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Mammography Quality Standards Act: Background and Issues

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Summary

Mammography uses X-rays to produce an image of the internal structure of the breast. There is a long history of public and professional concern over the safety and quality of mammography. Between 1985 and 1992, several studies found a wide range in image quality and patient radiation dose. National, comprehensive quality standards that applied to all mammography facilities were nonexistent until the Mammography Quality Standards Act (MQSA) was enacted on October 27, 1992 (P.L. 102-539). MQSA replaced the conflicting and overlapping patchwork of private voluntary standards and limited state and federal regulations. H.R. 4382, which reauthorized MQSA, was passed in September 1998 by the 105th Congress and signed into law by the President on October 9, 1998 (P.L. 105-248). This report will be updated periodically.

Background

For American women, breast cancer is the most commonly diagnosed cancer and the second leading cause of cancer mortality behind lung cancer. The American Cancer Society estimates that in 1998, 178,700 new cases of breast cancer will be diagnosed and 43,500 women will die from the disease. Mammography can be used as a diagnostic tool in women with symptoms or a screening tool in women without symptoms. Mammography screening combined with clinical breast examination is currently the best available method of breast cancer detection. Mammography uses X-rays to produce an image of the internal structure of the breast and can often detect breast cancer when it is very small, before it can be found by a woman or her physician.

In current practice, an X-ray technician, rather than a radiologist, performs the actual mammography procedure. Breast imaging is not straightforward, and an accurate image is among the most difficult to obtain for the X-ray technician; some technicians are better at positioning than others. After the image is taken, a technician develops the X-ray film. The radiologist reads the mammogram. Interpretation of a mammogram is not clear cut either; abnormalities can be very subtle and other factors can affect clarity. For example,

younger women and women taking estrogen replacement therapy have denser breast tissue which does not image well on X-ray. Mammograms are among the more challenging radiographic images to read and must have optimal clarity to be interpreted correctly.

Mammography was not widely used until the publication in 1960 by Dr. Robert L. Egan of a reproducible technique for performing the examination. In the late 1960s, the Health Insurance Plan of Greater New York (HIP) began a randomized clinical trial to determine whether regular screening with clinical examination and mammography could reduce deaths from breast cancer. In the study, 60,000 women were randomly assigned to a screening group or a control group. At a 7-year follow-up, the study showed a 30% reduction in breast cancer mortality in the screened women. The HIP study results greatly expanded interest in mammography and resulted in its increased use as a screening tool. Public awareness of breast cancer grew following the revelations by various celebrities of their personal battles with breast cancer. Consequently, the demand for and access to mammography gradually rose over time, albeit with some ups and downs.

There has been a long history of public and professional concern over the safety and quality of mammography. In the 1970s, the major fear was the radiation dose level. Some facilities were using X-ray doses too low to obtain diagnostic images, whereas others were delivering excessive radiation. By 1976, there was growing apprehension among scientists over the possibility of breast cancer being induced in healthy women through radiation exposure of breast tissue. When concerns over mammography safety were reported in the mass media, the result was a radiation scare that caused a marked decline in the use of mammography. At mammography facilities across the country, even symptomatic women were refusing to have mammography exams prescribed by their physicians. At the close of the 1970s, the future of mammography was uncertain.

In the 1980s, the type of equipment used in mammography was a focus of debate. Technological changes were aimed primarily at reducing the radiation dose and replacing general purpose X-ray equipment with dedicated mammography units. Toward the end of the 1980s, confidence in mammography was restored in the eyes of some by two factors: 1) the lowered X-ray dose; and, 2) the results of the European clinical trials of mammography screening, some of which echoed the HIP study's favorable results. As a result, in 1989, 11 organizations, including the American Cancer Society and the National Cancer Institute, endorsed screening mammography guidelines for women 40 and older.

Although studies had demonstrated that lower radiation and new equipment produced an improved image, several surveys found problems in the routine use of mammography across the country. The American Cancer Society in a 1988 study and the General Accounting Office in a January 1990 report found a wide range of image quality and patient radiation dose level from dedicated mammography equipment. The Food and Drug Administration (FDA) conducted surveys of mammography equipment in 1985, 1988, and 1992. The purpose of the surveys was to determine patient radiation exposure and assess image quality. The surveys found wide variations in image quality and radiation dose from site to site. Another study found variations from site to site and from day to day at the same site. The results of all these studies confirmed the need for ensuring compliance with mammography quality standards.

A false negative mammogram caused by poor quality mammography poses a serious health risk for women. According to the Physician Insurers Association of America,

"malignant neoplasms of the female breast continue to be the condition for which a patient most frequently files a medical malpractice claim.... Breast cancer is the second most expensive condition in terms of indemnity dollars, next to claims resulting from neurologically impaired newborns."[1] The average cost for payment of one malpractice case involving breast cancer is $307,000.[2]

Regulation of Mammography Prior to MQSA

Prior to the passage of MQSA, there were no national, comprehensive quality standards for mammography that applied to all facilities. The regulation of mammography involved an often conflicting and overlapping patchwork of private voluntary standards combined with limited state and federal regulations.

