# Optimizing Mammographic Screening and Diagnosis of Breast Cancer

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Mahesh K. Shetty

## Introduction

A robust quality assurance mechanism needs to be in place and rigorously enforced to ensure consistently high-quality screening mammography. Such a quality assurance program has three principal components, namely, the mammographic equipment, image quality issues, and interpretative accuracy. There are regulatory processes in place at both the national and state levels mandated by law that are aimed at achieving this objective [1–3], and these are presented in these direct citations that follow:

> The Mammography Quality Standards Act (MQSA) was passed by the United States Congress on October 27, 1992, to establish national quality standards for mammography. The MQSA requires that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA (Food and drug administration). [1]
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> The FDA is responsible for developing final standards, approving accrediting bodies, certifying all mammography facilities in the U.S., evaluating the effectiveness of the program, and implementing sanctions for noncompliant facilities. FDA is allowed to adopt existing standards from the American College of Radiology [ACR], HCFA [Health care financing Administration] and state regulations. The final Rules have additional changes in the Quality Assurance (QA) Sections (900.12 d and e) and direct facilities as to how to conduct document and evaluate the results of Quality assurance [QA] tests, taking responsibility for establishing and maintaining a QA program. [1]
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> The FDA [Food and Drug Administration] uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations. Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility needs to check with the State or local authorities regarding their requirements. [1]
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> MQSA aims to ensure safety, reliability, clarity and accuracy of the mammography services performed in each and every facility in the USA. The rules also specify the roles of interpreting physicians, medical physicists and quality control technologists. Data indicates that such regulation has improved mammography in the U.S. By January 1997, the Government Accounting Office reported that 1,500 facilities had undergone two rounds of MQSA inspections. During the first year of MQSA, 26 percent had significant violations, while only 10 percent did on the second round. [2]
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> The MQSA regulations are written by the FDA and are the national standards for quality of Mammography services. Adherence to these stated standards is the law and not optional. For lawful operation each facility and the Mammography unit has to be certified. [1]
>
> To obtain this certificate the facility has to fulfill the quality standards that is outlined in the section 900.12 of the final rule, in addition each facility has to be accredited by an approved entity which is designated by FDA. Currently the American College of Radiology and the States of Texas, Arkansas, Iowa and California have been authorized by MQSA to be the accreditation bodies, the State bodies are allowed to accredit facilities in their respective states. The accreditation body is responsible for reviewing the equipment, procedures, personnel and the Medical Physicist. Personnel including the radiologist and the technologists are reviewed to ensure compliance in qualifications and training as required by MQSA regulations. The physicist survey of the equipment includes dosimetry, quality control tests on the equipment, evaluation of the phantom images as well as clinical images of patients. Based on a facility fulfilling all of the requirements outlined in the MQSA, the accreditation process is complete. The accreditation body notifies the MQSA and the latter body issues a certificate. This certificate is valid for three years. However, annual inspection is conducted by the MQSA to ensure continued compliance. [1]

## Certification for Interpreting Physicians and Radiologic Technologists

The following is an outline of the requirements as stated in the MQSA manual describing the requirements of the various components to obtain MQSA certification to operate a

M.K. Shetty, MD, FRCR, FACR, FAIUM
Department of Radiology, Baylor College of Medicine, Houston, TX, USA

Woman's Center for Breast Care and MRI, Woman's Hospital of Texas, Fannin 7600, Houston, TX 77054, USA
e-mail: mshettymd@gmail.com

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mammography unit and provide screening and diagnostic mammography to patients [1]:

**Interpreting Physicians**

Interpreting physicians initially qualifying on or after the April 28, 1999 effective date of the final regulations must meet all of the following requirements. Physicians who qualified under FDA's interim regulations (prior to April 28, 1999) are considered to have met the initial requirements listed in items 2 through 4. They may continue to interpret mammograms if they continue to meet the licensure requirement in item 1, the new modality training requirement for item 5 (if applicable), and the continuing experience and continuing education requirements for items 6 and 7.

1. **Licensure**: Be licensed to practice medicine in a State.

**AND**

2. a. **Board Certification**: Be certified in radiology or diagnostic radiology by any of the following bodies:

- The American Board of Radiology (ABR)
- The American Osteopathic Board of Radiology (AOBR)
- The Royal College of Physicians and Surgeons of Canada (RCPSC)

**OR**

b. **Initial Training**: Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography (to include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation physics.

**AND**

3. **Initial Category I Education**: Have a minimum of 60 hours of documented category I medical education in mammography (including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography). At least 15 of the required 60 hours must have been acquired within the 3 years immediately before the physician's initial qualification date. These 60 hours may be included in the 3 months of training specified in 2.b. Hours received in residency training are considered equivalent to category I.

**AND**

4. **Initial Experience**: Have interpreted or multi-read, under direct supervision of a qualified interpreting physician, at least 240 mammographic examinations within the 6-month period immediately before the date that the physician qualifies as an interpreting physician (or in any 6-month period during the last 2 years of a diagnostic radiology residency for physicians who become appropriately board certified at the first allowable time, as defined by the board).

**AND**

5. **New Mammographic Modality**: Before an interpreting physician may begin independently interpreting mammograms produced by any mammographic modality in which the interpreting physician was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physician must have at least 8 hours of training in that mammographic modality.

