in Figure C-1, which represents a segment from the complete model shown in Tables 4-4 and 4-5 in Chapter 4 of this report.

The Radiologist Model

Because there are no special certificates that all radiologists performing mammography must earn in order to read mammograms, there is no independent data source that identifies or counts new entrants into mammography practice. Nor is there an independent source of data about the numbers of practitioners who leave mammography practice, whether by death, retirement, or other departure. These data shortcomings preclude the development of a full-blown age-cohort flow model. It is necessary to make a number of assumptions to fill in the missing data.

The Radiologic Technologist Model

The status quo estimates of new RTs performing mammography are based on data from ASRT on the number of people completing the mammography certification exam in recent years. Data from ASRT show that approximately 1,150 people take this exam. We have assumed that all of those who take the exam will practice mammography. Although some of those taking the exam may not enter practice, others not taking the exam will enter practice in some states and settings.



Practitioner Supply Forecasting Methodology

$Supply_{Year, Age\ Group}$ = $Supply_{Year-5, Prev\ Age\ Group}$ x (1-DDR Rate) + New Practitioners

Total Supply = Sum of practitioners in all age groups for given year

Illustration for RTs in Constant Rate Scenario (**Table C-1**)

$RTs_{2010, 50-54}$ = $RTs_{2005, 45-49}$ x (1-0.141) + (5x173)
= 4,817 x 0.859 + 865
= 5,003*

Baseline Values
Current supply: ACR/ASRT practitioner counts by age
New practitioners: RTs: ASRT; Physicians: Not available
Departure rates: Estimates developed by CHWS

Projected Values
Future entrants: Based on past estimates
Future departure rates: Based on past estimates

Other Factors
Adjustments for alternative numbers of new entrants

FIGURE C-1 Schematic diagram of age-cohort flow projection method.
NOTE: Number marked with asterix does not match Table C-1 exactly due to rounding.

TABLE C-1 Details of Calculations for Constant Rate Scenario for FTE[a] RTs Performing Mammography

1 Year Additions[b]					Baseline		Projection Year			
Percent by Age[b,c]	2,235[d,e]	Adjusted[f,g]	5-yr DDR (%)[h,i]	Age Group	2004[j]	2005	2010	2015	2020	2025
3.5	78	57	0.0	< 25	196	214	284	284	284	284
18.4	411	298	0.0	25–29	1,368	1,431	1,704	1,774	1,774	1,774
25.0	559	405	0.0	30–34	3,256	3,283	3,457	3,730	3,800	3,800
12.5	279	203	0.0	35–39	3,782	3,879	4,296	4,470	4,742	4,813
12.1	270	196	0.0	40–44	4,544	4,587	4,859	5,276	5,450	5,723
12.0	268	194	4.9	44–49	4,689	4,817	5,335	5,593	5,990	6,155
10.7	239	173	14.1	50–54	4,150	4,322	5,005[k]	5,449	5,672	6,012
3.9	87	63	41.0	55–59	2,663	2,763	2,866	3,269	3,531	3,662
1.7	38	28	67.2	60–64	1,153	1,239	1,044	1,078	1,210	1,296
0.2	4	3	77.8	65+	364	389	378	332	329	358
100	—	—	—	Total[l]	26,132	26,925	29,227	31,254	32,781	33,876
		Women 40+ (000s)[m]			68,357	70,197	75,265	79,633	83,888	88,583
		Number / 100K Pop[n]			38.2	38.4	38.8	39.2	39.1	38.2
		Percent Change (%)			—	0.3	1.2	1.1	–0.4	–2.1
		Cumulative Percent Change (%)			—	0.3	1.6	2.7	2.2	0.0

[a] FTE = (Mammography is first specialty)*1.0 + (Mammography is second specialty)*0.5.
[b] New RTs added every year to maintain new entrant counts, estimated; percentages represent estimated allocation of new practitioners by age group.
[c] Column displays the age distribution of the new entrants into practice, used to estimate the number of new entrants in each age group in a year.
[d] The number 2,235 is the total number of new entrants in each age group in each year in the future.
[e] Column displays the estimated number of new entrants into each age group each year. This is computed by multiplying *c* times *d*.
[f] Estimated first-year attrition of new mammography certificants = 27.5%. This is the estimated percentage of new entrants into mammography practice who leave mammography within the first year of certification. These data are available only for RTs.

Continued

[g] Column displays the estimated number of new entrants into each age group each year, adjusted for the estimated number of first-year dropouts (see *f* above).

