# Institute of Medicine Recommendations

National Mammography Quality Assurance Advisory Committee
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Helen J. Barr, M.D.
Director, Division of Mammography Quality and Radiation Programs
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
Food and Drug Administration
Department of Health and Human Services

# Background for IOM Report

- Questions regarding quality of image interpretation
- Congress commissioned study from IOM, in preparation for reauthorization of MQSA
  - Steps to increase accuracy of interpretation
  - Whether current regulations should be modified
  - Effect of recommendations on access to mammography
  - Identify steps to ensure safe and effective use of other screening or diagnostic tools

# IMPROVING BREAST IMAGING QUALITY STANDARDS

**Committee on Improving Mammography Quality Standards**

National Cancer Policy Board

Institute of Medicine and National Research Council

# Major Areas for Recommendations

- Improve Mammography Interpretations
- Revise MQSA Regulations, Inspections, And Enforcement
- Ensure Adequate Workforce for Breast Cancer Screening and Diagnosis
- Improve Breast Imaging Quality Beyond Mammography

# Improving Mammography Interpretation

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**Recommendations:**

1. Revise and standardize medical outcomes audit
2. Facilitate voluntary advanced medical audit with feedback
3. Establish specialized Breast Imaging Centers of Excellence
4. Study effectiveness of continuing medical information (CME), reader volume, double reading, and computer-aided detection (CAD)

# Recommendation 1

# Revise and Standardize Medical Outcomes Audit

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## Positive Predictive Value (PPV)

- $PPV_1$: The proportion of all women with positive examinations (Category 0, 4, or 5) who are diagnosed with breast cancer [$TP/(TP + FP_1)$]
- $PPV_2$: The proportion of all women recommended for biopsy after mammography (Category 4 or 5) that are diagnosed with breast cancer [$TP/(TP + FP_2)$]
- $PPV_3$: The proportion of all women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy [$TP/(TP+FP_3)$]

# Revise and Standardize Medical Outcomes Audit

## False Positive Measurement (FP)

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

# Revise and Standardize Medical Outcomes Audit

**A) Medical audit should include the calculation of three core measures:**

- Positive predictive value 2 ($PPV_2$) - proportion of women recommended for biopsy after mammography (Category 4, 5) who are diagnosed with breast cancer
- Cancer detection rate per 1,000 women
- Abnormal interpretation rate - women whose mammogram interpretations lead to additional imaging or biopsy

# Revise and Standardize Medical Outcomes Audit

**Rationale:**

- MQSA doesn't require calculation of specific performance statistics
- More useful than $PPV_3$ (proportion of women biopsied due to the interpreting physician's recommendation who are diagnosed with cancer at the time of biopsy)

# Revise and Standardize Medical Outcomes Audit

**Rationale (cont.):**

- Easier to calculate than $PPV_1$ (proportion of all women with positive examinations (Category 0, 4, 5) diagnosed with breast cancer)
- Additional imaging assessment – not included in MQSA-required audit

# Revise and Standardize Medical Outcomes Audit

**B) Performance measures should be stratified by screening and diagnostic mammography**

**Rationale:**

- Difficult to interpret and compare performance with current literature or established databases

# Revise and Standardize Medical Outcomes Audit

**C) Option of combining audit measures for physicians at multiple facilities**

**Rationale:**

- Data more meaningful when larger numbers of exams per physician are analyzed

# Revise and Standardize Medical Outcomes Audit

**D) Audit data collection and analysis verified at inspection but not collected**

**Rationale:**

- No change in procedure warranted because regulators not able to verify accuracy of data

# Revise and Standardize Medical Outcomes Audit

**E) Increase reimbursement rates to cover new audit procedures**

**Rationale:**

- Costs already significant
- New audit procedures will add to expense
- Costs were not factored in past reimbursement
- Health care payers should cover costs

# Recommendation 2

# Voluntary Advanced Medical Audit with Feedback

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**A) Audit should include collection of patient characteristics and tumor staging from pathology reports**

**Rationale:**

- Record more useful data from pathology reports such as tumor size and axillary lymph node status
- Record patient characteristics such as age, family history, breast density, presence of prior films, and time since last mammogram