**AND**

6. **Continuing Experience**: 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 beginning date for meeting the continuing experience requirement is the later of October 1, 1994, or the individual's actual starting date (the date on which an individual met all applicable requirements to begin independently providing mammography services). Failure to meet the continuing experience requirement will not be considered a noncompliance until at least 24 months after the individual's starting date.*

**AND**

7. **Continuing Education**: Have taught or completed at least 15 category I continuing medical education (CME) credits 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. CME credits earned through teaching a course can be counted only once toward meeting the 15 credits required in any 36-month period. Such training shall include at least 6 credits of category I CME in each mammographic modality used by the interpreting physician. *The beginning date for meeting the continuing education requirement is the later of October 1, 1994, or the individual's actual starting date (the date on which an individual met all applicable requirement to begin independently providing mammography services). Failure to meet the continuing education requirement will not be considered a noncompliance until at least 36 months after the individual's starting date.*

FDA permits multi-reading/interpreting of mammograms and summing of readings/interpretations from different facilities in calculating the total mammographic examinations for items 4 and 6. Multi-reading is defined as two or more physicians, at least one of whom is a fully qualified interpreting physician, interpreting the same mammogram. Multi-reading includes reading comparison mammograms not previously read by the physician. So that facilities are aware of potential problems, FDA recommends that facilities update education and experience records at least quarterly." [1]

**Radiologic Technologist**

Radiologic technologists initially qualifying on or after the April 28, 1999 effective date of the final regulations must meet all of the following requirements. Radiologic technologists, who qualified under FDA's interim regulations (before April 28, 1999), are considered to have met the initial training requirements listed in item 2. They may continue to perform mammograms if they continue to meet the licensure or certification requirements of item 1, any applicable new modality training requirement from item 3, and the continuing experience and education requirements of items 4 and 5.

1. a. **Licensure**: Have a general/full license to perform radiographic procedures issued by a State.

**OR**

b. **Board Certification**: Be certified by either of the following bodies:

- The American Registry of Radiologic Technologists (ARRT)
- The American Registry of Clinical Radiography Technologists (ARCRT)

**AND**

2. **Initial Training in Mammography**: Have at least 40 contact hours of mammography training, including breast

anatomy, physiology, positioning, compression, quality assurance/quality control techniques, imaging of patients with breast implants, and the performance of 25 supervised examinations. The actual time spent performing supervised examinations may be included in the 40 hour total. As guidance, however, no more than 12.5 hours of the required 40 should come from the performance of examinations.

**AND**

3. **New Mammographic Modality**: Before a radiologic technologist may independently perform mammographic examinations using any mammographic modality in which the radiologic technologist was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the radiologic technologist must have at least 8 hours of training in the modality.

**AND**

4. **Continuing Experience**: 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.

**AND**

5. **Continuing Education**: 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. At least 6 of these CEUs must be in each of the mammographic modalities used by the technologist. CEUs earned through teaching a course can be counted only once towards meeting the units required in any 36-month period.

*The beginning date for meeting the continuing education requirements is the later of October 1, 1994, or the individual's actual starting date* (*date on which the individual initially qualifies to work independently*), *whichever is later. Failure to meet the continuing education requirements will not be considered a noncompliance until at least 36 months after the technologist's starting date*. [1]

## Regulations for Medical Records

The following is an outline of the requirements as stated in the MQSA manual describing the requirements of the various components to obtain MQSA certification as regards patient permanent records [1]:

**Patient Permanent Records**

Medical records must contain certain required types of information. To ensure that both the mammographic images and reports are being retained as required, and to verify they contain the information outlined in this section, the inspector will randomly select records for review. In general, the inspector will request reports from those examinations performed since the last MQSA inspection, or since the facility's certification, whichever is the most recent. However, inspectors may examine records from other time frames. The inspector will not attempt to assess the correctness of these reports, but will determine that the records are being generated, properly maintained and identify the interpreting physician who originally interpreted the mammograms. For those mammography medical reports created on or after April 28, 1999, the inspector will also verify that one of the following assessment categories appears in each: "Negative," "Benign," "Probably Benign," "Suspicious," "Highly suggestive of malignancy," or "Incomplete: Need additional imaging evaluation."

These are based on the assessment categories as outlined in the American College of Radiology BI-RADS™ atlas [4].

The facility is also required to communicate the results, within 30 days of the examination, to the referring health care provider and to the patient (lay summary). In the case of self-referred patients, if a health care provider (or a responsible designee) is not named or is unavailable, then the report must be provided to the patient. Communications to the patient, if there is no health care provider, must include (1) the complete report of findings referenced previously and (2) the summary written in lay terms that is required for all patients.

When the assessment is "Suspicious" or "Highly suggestive of malignancy," the facility is required to communicate the results, as soon as possible, to the referring health care provider and to the patient (lay summary) and depending on health care provider availability, may need to send the complete report to the patient). Facility personnel should be prepared to explain the facility's procedure for communicating results to referring physicians and to patients and their mechanism for providing quick response for cases requiring such action.

FDA's concern is not the details of the communication system but rather:

- that one has been established by the facility,
- that it is in place, and
- that it meets the requirements of the regulations.

The inspector will verify that the communication system meets these criteria and that lay summaries are available. If patient records are stored in an electronic format, the inspector will ask the facility to assist in the selection and retrieval of the records to be inspected. The inspector will also examine the audit system for the inclusion of the previously-mentioned items, ascertain how biopsy results are obtained, and request to see examples of biopsy results that the facility has obtained. If biopsies were recommended but no results were obtained, the facility must provide documentation of attempts to get this information. [1]

## Follow-Up for Additional Imaging or Biopsy

Most facilities perform significantly better than required under MQSA in following up after a recommendation for additional imaging or for a biopsy after a diagnostic work-up. A study that looked at the timeliness of follow-up care following a recommendation for additional imaging in 214,897 women at 118 facilities and 35,622 recommendations for breast biopsy or surgical consultation found that the median time to subsequent follow-up care after additional imaging recommendation was 14 days and 16 days after a recommendation for breast biopsy or surgical consultation. Timely follow-up was associated with larger volume of the recommended procedures. Most patients returned within 3 weeks for follow-up care [5].