[h] DDR stands for the rate of deaths, departures, and retirements (for 5-year groups), estimated; percentages represent estimated percentages of an age cohort that will retire, die, or otherwise depart from practice in a five year interval.

[i] Column displays the percentage of practitioners in each age group leaving practice for any reason. These percentages are generally not available in association data sets.

[j] Column displays the group of RTs performing mammography in the baseline year of 2004. It is computed from estimates of full- and part-time practitioners provided by ASRT.

[k] Sample number represents the number of FTE practitioners in a particular age group in a particular year. These numbers are computed by the projection model.

[l] Row displays the estimated total FTE RTs performing mammography in the United States for each projection year, computed by the projection model.

[m] Row displays the number of women 40 and older in the population, a reference point for demand.

[n] Row displays the ratio of RTs performing mammography per 100,000 women 40 and older in the United States, computed by the projection model.

NOTE: Constant rate scenario projections for the United States, 2004–2025, assumes constant induction of new RTs performing mammograms, constant rate of departure of RTs performing mammograms, and increasing numbers of women 40 and older, per U.S. Census Bureau projections. The models for radiologists and RTs are similar but not identical, a reflection of the differences in availability of data required for the models.

SOURCES: Derived from ASRT (2004a), U.S. Census Bureau (2004).

TABLE C-2 Involvement of RTs in Mammography by Age Group, 2004

	Involvement in Mammography				
Age Group	Primary Specialty	Secondary Specialty	Neither Primary nor Secondary	Total	Percent Mammography
15–24	83	226	11,097	11,406	2.7
25–29	846	1,043	22,947	24,836	7.6
30–34	2,236	2,039	29,415	33,690	12.7
35–39	2,725	2,113	30,103	34,941	13.8
40–44	3,319	2,449	32,896	38,664	14.9
45–49	3,428	2,522	31,609	37,559	15.8
50–54	3,115	2,070	26,320	31,505	16.5
55–59	2,022	1,221	16,231	19,474	16.7
60–64	886	533	7,509	8,928	15.9
65+	280	167	3,999	4,446	10.1
Total	18,940	14,383	212,126	245,449	13.6

SOURCE: ASRT (2004b).

Other Tables of Interest

Tables C-2 through C-5 present a variety of basic data about RTs and radiologists performing mammography services. Some of the figures in each of the tables have been used in preparing the supply projections.

TABLE C-3 Estimated RTs Working in Mammography by Age Group, 2004

	Estimated Practitioners		
Age Group	Primary	Secondary	Full-Time Equivalent (FTE)
<25	83	226	196
25–29	846	1,043	1,368
30–34	2,236	2,039	3,256
35–39	2,725	2,113	3,782
40–44	3,319	2,449	4,544
45–49	3,428	2,522	4,689
50–54	3,115	2,070	4,150
55–59	2,022	1,221	2,633
60–64	886	533	1,153
65+	280	167	364
Total	18,940	14,383	26,132

NOTE: FTEs are 2004 baseline estimates for the projections.
SOURCE: ASRT (2004b).

TABLE C-4 Estimates of Radiologists Performing Mammography by Age Group, 2003

	Radiologists					Adjusted to Mammography		
Age Group	Resident	Fellow	Full-Time	Part-Time	Not in Radiology	Full-Time	Part-Time	Full-Time Equivalent (FTE)
<35	2,814	440	726	20	—	443	12	449
35–39	614	180	3,030	311	64	1,848	189	1,943
40–44	133	114	3,432	519	125	2,093	316	2,252
45–49	53	76	3,300	409	187	2,079	257	2,620
50–54	44	27	4,458	711	187	2,809	448	2,620
55–59	—	—	2,564	523	234	1,692	345	1,865
60–64	—	—	1,793	916	731	1,184	604	1,486
65–69	—	—	887	787	969	461	409	666
70–74	—	—	393	432	1,099	205	225	317
75+	—	—	155	436	2,094	81	227	194
Total	3,659	837	20,739	5,061	5,690	12,894	3,033	14,410

NOTE: FTEs are baseline estimates for radiologist projections.
SOURCE: Sunshine et al. (2004).

TABLE C-5 Mammography Certification Rates for a Sample of RTs Practicing Mammography in New York State, 2004

Age Group	Certified	Not Certified	Percent Certified	Percent Not Certified
20–24	4	8	33.3	66.7
25–29	23	18	56.1	43.9
30–34	73	10	88.0	12.0
35–39	79	4	95.2	4.8
40–44	85	8	91.4	8.6
44–49	90	7	92.8	7.2
50–54	88	9	90.7	9.3
55–59	49	7	87.5	12.5
60–64	15	3	83.3	16.7
65+	3	0	100.0	0.0
Total	509	74	87.3	12.7

SOURCE: Preliminary Results, New York State Mammography Survey (2004).