# Voluntary Advanced Medical Audit with Feedback

**B) Establish a data and statistical coordinating center to:**

- Electronically collect, analyze and report advanced-level audit data and provide regular feedback to interpreting physicians
- Develop, implement and evaluate self-improvement plans for interpreting physicians who do not achieve performance benchmarks
- Aggregate summary data on interpretive performance, including recall rates, PPV2 and cancer detection

# Voluntary Advanced Medical Audit with Feedback

**B) Establish a data and statistical coordinating center to (cont.):**

- Test different methods of delivering audit results to interpretive performance
- Study randomly selected facilities using required basic audit procedures for impact on interpretive quality
- Protect quality assurance data from discoverability

# Voluntary Advanced Medical Audit with Feedback

**Rationale:**

- Statistics and analysis group needed for uniform feedback to improve quality
- Studies needed on feedback to improvement performance
- National benchmarks needed for facilities to assess performance
- Test impact of basic audit procedures

# Voluntary Advanced Medical Audit with Feedback

**Rationale (cont.):**

- The Breast Cancer Surveillance Consortium and the Agency for Healthcare Research and Quality should be utilized as they are viable models for data collection procedures

Note: report indicated that it is important to protect audit data from discoverability

# Voluntary Advanced Medical Audit with Feedback

**C) Provide incentives for high standard of interpretive performance through advanced audit program**

**Rationale:**

- Health care payers should pay a higher reimbursement rate in exchange for meeting performance criteria

# Recommendation 3

# Designate Specialized Breast Imaging Centers of Excellence

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**A) Participate in basic and advanced medical audits and test approaches to improve quality and effectiveness**

- Test effects of high volume, double-reading, quality assurance processes, and patient reminders
- Further develop and evaluate interpretive skills assessment exams

# Designate Specialized Breast Imaging Centers of Excellence

**Rationale (cont.):**

- Several countries have integrated and centralized breast cancer screening programs, but in the U.S., screening is decentralized and offered in diverse practice settings
- Centers could provide multidisciplinary training and work environments for diagnosis; could increase job satisfaction, retention of practitioners, and productivity and quality of breast care team
- High-quality facilities could attract high-quality personnel

# Designate Specialized Breast Imaging Centers of Excellence

**B) Incentives could be similar in Recommendation 2 (higher reimbursement rates), and could be used to recruit patients and referrals**

**Rationale:**

- Supportive elements and incentives are critical to encouraging facilities and personnel to strive for higher quality

# Designate Specialized Breast Imaging Centers of Excellence

**C) Centers should serve as training centers for breast imaging and regional mammogram readers**

**Rationale:**

- Centers would have expertise to develop and host training programs in breast imaging
- Interpretation at centralized facilities could help alleviate access in low-volume areas

# Designate Specialized Breast Imaging Centers of Excellence

**D) Centers should be linked with facilities that provide comprehensive and multidisciplinary breast care**

**Rationale:**

- Imaging-based centers need continuity with facilities providing nonimaging breast care treatment and follow-up

# Recommendation 4

## Study Effectiveness of Continuing Medical Education (CME), Reader Volume, Double-Reading, And Computer-Aided Detection (CAD)

# Study Effects of CME, Reader Volume, Double-Reading, and CAD

**A) Demonstrate value of CME for improving interpretative skills**

**Rationale:**

- Enable interpreting physicians to identify weaknesses and take steps to improve interpretive performance
- Continue to develop innovative teaching interventions to improve interpretive skills

# Study Effects of CME, Reader Volume, Double-Reading, and CAD

**B) Determine effects of reader volume on interpretive accuracy**

**Rationale:**

- Insufficient evidence to recommend increase in minimum interpretive volume
- No basis for specifying higher level of reader volume

# Study Effects of CME, Reader Volume, Double-Reading, and CAD

**C) Impact of double-reading and CAD on interpretive performance over time, in different practice settings, and at different levels of experience**

**Rationale:**

- Second look by another reader or computer program not verified by prospective clinical trials
- Effects on specificity not fully understood

# Study Effects of CME, Reader Volume, Double-Reading, and CAD

**C) Rationale (cont.):**

- CAD programs being refined so effect and use could change over time. Studies needed on effectiveness. Findings could help use more effectively
- Studies needed to confirm if consensus double reading may be most effective