The time to follow up after an abnormal screening or diagnostic mammogram may also be influenced by woman-level characteristics. In a large series of 20,060 screening and

3,184 diagnostic studies after an abnormal screening mammogram, later follow-up was observed among older women and Asians and in those who had a college degree. For diagnostic mammograms, presence of symptoms or being obese was associated with earlier follow-up [6].

## Recommendations Outside the USA

Similar to the MQSA, the Europe against cancer has developed a European guideline for quality control and quality assurance in breast cancer screening and diagnosis. The purpose of such a rigorous quality assurance program in breast cancer screening was to diminish the potential harm that can result from mammography such as unnecessary anxiety and morbidity, inappropriate economic cost, and the use of ionizing radiation [7]. The guidelines emphasize that a breast cancer screening program should aim to avoid unnecessary work-up of clearly benign abnormalities so as to reduce unnecessary anxiety and maintain a cost-effective program. Somewhat similar to the mandated requirements in the USA, the European guidelines for quality assurance recommend the need for quality assurance on all mammography units, implementation of a robust accreditation of all screening programs, and the need for all staff to hold professional qualifications to perform and interpret mammograms and to undertake specialist training and participate in CME and updates and participate in external quality assessment schemes. Each screening unit is required to have a lead professional to oversee overall quality assurance and performance of the screening mammography program. Strict adherence to such national and regional guidelines is critical for a successful screening program, and many countries where screening programs are in place or are being implemented adopt similar measures to ensure quality [7].

## Mammography Audit

The goal of screening mammography is to detect clinically occult breast cancer. A mammography audit aims to measure the success of such a program. An audit of a mammography practice essentially looks at the appropriateness and interpretive accuracy of a facility and the individual physicians [4, 8, 9]. The MQSA-mandated mammography audit is quite basic; the American College of Radiology on the other hand outlines both a basic and a comprehensive audit process in its BI-RADS™ atlas. The expanded mammography audit as outlined in the American College of Radiology Breast Imaging and Data Systems is a comprehensive method of analyzing the quality of performance of a breast cancer screening and diagnostic program and of the individual physicians [4]. See Boxes 10.1 and 10.2.

**Box 10.1. Basic Clinical Mammography Audit**

| |
|---|
| *Raw data* |
| Time period being audited and the total number of examinations during that time |
| Number of screening and number of diagnostic examinations and separate audit for each of these two groups |
| Number of BI-RADS Category 0 assessment |
| Number of BI-RADS Category 4 and 5 assessment [MQSA mandated] |
| Biopsy results for fine needle, core biopsy, and open surgical biopsy |
| Cancer staging: size of the tumor, histological type, nodal status, and grading |
| All cases of known false-negative mammograms have to be analyzed and mammograms prior to the diagnosis of cancer should be reviewed [MQSA mandated] |
| *Derived data* |
| True positives |
| False positives |
| Positive predictive value [PPV1, PPV2, PPV3] |
| Cancer detection rate for screening examinations |
| Percentage of minimal cancers [DCIS or invasive cancers 1 cm or less] |
| Node-negative cancers |
| Abnormal interpretation rates |

Data from D'Orsi et al. [4]

**Box 10.2. Complete Mammography Audit**

| |
|---|
| *Additional data to be collected for a complete mammography audit* |
| Risk factors |
| Patients' age |
| Breast cancer history: personal and family |
| Hormone replacement therapy |
| Previous biopsy proven atypia or lobular carcinoma in situ |
| Baseline, routine follow-up or short interval follow-up examination |
| Mammographic assessment |
| BI-RADS Category 1, negative, and BI-RADS Category 2 benign findings |
| Short interval follow-up: BI-RADS Category 3 |
| Cancer data |
| Mammographic findings: mass, calcifications, indirect signs of cancer, no mammographic signs of cancer |
| Palpable or not |
| *Derived data to be calculated from the more complete mammographic audit* |
| True negatives, false negatives |
| Sensitivity |
| Specificity |

| |
|---|
| Cancer detection rate |
| Prevalent vs. incident cancer detection rates for screening |
| Cancer detection rate for diagnostic examinations |
| Rates for various age groups |
| Percentages of nonpalpable cancers calculated separately for screening and diagnostic examinations |
| Percentage of minimal cancers separately for screening and diagnostic examinations |
| Percentage of node-negative cancers separately for screening and diagnostic examinations |
| Abnormal interpretation rate for diagnostic examinations |

## Mammography Audit Definitions [4]

It is important to understand the definitions of the types of a breast imaging studies and the parameters that are used in a mammography audit. These are outlined next as they appear in the BI-RADS™ atlas [4]:

- A *screening examination* is defined as an examination performed on asymptomatic woman to detect early, clinically unsuspected cancer. The screening group also includes special sub-groups namely women with augmented breast who need additional views optimized to assess breast and women with a personal history of breast cancer.
- A *diagnostic mammographic* examination is performed when there are clinical signs and symptoms that suggest breast cancer, and on a woman with an abnormal screening examination.
- A *tissue diagnosis* is a pathologic diagnosis rendered after any type of biopsy, percutaneous or open surgical with or without image guidance and or localization.
- A *positive screening examination* includes one for which a recall is initiated or a tissue diagnosis is recommended. It is to be noted that the MQSA final rules includes only those that have been recommended for tissue diagnosis as being a positive screening examination.
- A *positive diagnostic examination* is one that requires a tissue diagnosis
- A *negative screening examination* is one that is negative or benign findings (BI-RADS Category 1 or 2)
- A *negative diagnostic examination* includes, a negative, benign or probably benign assessment (BI-RADS Category 1, 2, 3)
- *Cancer diagnosis* refers to Ductal carcinoma in situ or any type of primary invasive breast carcinoma, metastatic carcinoma is not included.
- *True positive* (*TP*) is when there is a tissue diagnosis of cancer within one year of a positive examination. (BI-RADS Category 0, 4, or 5 for screening study and BI-RADS Category 4 or 5 for diagnostic study).
- *True negative* (*TN*) is when there is no tissue diagnosis of cancer within one year of a negative examination (BI-RADS Category 1 or 2 for screening; BI-RADS Category 1, 2 or 3 for diagnostic).
- *False negative* (*FN*) is when there is a tissue diagnosis of cancer within one year of a negative examination (BI-RADS Category 1 or 2 for screening; BI-RADS Category 1,2 or 3 for diagnostic).
- *False positive* (*FP*) has three definitions:
  *FP 1*: No known tissue diagnosis of cancer within one year of a positive screening examination
  (BI-RADS Category 0, 4, or 5)
  *FP 2*: No known tissue diagnosis of cancer within one year after recommendation for biopsy or surgical consultation resulting from a positive examination (BI-RADS Category 4, or 5)
  *FP3*: A benign tissue diagnosis of cancer within one year after recommendation for biopsy or surgical consultation resulting from a positive examination (BI-RADS Category 4, or 5)
- *Positive Predictive Value* (*PPV*)
  *PPV 1*: The percentage of all positive screening examinations with a tissue diagnosis of cancer within one year (BI-RADS Category 0, 4, or 5). It is very unusual yet possible to assign a category 4 or 5 on an initial screening assessment.
  PPV 2: The percentage of all positive screening or diagnostic examinations that were recommended for biopsy or surgical consultations and with a tissue diagnosis of cancer within one year (BI-RADS Category 4, or 5).
  PPV 3: The percentage of all known biopsies done as a result of a positive screening or diagnostic examinations [BI-RADS 4 and 5] that resulted in a tissue diagnosis of cancer within one year.
- Sensitivity is the probability of detecting cancer when a cancer exists or the number of cancers diagnosed after being identified at mammography in a population within one year of the imaging examination divided by all cancers present in the population in the same time period. Sensitivity = TP/TP + FN
- Specificity: The probability of interpreting a mammogram as negative when cancer does not exist or the number of true negative mammograms in a population divided by all actual negative cases in the population. Specificity = TN/TN + FP
- *Cancer detection rate*: The number of cancers correctly detected at Screening Mammography per 1,000 patients and if calculated for diagnostic mammography should be reported separate from Screening Mammography.
- *Abnormal Interpretation Rate*: This is the rate of examinations that are positive, for screening examinations this will include BI-RADS Category 0, 4 and 5 assessments and BI-RADS 4 or 5 for diagnostic mammography. For the most part abnormal interpretation rate is the same as recall rate; the only rare exception is when a BI-RADS 4 or 5 assessments is given on a screening mammogram. Even in cases of obvious suspicious findings, additional imaging is generally needed to determine extent of disease and to plan type of image guidance for biopsy.

## MQSA-Mandated Mammography Audit

MQSA requires that each facility designate a lead interpreting physician who is responsible for reviewing medical audit outcomes yearly. Results have to be analyzed and individual radiologists and the facility have to be notified. The audit data have to be maintained for at least 24 months and longer if required to do so by state regulatory bodies. A system should be in place to collect and review outcome data on all mammograms performed. Follow-up on all positive

mammograms is required. A system needs to be in place to attempt obtaining pathology results on all mammograms with a recommendation for biopsy with correlation of biopsy results with the mammographic findings. Outcome data analysis is required for individual physicians as well as for the facility. Computerized tracking and analyzing system is acceptable and desirable but not required. FDA requires only determining that the biopsy is benign or malignant. Any case with a benign or negative assessment with a breast cancer diagnosis within a year, considered as false negative, should be analyzed.

The MQSA basic audit is likely to be expanded in the near future. The United States Congress has commissioned the Institute of Medicine [IOM] to produce a report to enhance quality of breast imaging practice [10]. The IOM report has conclude that the current requirements are inadequate for measuring or improving the quality of mammographic interpretation [10].

**Box 10.3. Summary of Recommendations to Improve Breast Imaging Quality**

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
5. Revise MQSA regulations, inspections, and enforcement
6. Modify regulations to clarify their intent and address current technology
7. Streamline inspections and strengthen enforcement for patient protection
8. Ensure an adequate workforce for breast cancer screening and diagnosis
9. Collect and analyze data on the mammography workforce and service capacity
10. Devise strategies to recruit and retain highly skilled breast imaging professionals
11. Make more effective use of breast imaging specialists
12. Improve breast imaging quality beyond mammography by mandating accreditation for nonmammographic breast imaging methods that are routinely used for breast cancer detection and diagnosis, such as ultrasound and magnetic resonance imaging (MRI)

Data from Institute of Medicine [10]

## IOM Recommendations to Improve Interpretative Performance [10]

The institute of medicine in its manual on improving breast imaging quality standards has recommended carrying out studies to determine what additional approaches would improve the quality of mammography interpretation since the currently available data not sufficient to justify regulatory changes. Among the suggested studies to be undertaken are those that would demonstrate the efficacy of continuing medical education specifically dedicated to improving interpretive skills and effects of reader volume on interpretive performance, measuring the impact of double reading and computer-aided detection on interpretive performance over time and at different levels of experience and in different practice setting. The funding for such studies is recommended to be granted by the National Cancer Institute.