Demand Projections

Economists refer to demand as the volume of product or service that an informed buyer will purchase for a particular price. In the context of the health workforce, this approach to defining demand is not particularly useful because the consumer does not purchase a professional, only some of the services offered by a professional. The demand can be partitioned into demand by a patient for services offered by a professional and demand for a professional by a health service provider organization, with both often modified by a fiscal intermediary (e.g., Medicaid or an insurance company).

The economic concept of demand is further blurred because the price paid for a professional's services are often only a fraction of the true price, due to insurance coverage of one sort or another. This difficulty is compounded by the fact that often consumers have incomplete and even inaccurate information about the services offered by the professionals and their ultimate outcomes.

In this complex environment, the demand for a health profession is typically linked to shortages or surpluses in the labor market that reflect the relative ease that an employer has in hiring the professionals needed to provide services demanded by patients. A profession is said to be in shortage if employers collectively cannot hire enough professionals to support a full complement of services to patients and prospective patients.

A variety of indirect measures have been shown to be related to the demand for a health profession, including wage levels, change in wage levels, vacancy rates, turnover rates, delays in scheduling services, etc. None of these measure demand directly, but most are related to demand in some way.

The estimates of demand referred to in this document are couched in relative terms. For example, if the population of patients or prospective patients increases by 10 percent, then it is assumed that the demand for professional services will increase by 10 percent, and that the demand for professionals will increase by 10 percent. Or, if a new service that has a positive impact on patients is introduced by a health profession, then

the demand for the profession will increase. It is generally not an easy task to titrate the impact on demand of different levels or types of changes in professional services or costs.

In this study, only the most basic types of changes are examined, specifically projected increases in the numbers of patients to be served. It would be possible to examine other demand scenarios (e.g., an increase in productivity due to the introduction of new technology), if one is willing and able to develop justifiable estimates of the impact of the scenario on demand.

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Glossary

Abnormal interpretation rate—a measure of the number of women whose mammogram interpretation leads to additional imaging or biopsy. See also *Recall rate*.

Accreditation—in terms of mammography, the recognition of a facility that has been reviewed and meets specific measures of quality set forth by the Mammography Quality Standards Act (MQSA).

Adverse event—an undesirable experience associated with mammography activities within the scope of MQSA, as defined by MQSA regulations.

Area under the receiver operating curve (AUC)—can be interpreted for mammography as a measure of the ability of a diagnostician to discriminate a mammogram showing breast cancer from one not showing breast cancer when two such mammograms have been randomly selected and presented together.

Asymptomatic—having no signs or symptoms of disease.

Automatic exposure control (AEC)—a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a pre-selected location; such a device automatically terminates the exposure when the selected quantity of radiation has been delivered.

Axillary lymph node—a lymph node in the armpit region that drains lymph channels from the breast. Axillary lymph node dissections are performed on women to determine if breast cancer cells have spread from the breast; the presence or absence of positive axillary lymph nodes is one of the most important predictors of patient outcome.

Benchmarks—standard points of reference for performance measurements by which interpretive performance can be evaluated or compared.

Benign—a non-cancerous growth or tumor; benign tumors do not spread to tissues around them or to other parts of the body.

BRCA1—a gene located on the short arm of chromosome 17; when this gene is mutated, a woman is at greater risk of developing breast or ovarian cancer, or both, than women who do not have the mutation.

BRCA2—a gene located on chromosome 13; a germ-line mutation (an inherited mutation found in all cells in the body) in this gene is associated with increased risk of breast cancer.

Breast biopsy—refers to a procedure that involves obtaining a breast tissue specimen for microscopic analysis to establish a diagnosis; can be done surgically or with needles.

Breast Imaging Reporting and Data System (BI-RADS)—a method used by radiologists to interpret and report in a standardized manner the results of mammography, ultrasound, and MRI used in breast cancer screening and diagnosis. There are currently seven BI-RADS assessment categories: Category 0, Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison; Category 1, Negative; Cate-

gory 2, Benign Finding(s); Category 3, Probably Benign Finding—Short Interval Follow-Up Suggested; Category 4, Suspicious Abnormality—Biopsy Should Be Considered; Category 5, Highly Suggestive of Malignancy—Appropriate Action Should Be Taken; and Category 6, Known Biopsy—Proven Malignancy—Appropriate Action Should be Taken.