Private Voluntary Standards. In response to the problems identified in the 1980s, the American College of Radiology (ACR) established a private voluntary accreditation program in August 1987. The ACR attempted to fill a gap with a program that was generally well received; however, its voluntary nature as well as other aspects of the standards raised some concerns. For example, although the image quality, (reflecting the skills of the technician) was addressed, the image interpretation (reflecting the skills of the radiologist) was not addressed. Less than half of mammography facilities met ACR's professional standards. Also, the ACR program had a surprisingly high failure rate of 28% among first-time applicants. This was especially alarming due to the voluntary nature of the program; presumably the applicants had applied because they believed they were performing well and would met the ACR standards.

State Regulations. Prior to MQSA, only 11 states had established comprehensive quality assurance standards. Michigan was among the first to implement such standards and had one of the most all-encompassing programs. The Michigan program had a significant impact on the quality of its mammography services. When the Michigan legislation was enacted in 1989, 34% of mammography machines tested failed the image quality test; the rate subsequently dropped to 16%. However, upon reinspection, even accredited machines had a failure rate of 11%. The failure rate was of great concern to the Michigan Department of Public Health, which was responsible for on site inspections of mammography facilities, and the agency called for federal quality standards and oversight of mammography. The wide variation in state laws, the potential for nonuniformity of patient care from state to state, and the resulting confusion and fear such a situation might cause influenced many to call for national mammography standards monitored by a central body.

Federal Regulations. Oversight of mammography prior to MQSA involved FDA, the Centers for Disease Control and Prevention (CDC), and the Health Care Financing Administration (HCFA) through the Medicare program. FDA was responsible only for regulating the proper manufacture and installation of mammography equipment by monitoring equipment alignment and radiation leakage. FDA did not monitor its use.

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[1]Physician Insurers Association of America, *PIAA Breast Cancer Study*, June 1995.

[2]Ibid.

CDC's breast and cervical cancer screening program was authorized by legislation passed in 1990 (P.L. 101-354). The program provides grants to states to establish screening programs for low income women. CDC assisted the states in establishing screening programs and meeting CDC quality control guidelines, but CDC had no authority to ensure compliance. In 1992, when MQSA was being drafted, CDC's program was providing grants to 10 states, and CDC expected to expand the program to five more in FY1993; therefore, the scope of CDC's quality control guidelines was limited.

The Catastrophic Health Care Coverage Act of 1988 (P.L. 100-360) required that Medicare cover the costs of screening mammography. The Secretary of Health and Human Services (HHS) was directed to establish standards assuring the safety and accuracy of Medicare-funded screening mammography. On September 1, 1989, HHS published proposed regulations. The benefit never took effect and the proposed regulations were withdrawn because P.L. 100-360 was repealed in November 1989 (P.L. 101-234). Medicare coverage of screening mammography began on January 1, 1991, following passage of the Omnibus Budget Reconcilation Act of 1990. Medicare had a somewhat limited quality standards program that was described in an interim final rule issued on December 31, 1990. The standards were similar to those proposed previously under the Catastrophic Health Care Coverage Act.

Concerns Over Mammography Regulation. Prior to MQSA, congressional hearings and reports documented a wide range of problems with the country's mammography system including poor quality equipment, the lack of quality assurance procedures, poorly trained technologists and physicians, false representation of accreditation, and the lack of inspections or government oversight. The burden for obtaining a high quality mammogram fell on each woman. She needed to find out if the facility was accredited by ACR, certified under the Medicare program, or regularly inspected by the state, and then verify that the information supplied by the facility was accurate. This was often a difficult task: one TV news show (Prime Time Live) found that half the facilities their reporters visited falsely claimed to be accredited.

House and Senate committee reports on MQSA legislation (H.Rept. 102-889 and S.Rept. 102-448) mentioned a number of other concerns over mammography quality standards under the Medicare program. Medicare standards did not apply to all facilities providing mammography, but only to facilities seeking reimbursement for mammography screening of women eligible for Medicare. Facilities that did not meet Medicare's quality standards lost reimbursement, but were not required to stop performing mammography. Therefore, although screening was recommended for millions of women under the age of 65, they were not protected by federal quality standards under Medicare.

Initially site inspections were not performed and Medicare certification required only that facilities submit a statement indicating that they met the Medicare standards; inspections by HCFA were required after September 6, 1992. However, Congress was concerned that the inspections were being performed by individuals with insufficient knowledge or experience in mammography. The Medicare program did not require an evaluation of the images obtained by the facilities, and therefore there was no assurance that the X-ray technician was using proper positioning of the patient or proper compression of the breast tissue. In addition the Senate report stated that HCFA lacked sufficient personnel trained in radiology or radiological physics to properly administer its mammography quality standards program as well as oversee inspection of facilities.