An outline of the recommendations appears in Box 10.3. The summary of these recommendations follows:

Include PPV2, cancer detection rate, and abnormal interpretation rate in the required basic medical audit.

- In addition to tracking BI-RADS 4 and 5 assessments, all women for whom additional imaging has been recommended should also be tracked. [BI-RADS 0; incomplete assessment, needs additional imaging].
- All performance measures should be measured separately for screening and diagnostic mammography.
- Each interpreting physician should be allowed to combine audit data from all facilities that he or she is interpreting.
- Encourage facilities to participate in a voluntary enhanced mammography audit that would collect data on patient characteristics and tumor staging information from pathology reports. This should be tied into a central data and statistical coordinating center that would collect data from interpreting physicians and provide feedback for quality assurance and improvement. Implementation of such an audit needs to be incentivized by tying in pay for performance by Centers for Medicare & Medicaid Services [CMS] and payors by providing higher reimbursement rates for those meeting performance criteria that are set by a group of experts and patient advocates and periodically updates. Exempting such facilities from FDA inspection of medical audit data is an additional incentive.

Given the fact that the current MQSA-required audit is bare bones, it is desirable for each breast imaging facility to perform at a minimum the BI-RADS basic audit. Unlike the USA, in countries where organized screening is in place, a more stringent audit is mandated by government regulatory bodies. Additionally audit results should be examined for the facility as a whole as well as for individual radiologists interpreting mammograms. There are several commercially available software programs that continually accumulate data and produce metrics at defined intervals. The lead interpreting

**Table 10.1** Mammography interpretative performance benchmarks for screening mammography

| Measure | Minimal acceptable criteria |
|---|---|
| Sensitivity | <75 % |
| Specificity | <88 % or greater than 95 % |
| Recall rate | <5 % or greater than 12 % |
| PPV2 | <20 % or greater than 40 % |
| Cancer detection rate | <2.5 % per 1,000 screens |

Data from Carney et al. [12]

radiologist should monitor metrics of his or her colleagues and initiate remedial measures if performance metrics falls significantly out of the expected benchmarks (Table 10.1).

Audits are meaningful when performed separately for diagnostic and screening mammographic examinations due to expected variation in outcomes [11, 12]. In an analysis of 51,805 mammographies where screening and diagnostic examinations were audited separately, expected outcomes for various mixes were calculated based on a known mix of 79 and 21 % in the study group. For a screening diagnostic mix of 90 and 10 %, compared to a 50–50 % mix, the expected rate of abnormal findings was 6–11 %, rate of positive biopsy findings was 38 % vs. 42 %, cancer detection rate was 10 per 10,000 to 30 per 10,000, invasive cancer size was 14.4 vs. 16.0 mm, nodal metastasis was 8–11 %, and rate of stage 0 and stage 1 cancers was 87 % vs. 82 %. Among diagnostic mammographic examinations, a higher percentage for all these numbers is expected for those with palpable findings [11]. Extrapolation from known outcomes is suggested when audit data for screening and diagnostic examinations are combined. As was shown in this study, the mix of screening and diagnostic, as well as the type of indication for a diagnostic examination, will influence the outcomes [11].

## Mammographic Interpretation, Interpretive Accuracy, and Benchmarks

Benchmarks that are used to determine interpretive performance may be derived from expert panels or derived from published large samples of data from clinical practice. The introduction and implementation of MQSA has had the intended effect of improving the technical quality of mammographic examinations; however, there has not been a corresponding improvement in the interpretative quality of mammograms as judged by sensitivity and specificity [10].

Minimally acceptable criteria for interpretive performance for screening and diagnostic mammography have been published [11–16]. One of these studies examined minimally acceptable performance standards for interpreting screening mammograms: a sensitivity of less than 75 %, a specificity that was less than 88 % or greater than 95 %, a recall rate that was less than 5 % or greater than 12 %, PPV2 of less than 20 % or greater than 40 %, and cancer detection rate of 2.5 per 1,000 interpretations as indicating low performance (Table 10.1). If underperforming physicians moved into the acceptable range by additional training, detection of an additional 14 cancers per 100,000 women screened and a reduction in the number of false-positive examinations by 880 per 100,000 women screened would be expected [12]. Radiologists interpreting moderate (1,001–2,000) and those with high volume (>2,000) had a higher sensitivity [12].

## Reducing Recall and False Positives

The recall rate remains one of the most important benchmark of interpretive performance in screening mammography. A high recall rate leads an increased false-positive rate which is one of the most frequently cited as a cause of unnecessary patient anxiety and a shortcoming of mammography. Recall rate is used as an indicator of quality of imaging performance in the National Accreditation Program for Breast Centers as well as in the National Quality Benchmarks for Breast Centers. False-positive mammogram not only causes increased anxiety; it also leads to excess costs and morbidity from subsequent biopsies, many of which result in a benign diagnosis. The rate of recall for screening mammography in the USA is twice the recall rate in the UK (e.g., 12.5–14.4 % vs. 7.6 %), with no difference in cancer detection rate [17]. One of the contributory factors for this difference maybe the practice of defensive medicine; failure to diagnose breast cancer is the leading cause of malpractice litigation in the USA [18]. Additional factor that is in play is the higher interpretive volume of screening mammography among breast imagers in the UK [17, 19].