Breast imaging specialist—specializes in interpreting the results of mammographic and non-mammographic imaging examinations of the breast, and performs interventional procedures including image-guided biopsies of the breast.

Breast MRI—a magnetic resonance image taken of the breast. See also *Magnetic resonance imaging*.

Breast ultrasound—an ultrasound image of the breast. See also *Ultrasound*.

Cancer—a general term for more than 100 diseases in which abnormal cells divide without control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body. There are several main types of cancer. Carcinoma is cancer that begins in the skin or in tissues that line or cover internal organs. Sarcoma is cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is cancer that starts in blood-forming tissue such as the bone marrow and causes large numbers of abnormal blood cells to be produced and enter the bloodstream. Lymphoma is cancer that begins in the cells of the immune system.

Cancer detection rate—the number of women identified as having breast cancer per 1,000 women examined.

Cancer outcome—as defined in this report, the presence or absence of cancer as determined by the results of a biopsy.

Cancer staging—performed after a cancer is diagnosed and generally derived from pathology reports; used in conjunction with other tumor prognostic indicators (such as tumor grade, hormone receptor status, and other factors) to determine the patient's prognosis and treatment options.

Cancer status—as defined in this report, the presence or absence of cancer in a given individual.

Centralized interpretation—expert interpretation at one central location of either films or digitized data collected at multiple remote locations.

Certification—as defined by MQSA regulations, the process of approval of a facility by FDA or a certification agency to provide mammography services.

Clinical image—as defined by MQSA regulations, a mammogram. See also *Mammogram*.

Clinical trial—a formal study carried out according to a prospectively defined protocol that is intended to discover or verify the safety and effectiveness of procedures or interventions in humans. The term may refer to a controlled or uncontrolled trial. Randomized controlled clinical trials are considered the gold standard for clinical evidence.

Cohort study—an observational study in which outcomes in a group of patients that received an intervention are compared with outcomes in a similar group, that is, the cohort, either contemporary or historical, of patients that did not receive the intervention. In an adjusted- (or matched-) cohort study, investigators identify (or make

statistical adjustments to provide) a cohort group that has characteristics (e.g., age, gender, disease severity) that are as similar as possible to the group that experienced the intervention.

Collimator—a device on the mammography unit used to control the size and shape of the x-ray beam.

Compression paddle—a component of the mammography unit used to compress the breast in order to spread the breast tissue evenly for the x-ray; the correct amount of compression allows for the highest quality image with the lowest possible radiation dose. Compression paddles are regulated under MQSA.

Computed tomography (CT)—a special radiographic modality that uses a computer to assimilate multiple x-ray images into a two-dimensional, cross-sectional image, which also can be reconstructed into a three-dimensional image. This can reveal many soft tissue structures not shown by conventional radiography.

Computer-aided detection (CAD)—use of sophisticated computer programs designed to recognize patterns in images and provide assistance to interpreters to detect the presence of disease. This approach has been used along with mammography for the detection of breast cancer.

Confidence interval—a range within which an estimate is deemed to be close to the actual value being measured. In statistical measurements, estimates cannot be said to be exact matches, but rather, are defined in terms of their probability of matching the value of the characteristic being measured.

Confounding factors—factors for which data adjustment is needed because they are entangled with other factors related to the disease or condition of interest.

Consensus double reading—see *Double reading*.

Conspicuity—the ability of a lesion or abnormality to be seen over the background "noise" of a mammogram; conspicuity = lesion contrast / background complexity.

Context bias—as defined in mammography, when an individual is more likely to consider a mammogram abnormal when it is reviewed in a specially assembled sample with high disease prevalence than when the same film is interpreted as part of a group with lower disease prevalence.

Core-needle biopsy—procedure in which a hollow needle is used to remove small cylinders of tissue from a suspected tumor.

Cost-benefit analysis—a comparison of alternative interventions in which costs and outcomes are quantified in common monetary units.

Cumulative risk—a quantitative measure of the probability of an occurrence over a specific time period.

Cytological screening—examination of cells for changes indicative of a disease or risk of disease, for example, Papanicolaou test (Pap smear) for cervical cancer.

Cytology—the study of cells using a microscope to examine the characteristics of formation, structure, and function of cells.

Darkroom fog—added optical density on a film due to light leaks or safe lights in a darkroom; degrades image contrast and must be tested and eliminated to ensure image quality.