Mammography Quality Standards Act

The Mammography Quality Standards Act (MQSA) became law on October 27, 1992 (P.L. 102-539). The law required that the Department of Health and Human Services (DHHS) develop standards for equipment and personnel in mammography facilities and certify the facilities by October 1, 1994 (except for mammography facilities operated by the Department of Veterans Affairs, which are governed by another law that mandates a similar certification program). Enforcement of the standards is achieved through accreditation, certification, and annual inspection. All mammography facilities must be accredited by an accrediting body (approved by DHHS) before the facility can gain certification from the government. FDA was assigned primary responsibility for implementing MQSA by the Secretary of DHHS on June 2, 1993. Costs to FDA related to annual inspections of mammography facilities are covered by user fees collected from the facilities. Other MQSA activities are funded by appropriation (see table on next page).

On December 14, 1993, the President signed legislation (H.R. 2202, P.L. 103-183) amending MQSA and allowing DHHS/FDA to issue temporary, but immediately enforceable, interim regulations. The interim MQSA regulations were published in the *Federal Register* on December 21, 1993 and became effective on February 22, 1994. The interim rule allowed FDA to establish legally binding initial accreditation and quality standards based on standards used by Medicare, ACR, and some states. The interim standards were used to accredit and certify facilities by the October 1, 1994 deadline while FDA developed final standards. The proposed final rule was published on April 3, 1996; FDA received approximately 1,900 comments. Final regulations were published and became effective on October 28, 1997. The final regulations expanded and strengthened the standards for personnel, equipment, quality assurance, quality control, patient notification of results, and performance of accreditation bodies.

The General Accounting Office (GAO) has issued three reports on MQSA. The first report looked at MQSA's initial impact on access to and quality of mammography services.[3] GAO found that MQSA had a positive impact on mammography services by requiring the use of higher quality equipment, better trained personnel and improved practices. Access to mammography services was not limited by MQSA standards; FDA's gradual approach to implementing the new standards encouraged providers to upgrade their operations rather than drop their mammography services. The second report focused on FDA's annual inspection program.[4] GAO found that FDA's inspection program had a positive effect on the more than 9,000 mammography facilities in the United States. First-year inspections found that 80% of the facilities had either no violations or minor ones and only 2% had violations serious enough to warrant a warning letter from FDA. Second-year inspections found a considerable reduction in the proportion of facilities cited for violations. Moreover, the serious violations identified in the first-year inspections had not recurred at any of the facilities where they were initially found.

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[3]General Accounting Office, *Mammography Services: Initial Impact of New Federal Law Has Been Positive*, GAO/HEHS-96-17, 27 October 1995.

[4]General Accounting Office, *FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance is Growing*, GAO/HEHS-97-25, 27 January 1997.

Table 1: FDA MQSA Program Budget

	FY1998	FY1999
Appropriation	$10,000,000	$10,000,000
User Fees	13,965,000	14,385,000
Total	**$23,965,000**	**$24,385,000**

Source: FDA Budget Office.

The third GAO report assessed MQSA's effect on: (1) women's access to mammography services; (2) the quality of mammography services; and (3) health outcome and lives saved due to the early detection of breast cancer.[5] The report again found that MQSA has not had a negative impact on women's access to mammography services and has improved the quality of X-ray images. Improving the quality of mammography images should result in more accurate interpretation by radiologists, leading to lives saved through better early detection of breast cancer. However, GAO was unable to determine if MQSA has improved the accuracy and reliability of mammography interpretation. Several academic studies have shown a wide variation in the interpretation of the same mammogram by different radiologists. There are no data from FDA to verify that the MQSA program has improved early detection of breast cancer and saved lives, nor are there research methodologies in place to confirm this in the near future. According to GAO, "FDA has established federal qualification requirements for physicians who interpret mammograms but has not established criteria for measuring interpretation accuracy. Furthermore, comparable pre- and post-MQSA clinical data for measuring mammography performance and cancer outcome either do not exist or, for a number of reasons, are too limited to be useful."[6]

Congressional Action

S. 537, the Mammography Quality Standards Reauthorization Act, was passed by the Senate on November 9, 1997. On May 8, 1998, the Health and Environment Subcommittee of the House Committee on Commerce held a hearing on the "Reauthorization of the Mammography Quality Standards Act." H.R. 4382 was introduced in the House on August 3, 1998, and referred to the Committee on Commerce. On August 5, 1998, a committee mark-up session was held and the bill was ordered to be reported. On September 14, 1998, H.Rept. 105-713 was filed. H.R. 4382 passed the House on September 15, 1998, passed the Senate on September 25, 1998, and was signed into law by the President on October 9, 1998 (P.L. 105-248). H.R. 4382 is essentially consistent with S. 537 except for two added provisions: (1) a section that requires direct reports of mammography results to patients; and, (2) a section that allows for a demonstration project to determine if inspections of high-performing mammography facilities could occur less frequently than the current annual basis.

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[5]General Accounting Office, *Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcome*, GAO/HEHS-98-11, 21 October 1997.

[6]Ibid.