In a study that looked at three groups of radiologists interpreting mammograms, the sensitivity in the group considered as high-volume readers which included those who read >301 mammograms each month was significantly higher than in those who read <100 or those who read between 100 and 300 mammograms. The specificity was also better among high-volume readers although was not statistically significant [19, 20]. In the USA the minimum number of mammograms required to be read per MQSA regulations is 480/year compared to 5,000/year required in the UK [17]. Others have also shown that increasing minimum interpretive volume requirements in the USA while adding a minimal requirement for diagnostic interpretation could reduce the number of false-positive work-ups without hindering cancer detection [20].

Several studies have been published describing ways of optimizing recall rate in screening mammography. Large studies of performance metrics for radiologists in community practice have shown that cancer outcomes for the majority of

radiologists exceed the set benchmarks except for recall rate which has been shown to be outside of the recommended range in greater than half of the radiologists studied [21]. Baseline mammography or when no comparison is available also contributes to a higher rate of recall. The false-positive rate is significantly higher, 16.3 % in one large series on the initial screening round than at subsequent mammography, and the same applies to false-positive biopsy rate which was shown to be 2.5 % at first and 1.0 % at subsequent examinations. Having prior films available was shown to halve the odds of a false-positive examination. Over a 10-year period of annual screening, more than 50 % of women received a false-positive recall and 7–9 % a false-positive biopsy recommendation. These investigators also found a lower rate in those undergoing biennial mammography albeit with a small absolute increase in the probability of being diagnosed with late stage of cancer [22]. Availability of comparison mammograms not only is beneficial in reducing recall rate but has been shown to permit cancer detection at an early stage for screening mammograms. An analysis of 48,281 consecutive mammography examinations for which previous mammography (9,825 diagnostic, 38,456 screening) had been performed between 1997 and 2001 reported that for screening mammography, comparison with previous examinations significantly decreases false positives and permits detection of cancers at an earlier stage. For diagnostic mammography, comparison with previous examinations increases true-positive findings. In the diagnostic setting, comparison with previous examinations increases the biopsy yield from 38 to 51 % and the overall cancer detection rate from 11/1,000 to 39/1,000. A significant decrease in the frequency of axillary node metastasis and the cancer stage for screening mammography was observed [23].

## Educational Intervention to Improve Recall

Several investigators have looked into the value of improving recall rate by educational intervention [24–26]. In a study where, among a group of 31 radiologists, 22 received 1 h Web-based training and 9 radiologists in the control group received none, there was no positive benefit seen in the group that received the training. A multi-institutional study that used a tailored Web-based intervention to assess radiologist's ability to set goals to improve recall rates had better results. Peer comparison data that profiled breast cancer risk in the radiologist's patient populations was provided to the radiologists. Such an intervention was successful in helping radiologists develop goals that ultimately reduce unnecessary recall. There have been other studies evaluating effectiveness of a more rigorous and comprehensive intervention [27, 28]. The UK national health program evaluated a 2-week multidisciplinary course with a specialist training at high-volume screening sites which was combined with breast disease–related meetings and personal and group audit reports inclusive of cancer detection rate, recall rate, and PPV2. An impressive reduction in the recall rate from 7 to 4 % was observed with an increase in the small invasive cancer detection rate from 1.6 per 1,000 women screened to 2.5 per 1,000 women screened [27]. In the USA, a study group of 21 radiologists were provided personal and group audits and attended a self-assessment, case review sessions and were required to interpret 8,000 mammogram annually. An improvement in sensitivity from 70 to 80 % was noted with a mean cancer detection rate of 7.5/1,000 and a mean recall rate of 7 % [28].

## Interpretative Benchmarks for Diagnostic Mammograms

Monitoring clinical outcome is well accepted as a measure of quality of interpretation and is a requirement in a basic form by the MQSA. However, performance benchmarks need to be separate for screening and diagnostic studies since the expected outcomes are significantly different for these two categories of breast imaging studies [12, 13, 15]. A large series of 332,926 diagnostic mammography examinations derived from six mammography registries that submitted data to the Breast Cancer Surveillance Consortium (BCSC) looked at the mean performance parameter values and reported an abnormal interpretation rate of 8 %, PPV2 of 31.5 %, PPV3 of 39.5 %, and cancer detection rate of 25.3 % per 1,000 examinations; invasive cancer size was 20.2 mm, the percentage of minimal cancers was 42 %, percentage of node-negative cancers was 73.6 %, and percentage of early-stage [stage 0 and I] cancers was 62.4 % [15]. A recently published article outlined minimally acceptable interpretive performance criteria for diagnostic mammography [13]. Simulations and normative data from the BCSC were used to help a panel of breast imaging expert radiologists to identify the impact of cutoff points and estimate the expected clinical impact from setting of performance thresholds. Thresholds were determined for work-up of screen-recalled abnormalities separately from those being worked up for a breast lump. In the former group minimum acceptable threshold was set as a sensitivity less than 80 %, specificity less than 80 % or greater than 95 %, abnormal interpretation rate of less than 8 % or greater than 25 %, PPV2 of less than 15 % or greater than 40 %, PPV3 of less than 20 % or greater than 45 %, and a cancer diagnosis rate of less than 20 per 1,000 interpretations. Following work-up of breast lump, the thresholds were sensitivity less than 85 %, specificity less than 83 % or greater than 95 %, abnormal interpretation rate of less than 10 % or greater than 25 %, a PPV2 less than 25 % or greater than 50 %, PPV3 less than 30 % or greater than 55 %, and a