Detection—identifying disease. Early detection means that the disease is found at an early stage, before it has grown large or spread to other sites.

Diagnosis—definitive confirmation of a specific disease usually by imaging procedures and from the use of laboratory findings.

Diagnostic mammography—x-ray-based breast imaging undertaken for the purpose of diagnosing an abnormality discovered by physical exam or screening mammography. Women who have physical symptoms, a personal history of breast cancer, or breast implants also often undergo diagnostic mammograms.

Digital mammography—see *Full field digital mammography*.

Dosimetry—measurement or calculation of radiation dose. Radiation dose is the energy absorbed per unit mass of tissue.

Double reading—a process by which a mammogram is reviewed twice for any potential abnormalities. Independent double reading is when both readers interpret the mammography films without knowledge of the other's assessment and the most abnormal reading is acted upon. Consensus double reading is when both readers learn the other's interpretation result and resolve the differences together (arbitration).

Duct—a hollow passage for gland secretions. In the breast, a passage through which milk passes from the lobule (which makes the milk) to the nipple.

Ductal carcinoma in situ—a lesion in which there is proliferation of abnormal cells within the ducts of the breast, but no visible evidence of invasion into the duct walls or surrounding tissues; sometimes referred to as "precancer" or "preinvasive cancer."

Established operating level—the value of a particular quality assurance parameter that has been established as an acceptable normal level by a mammography facility's quality assurance program.

Exposure reproducibility coefficient of variation evaluation—a test performed to ensure radiation exposure levels from a radiographic unit are reproducible within a certain range; ensures consistency in the amount of radiation emitted from a radiographic device.

Facility—as defined in this report, a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for the interpretation.

False-negative result—a test result that incorrectly indicates that the abnormality or disease being investigated is not present when in fact it is present.

False-positive rate—the number of false-positive results per 100 women screened.

False-positive result—a test result that indicates that the abnormality or disease being investigated is present when in fact it is not. There are three levels of false-positive measurement in mammography: FP_1, no known cancer within one year of a BI-RADS Category 0, 4, or 5 assessment (of a screening mammogram); FP_2, no known cancer within one year of a BI-RADS Category 4 or 5 assessment (usually from a diagnostic mammogram); and FP_3, no known cancer within one year of a BI-RADS Category 4 or 5 assessment, for which biopsy was actually performed.

Federal Certificates of Confidentiality—a certificate issued by the federal government that protects those with access to research data from being compelled to identify re-

search subjects in any "Federal, State, or local civil, criminal, administrative, legislative, or other proceedings," with limited exceptions.

Film processor—a machine for developing and treating photographic films (e.g., x-ray films) to produce permanent visible images.

Fine-needle aspiration—a procedure by which a thin needle is used to draw up (aspirate) samples for examination under a microscope.

Full field digital mammography (FFDM)—similar to conventional mammography (film-screen mammography) except that a dedicated electronic detector system is used to computerize and display the x-ray information.

Full-time equivalent—as defined in this report, a person employed full-time (37.5+ hours per week of paid employment for 40 or more weeks per year) and spends at least 80 percent of his or her time performing clinical radiology imaging interpretation or related imaging tasks.

Half value layer—the thickness of an absorbing substance necessary to reduce by one half the initial intensity of the radiation passing through it.

Health maintenance organization (HMO)—organized system for providing comprehensive prepaid health care that has five basic attributes: (1) provides care in a defined geographic area; (2) provides or ensures delivery of an agreed-upon set of basic and supplemental health maintenance and treatment services; (3) provides care to a voluntarily enrolled group of persons; (4) requires their enrollees to use the services of designated providers; and (5) receives reimbursement through a predetermined, fixed, periodic prepayment made by the enrollee without regard to the degree of services provided.

Illumination—the total luminous flux (the amount of energy emitted by a light source in all directions) incident per unit area; refers to the amount of incident light.

In situ—in position, localized. In breast tissue, it usually refers to either ductal carcinoma in situ (DCIS) or lobular carcinoma in situ (LCIS).

Incidence—the number of new cases of a disease that occur in the population per unit of time.

Incident screen—screening tests performed at regular intervals after an initial (prevalent) screen for a particular disease.

Indemnity payments—compensation for damage, loss, or injury suffered.

Independent double reading—see *Double reading*.

Interobserver variability—variability between observers.

Interpreting physician—a licensed physician who meets MQSA requirements for interpreting mammograms.

Interpretive volume—the number of mammograms an interpreting physician reads over a given period of time. Currently, MQSA requires interpreting physicians to read at least 960 mammograms over a given 2-year period.

Interval cancer—a cancer detected between regular screening examinations. See also *Screening interval*.

Interventional mammographic procedures—minimally invasive procedures that are done under the guidance of mammography images, such as needle biopsies and presurgery wire localization of a tumor.

Intraobserver variability—variability by the same observer.

Invasive cancer—cancers capable of growing beyond their site of origin and invading neighboring tissue.

Invasive ductal carcinoma—a cancer that starts in the ducts of the breast and then breaks through the duct wall, where it invades the surrounding tissue; it is the most common type of breast cancer and accounts for about 80 percent of breast malignancies.

Invasive lobular carcinoma—a cancer that starts in the milk-producing glands (lobules) of the breast and then breaks through the lobule walls to involve the surrounding tissue; accounts for about 15 percent of invasive breast cancers.

Ionizing radiation—a form of electromagnetic radiation capable of removing electrons from atoms in a substance, such as cellular material; examples include x-rays, which can be used in medical diagnosis and treatment.

Kilovolt peak (kVp)—a measure of the maximum energy of an x-ray produced across an x-ray tube; standards for accuracy and reproducibility of the clinical kVp for mammography are established under MQSA.

Latent distribution—distribution of a continuous variable that cannot be measured directly, but is hypothesized to underlie an observed categorical variable.

Lesion—an abnormal change in the structure of an organ or other body part due to injury or disease; especially one that is circumscribed and well defined.

Lobular carcinoma in situ—abnormal cells within a breast lobule that have not invaded surrounding tissue. Not cancer *per se*, but can serve as a marker of future cancer risk.

Lobular—of or pertaining to the lobes of an organ, such as the liver, lung, breast, thyroid, or brain.

Luminance—the amount of light "reflected" from a surface.

Magnetic resonance imaging (MRI)—method by which images are created by recording signals generated from the excitation (the gain and loss of energy) of elements such as the hydrogen of water in tissue when placed within a powerful magnetic field and pulsed with radio frequencies.

Malignant—a tumor that has the potential to become lethal through destructive growth or by having the ability to invade surrounding tissue and metastasize.

Mammogram—x-ray image of the breast.

Mammography—the practice of imaging breast tissue with x-rays for screening or diagnostic purposes in detecting or diagnosing cancer.

Mammography Quality Standards Act (MQSA)—enacted by Congress (initially in 1992 and reauthorized in 1998 and 2004) to ensure that all women have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. MQSA regulations, promulgated by FDA 1993 and updated in 1999, established national quality standards for mammography equipment and personnel.

Medicaid—federal- and state-funded health insurance program for certain low-income people. It covers approximately 36 million individuals including children; aged, blind, and/or disabled people; and people who are eligible to receive federally assisted income maintenance payments.

Medical audit—a formal examination of the quality of practice in a particular area of medicine; often involves benchmarking against best practice.

Medical physicist—an individual who is competent to practice, independently, one or more of the sub-fields of medical physics, including therapeutic radiological physics, diagnostic radiological physics, medical health physics, or medical nuclear physics. In this report, a person trained in evaluating the performance of mammography equipment and facility quality assurance programs, and who meets MQSA requirements.

Medicare— a program that provides health insurance to people age 65 and over, those who have permanent kidney failure, and people with certain disabilities.

Meta-analysis—systematic methods that use statistical techniques for combining results from different studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This combination may produce a stronger conclusion than can be provided by any individual study (also known as data synthesis or quantitative overview).

Microcalcifications—tiny calcium deposits within the breast, singly or in clusters; often found by mammography. They may be a sign of cancer.

Mobile mammography—a mammography x-ray unit located in a vehicle (truck, van, etc.) that is driven from one location to another to perform mammography. Typically, services are provided in one of two types of vehicles, either a recreational vehicle that has been customized to fit a mammography unit, processor, and exam rooms (mobile van), or a standard passenger van that has been customized to allow for the transportation of a mammography unit to various indoor locations (portable unit).

Modality—a method of application or use of any therapy or medical device. A mammographic modality is a technology for radiography of the breast, for example screen-film mammography.

Mode of interpretation (online vs. batch)—methods by which screening mammograms can be interpreted; online interpretation is when an interpreting physician reads the mammogram while the patient is still at the facility; batch interpretation is when screening mammograms are grouped by facility personnel for later interpretation by an interpreting physician during a focused, uninterrupted period of time.