cancer diagnosis rate of less than 40 per 1,000 interpretations. These cutoff points for performance benchmarks were expected to lead to 16–34 % of interpreting physicians and 11–24 % of facilities being recommended for additional training in diagnostic mammography following abnormal screening examinations and 21–42 % of radiologists and 14–54 % of facilities for additional training in diagnostic mammography performed to evaluate a breast lump. Those radiologists who fell outside the acceptable threshold would benefit from remedial training and consequently be expected to diagnose an additional 186 cancers per 100,000 screening examinations and reduce the number of false-positive examinations by 1,067 per 100,000 women and, following work-up of a breast lump, would be expected to diagnose an additional 335 cancers per 100,000 women with a reduction of false-positive examinations by 634 per 100,000 women [13]. Published goals are important guidelines but making radiologists aware of these goals is a challenge; a study found that many radiologists' understanding of the desirable goals for interpretative accuracy in fact falls outside of the published benchmarks. Those who were in academic practice and receive breast imaging CME and receive annual feedback were more likely to report desirable PPV2 goals. Cancer detection rates were also higher among those who have had >10 years of experience reading mammograms and in those who read >1,000 mammograms per year [16].

## The Breast Cancer Surveillance Consortium [BCSC] [29]

The National cancer Institute [NCI], USA, outlines a "discovery-development-delivery" approach to cancer research [29]. "Discovery is the process of generating new information about fundamental cancer processes from the genetic to the population level. Development is the process of creating and evaluating tools and interventions that are valuable in detecting, diagnosing, predicting, treating, and preventing cancer. Delivery involves promoting and facilitating the application of evidence-based cancer interventions" [29]. The Breast Cancer Surveillance Consortium [BCSC] was established by the NCI in 1994. The benefits of screening mammography have been well established in large randomized clinical trials; however, there was a need to study the effectiveness of screening mammography more thoroughly in routine clinical practice. It was also recognized that useful information could only be obtained by linking screening patterns and performance parameters as outlined by national bodies and professional societies such as the American College of Radiology, with cancer outcomes. At the present time seven data collection and research centers and the statistical coordinating center comprise the BCSC. A key program of NCI's Division of Cancer Control and Population Sciences focuses on the delivery component, and its research wing aims to promote adoption of proven intervention methods in clinical and public health practice. The BCSC links surveillance data on breast screening practices with data from population-based cancer registries. Most recent data, which include data on screening mammography performed from 2002 to 2006 and analyzed in 2009, show a cancer detection rate of 4.6 per 1,000 women among 1,960,500 mammograms performed. Sensitivity and specificity for 2,264,089 screening mammography examinations from 2002 to 2006—based on BCSC data as of 2009—are 84.1 % and 90.4 %, respectively. The recall rate was 10 %. PPV 2 was 23.6 % [cases where biopsy was recommended], and PPV 3 was 28.9 % [cases where biopsy was performed within 1 year] [29]. An analysis of the results of 47,798 screening and 13,286 diagnostic mammograms found that radiologists that are specialized in breast imaging detected more cancers and more early-stage cancers, recommended more biopsies, and had lower recall rates than did the general radiologists. Cancer detection rate of specialists was 6 % compared to 3.4 % for generalists. A database of such large samples of screened population allows the consortium to study and publish several key features of community-based breast cancer screening programs such as characteristics of women that affect the performance of screening mammography; characteristics of radiologist, radiology facility, or mammographic technologists affecting performance of screening mammography; and characteristics of mammography equipment that affects the performance of screening mammography. The low-contrast detectability was studied using a full-field digital mammography system in terms of and compared with results obtained from an optimized screen-film system. Results showed that using a softer x-ray beam for thin breasts and a harder x-ray beam for thick breasts improved digital mammography's ability to detect low-contrast lesions when the average glandular dose was kept constant. Under this constraint, optimum low-contrast lesion detection with digital mammography was superior to that of conventional screen-film mammography for all but the thinnest breasts [30].

## Mammographic Interpretative Accuracy: Film vs. Digital Mammography [30, 31]

About 2/3 of all mammography equipment in the USA is digital, predominantly full-field digital systems. In one study, a total of 49,528 asymptomatic women presenting for screening mammography at 33 sites in the USA and Canada underwent both digital and film mammography [30]. The overall diagnostic accuracy of full-field digital mammography [FFDM] and screen-film mammography [SFM] as a means of screening for breast cancer was found

to be similar, but digital mammography was found to be more accurate in women under the age of 50 years, women with radiographically dense breasts, and premenopausal or perimenopausal women [28]. Another study that compared the miss rate of breast cancer found no difference in those who underwent screen-film mammography from those who underwent full-field digital mammography. The missed cancers in the SFM group of 52,444 women had microcalcifications on the prior mammograms in 34 %, compared to 18 % in the FFDM group of 35,127 women; focal asymmetry at the site of cancer was seen more frequently at the site of missed cancers in women who underwent FFDM, 27 % compared to 10 % in those who underwent SFM [30, 31].