Morbidity—a diseased condition or state; the incidence of a disease or of all diseases in a population.

Mortality rate—the death rate; expresses the number of deaths in a unit of population within a prescribed time and may be expressed as crude death rates or as death rates specific for diseases and, sometimes, for age, sex, or other attributes.

Negative predictive value (NPV)—the proportion of all women with a negative result who are actually free of the disease. Calculated as the number of true-negative results divided by the number of true-negative results plus the number of false-negative results; formula (NPV = TN/[TN + FN]).

Node positivity—the presence of cancer cells in lymph nodes near the primary cancer site.

Non-invasive ductal carcinoma in situ (DCIS)—see *Ductal carcinoma in situ*.

Nonpalpable abnormality—breast abnormalities that can be seen on a mammogram but cannot be felt.

Normal distribution—a family of probability distributions of the same general form, differing in their location (mean) and scale (standard deviation) parameters; also known as a Gaussian distribution or bell curve.

Occult tumor—a tumor that is undetected and without symptoms.

Oncology—the branch of medicine dealing with tumors.

Optical density—a measure of light transmitted through film. The higher the optical density, the darker the film. Scientifically it is defined as the base ten logarithm of the ratio of the incident intensity of light to the transmitted intensity. Mean optical density, monitored under MQSA, is the average of the optical densities measured on the images produced with a given equipment configuration during the AEC performance test using 2, 4, and 6 centimeter thicknesses of a homogeneous material.

Ordinal-level data—categorical data that can be grouped or ranked; however, differences in data values either cannot be determined or are meaningless.

Palpable tumor—a tumor that can be felt during a physical examination.

Papanicolaou (Pap) smear—a cytological test developed by George N. Papanicolaou for the detection of cervical cancer.

Pathology—examination of a tissue sample (from a biopsy or surgical resection) to determine whether a lesion is benign or malignant, to differentiate between different types of cancer, and to reveal the extent of the cancer's spread.

Phantom image—a radiographic image of a test object (a phantom) used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

Positive mammogram—a mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

Positive predictive value (PPV)—a measure of accuracy for a screening or diagnostic test; indicates what portion of those with an abnormal test result actually have the disease. Calculated as the number of true-positive results divided by the number of true-positive results plus the number of false-positive results; formula (PPV = TP/[TP + FP]).

Positron emission tomography (PET)—use of radioactive tracers such as labeled glucose to identify regions in the body with altered metabolic activity.

PPV_1—the proportion of all women with positive examinations (BI-RADS Category 0, 4, or 5) who are diagnosed with breast cancer; formula ($PPV_1 = TP/[TP + FP_1]$).

PPV_2—the proportion of all women recommended for biopsy after mammography (BI-RADS Category 4 or 5) who are diagnosed with breast cancer; formula ($PPV_2 = TP/[TP + FP_2]$).

PPV_3—the proportion of all women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy; formula ($PPV_3 = TP/[TP + FP_3]$).

Preoperative mammographic needle localization—see *Core-needle biopsy* and *Stereotactic breast biopsy*.

Prevalence—the number of cases of disease, infected persons, or persons with some other attribute, present at a particular time and in relation to the size of the population from which they are drawn.

Prevalent screen—initial screening test for a particular disease.

Progression—the growth or advancement of cancer, indicating a worsening of the disease.

Radiation dose—a generic term to describe the amount of radiation a person receives, either naturally or through medical procedures, for example x-ray imaging.

Radiologic technologist—an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and, in this report, who meets MQSA requirements.

Radiologist assistant—an advanced-level radiologic technologist who works under the supervision of a radiologist.

Radiology information systems—computerized management systems developed to assist radiology facilities in collecting and organizing patient information; services include patient registration and scheduling, dictation and transcription, multisite support, data access, and image routing and archive management.

Recall rate—the proportion of all women undergoing screening mammography who are given a positive interpretation that requires additional examinations. See also *Abnormal interpretation rate*.

Receiver operating curve (ROC) analysis—a statistical methodology used to quantify the ability to correctly distinguish signals of interest from background noise in the system. ROC analysis can be used in mammography to demonstrate the relationship between the true-positive (sensitivity) and false-positive rates (specificity).

Resource-based relative value scale (RBRVS)—a method of comparing the relative work for a physician providing a particular service to the work involved with providing other services; the Centers for Medicare and Medicaid Services use this system to reimburse physicians for services provided to Medicare recipients.

Review physician—a physician qualified under MQSA regulations to review clinical images on behalf of an accreditation body.

Risk—a quantitative measure of the probability of developing or dying from a particular disease such as cancer.

Scintimammography—use of radioactive tracers to produce an image of the breast.

Screen-film (analog) mammography—conventional mammography in which the x-rays are recorded on film.

Screen-film contact—the contact between the intensifying screen and the x-ray film when performing mammography, which has a significant influence on image sharpness. Mammography cassettes are to be replaced when radiographs of a special screen-film test tool reveal persistent large areas of increased optical density.

Screening—systematic testing of an asymptomatic population to determine the presence of a particular disease.

Screening interval—the frequency with which a screening test is carried out. Recommended screening intervals vary for mammography; the American Cancer Society recommends annual screening for women over the age of 40, the U.S. Preventative Services Task Force recommends screening every 1 to 2 years for the same age group, and the American College of Obstetricians and Gynecologists suggest screen-

ing every 1 to 2 years for women aged 40–49 and annually for women aged 50 and older.

Screening mammography—x-ray-based breast imaging in an asymptomatic population used to detect breast cancers at an early stage.

SEER registries—the Surveillance, Epidemiology, and End Results (SEER) Program currently collects and publishes cancer incidence and survival data from 14 population-based cancer registries and three supplemental registries covering approximately 26 percent of the U.S. population. The SEER registries routinely collect data on patient demographics, primary tumor site, morphology, stage at diagnosis, first course of treatment, and follow-up for vital status.

Sensitivity—a measure of how often a test correctly identifies women with breast cancer. Calculated as the number of true-positive results divided by the number of true-positive results plus the number of false-negative results; formula (Se = TP/[TP + FN]).

Short interval follow-up examination—typically assigned in BI-RADS Category 3 cases, when a finding has a high probability of being benign, is not expected to change over the follow-up interval (typically 6 months), and the interpreting physician wishes to ascertain its stability.

Soft copy—image display on a computer screen rather than on film.

Sonography—a technique in which high-frequency sound waves are bounced off internal organs and the echo pattern is converted into a two-dimensional picture of the structures beneath the transducer. See also *Ultrasound*.

Specificity—the proportion of persons without disease who correctly test negative. Calculated as the number of true-negative results divided by the number of true-negative results plus the number of false-positive results; formula (Sp = TN/[TN + FP]).

Stereotactic breast biopsy—use of breast images (x-rays) taken at various angles to generate a three-dimensional image for plotting the exact position of a suspicious lesion and for guiding the placement of a biopsy needle.

System artifacts—abnormalities that result from problems with any part the of mammography system including the x-ray unit and the processing of mammographic films, potentially complicating accurate interpretation; causes include use of abrasive materials to clean processor rollers, an improperly installed or vented processor, inadequate chemical quality, and variations in developer temperature.

Tail coverage—malpractice insurance that can be purchased after the expiration of a claims-made liability policy to cover claims made during an extended reporting or discovery period. Such insurance covers radiologists who retire (or move) who are later sued for missed diagnoses made at facilities at which they were formerly employed.

Telemammography—the process of satellite or long-distance transmission of digital mammography for consultation.

Three phase x-ray generator—a machine that transforms the commercial electric power current (or line voltage, usually produced and delivered as a three phase alternating current) into a high-voltage direct current for x-ray production.

True-negative rate—see *Specificity*.

True-positive rate—see *Sensitivity*.

Tumor registry—a population-based resource for examining cancer patterns.

Tumor size—the physical dimensions of a tumor, which may be determined based on palpation, imaging, or pathology; an important element of tumor staging.

Tumor staging—the grouping of cancer cases into broad categories based on extent of disease using a coded format, such as a numerical system with increasing values meaning more involvement or severity. Extent of disease is a detailed description of how far the tumor has spread from the site of origin (the primary site).

Ultrasound—use of inaudible, high-frequency sound waves to create an image of the body.

Verification bias— the potential for overestimation of sensitivity and underestimation of specificity when a gold standard assessment of disease status may only be partially available.

Wire needle localization—a procedure used to guide a surgical breast biopsy when the breast lump is difficult to locate or in areas that look suspicious on the mammogram but do not have a distinct lump (nonpalpable abnormalities); mammogram images are used to guide the needle to the suspicious area of the breast.

X-ray—a type of ionizing radiation used for imaging purposes that uses energy beams of very short wavelengths (0.1 to 100 Angstroms) that can penetrate most substances except heavy metals.