## Attaining Excellence in Comprehensive Breast Cancer Care

The importance of a multidisciplinary approach in managing the breast cancer patient is well recognized. There are both discipline-specific programs and breast center–specific programs. Professional organizations have taken on the task of ensuring excellence in breast cancer care in multidisciplinary breast centers. There are several major voluntary accreditation programs in the USA, some discipline specific and some conducted by national professional bodies. Notable of these are the American College of Radiology program for accreditation of Breast Imaging Centers of Excellence, the National Quality Measures for Breast Centers Program, and the National Accreditation Program for Breast Centers.

### Breast Imaging Center of Excellence [American College of Radiology]

The American College of Radiology recognizes breast imaging centers that achieve excellence by seeking and earning accreditation in the ACR's entire voluntary breast imaging accreditation programs and modules in addition to the mandatory Mammography Accreditation Program by providing them a certificate that identifies them as a Breast Imaging Center of Excellence [32].

In order to receive the ACR's Breast Imaging Center of Excellence designation, a center must be fully accredited in [32]:

- Mammography by the ACR (or an FDA-approved state accrediting body)
- Stereotactic breast biopsy by the ACR
- Breast ultrasound by the ACR (including the Ultrasound-Guided Breast Biopsy module)

### National Quality Measures for Breast Centers™ (NQMBC™)

The National Quality Measures for Breast Centers™ Program (NQMBC™) is a free interactive Internet model for breast centers to track and measure quality performance in more than 30 separate quality indicators. The NQMBC™ Program identifies quality care measures and provides immediate access to information that allows participating breast centers to compare performance with other centers across the USA. The NQMBC™ Program is a result of the National Consortium of Breast Centers' (NCBC) commitment to increase the quality of breast health care provided by professionals to their patients [http://www.nqmbc.org/] [33, 34]. There are three levels of designation: participant [data should be supplied for 40 % of the measures], quality breast center [data should be supplied for 75 % of the measures], and breast center of excellence [data should be supplied for 90 % of the measures]:

- The breast center must have supplied data for 40–90 % of the measures for which their quality breast center type should be able to measure performance.
- This quality data being considered for evaluation must span two consecutive data collection periods. (A data period is a 6-month range during which time data is collected according to the parameters of the indicator.)
- These two consecutive data collection periods being audited for certification must be within the last 3 years.
- After the initial certification at this level, the two consecutive data periods being audited for certification must be after the two consecutive data collection periods and within the last 2 year's data. A data period may be audited only once for certification.

Box 10.4 summarizes the performance measures required for a screening and diagnostic breast center to achieve NQMBC™ quality certification.

### National Accreditation Program for Breast Centers [NAPBC] [34–37]

Breast care quality can be assessed by three measures, an outcome of care, structure of care, or process of care. Outcome care that needs long-term data on survival, morbidity, and mortality is not useful to assess breast care due to its complexity. Structural measurements include an interdisciplinary breast conference, having a sentinel node protocol, and having a standardized synoptic pathology reporting system. These elements lead to a higher quality of care. Of greater importance is a process measurement that evaluated the type of care that is actually provided [34]. NAPBC was developed by a multidisciplinary team which combined its expertise in breast health care to create a validation process for breast programs. This program focuses on the process of care that includes self-monitoring of process measures, peer compari-

**Box 10.4. Summary of Performance Measures for Screening and Diagnostic Breast Center to Achieve NQMBC™ (National Quality Measures for Breast Centers) Quality Certification**

| |
|---|
| Screening breast center |
| Mammography call back rate |
| Diagnostic breast center |
| Imaging timeliness of care: time between screening and diagnostic mammogram |
| Mammography call back rate |
| Surgical timeliness of care: time between diagnostic and open surgical biopsy |
| Imaging timeliness of care: time between diagnostic mammogram and core needle biopsy |
| Core needle biopsy rate |
| Pathology timeliness of care: time between initial breast biopsy excluding open surgical biopsy and pathology results |

Used with permission of the National Consortium of Breast Centers, Inc. From http://www.nqmbc.org/QualityPerformanceYouShouldMeasure.htm

**Box 10 5. Summary of Breast Imaging Specific Components of NAPBC (National Accreditation Program for Breast Centers)**

1. Community outreach program to educate on benefits of screening mammography
2. Screening mammography and diagnostic mammography are performed at Mammography Quality Standards Act (MQSA)-certified facilities and interpreted by MQSA-certified physicians
3. Palpation-guided or image-guided needle biopsy is the initial diagnostic approach rather than open biopsy. Diagnostic ultrasound and/or ultrasound-guided needle biopsy are performed at an American College of Radiology (ACR)-accredited facility or by an American Society of Breast Surgeons (ASBS)-certified physician

son, and local intervention that is aimed at improvement in the process of care. The NAPBC is a consortium of national, professional organizations focused on breast health, dedicated to the improvement of the quality of care and outcomes of patients with diseases of the breast through evidence-based standards, and patient and professional education [35]. From a breast imagers' perspective, there are components of the requirements to be accredited that are listed in Box 10.5. An analysis of the NAPBC 2-year data suggests that a wide variety of BC models adequately provide a high level of care and services for patients across the nation [37].

## Summary

Benefits of a breast cancer screening and diagnostic program can only be realized by maintaining a rigorous quality assurance program that encompasses image quality, personnel qualifications, and interpretive accuracy. MQSA ensures quality of mammographic screening for breast cancer in the USA. Continuing monitoring of performance of image quality and radiologists' interpretive performance is needed to maintain the highest possible quality. Accreditation programs offered by professional societies offer a voluntary opportunity for breast centers to achieve excellence in breast care and be recognized for being one.

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