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The Impact of the Mammography Quality Standards Act on the Availability of Mammography Facilities

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Background. **The Mammography Quality Standards Act (MQSA) became effective October 1, 1994, and requires all mammography facilities to meet quality standards as promulgated by the Food and Drug Administration (FDA). The FDA undertook an assessment of the MQSA federal certification requirements on the availability of mammography facilities.**

Methods. **A survey of states on mammography facility closures between October 1, 1993, and October 1, 1994, was conducted. MapInfo software was used to link zip codes to demographic databases. The characteristics of closed facilities were compared to certified facilities as of December 15, 1994.**

Results. **A total of 369 facilities (3.5%) had closed. This closure rate was comparable to previous years' rates (2.5–10%). As of December 15, 1994, 10,142 certified facilities were operating. Relative to their distribution in the United States, closures in rural areas were proportional, but there were more facility closures in the minority areas and in poverty areas. However, the relative distributions of facilities to these areas' populations were unchanged.**

Conclusions. **Impact on facility availability has been minimal.**

Key Words: **mammography; regulations; access; breast cancer; early detection.**

INTRODUCTION

The Mammography Quality Standards Act (MQSA) of 1992 is landmark public health legislation that ensures that the best available method of breast cancer early detection meets national standards for quality. MQSA requires all facilities providing screening or diagnostic mammography to be certified by the Food and Drug Administration (FDA) as having met quality standards. On October 1, 1994, all facilities in the United States, with the exception of those under the authority of the Veterans Health Administration, must have been certified under MQSA to legally perform mammography. This deadline was widely anticipated as the start of a new era in high-quality early detection of breast cancer [*1*]. However, concern was expressed about the possibility of decreased access to this important screening tool, especially in rural, minority, and poverty areas, if facilities did not qualify for certification [*2*]. This paper will present an overview of the impact of this new regulation on access to U.S. mammography services.

"Access," from a health services perspective, is a complicated concept involving multiple parameters [*3–6*]. One approach describes access as a continuum of coverage categorized by proportions of the population (1) for whom the service is available (availability), (2) who can use the service (accessibility), (3) who are willing to use the service (acceptability), (4) who actually use the service (contact), and (5) who receive effective care (effectiveness) [*7*]. This paper will examine the impact of MQSA on one aspect of the access spectrum, the availability of mammography services.

The MQSA states, "No facility may conduct an examination or procedure . . . involving [screening or diagnostic] mammography after October 1, 1994, unless the facility obtains a certificate . . . ." [*8*]. Interim regulations effective February 20, 1994, require facilities to meet quality standards in personnel, equipment, dose, quality assurance programs, and medical record keeping and reporting [*9*]. In order to maintain certification, a facility must pass annual inspections and maintain its accredited status with an FDA-approved accreditation body (so far the American College of Radiology (ACR) and the states of Arkansas, California, and Iowa).

For new facilities, the Act allows the issuance of a provisional 6-month certificate that enables a facility to provide mammography services while undergoing

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accreditation. Selected mammogram films will then be submitted to the accreditation body for image quality evaluation, called clinical image review. Without such a certificate, it would be unlawful to perform mammography and impossible to complete the accreditation process' clinical image review. A 90-day extension of provisional certification to complete accreditation in areas with access limitations is permissible under the law. A facility that fails accreditation can obtain a provisional reinstatement certificate provided it can correct the problems that led to the denial. The facility then has 6 months to complete and pass accreditation.

Within the breast cancer literature, numerous studies have documented that rural status, being a racial minority, and low socioeconomic status are predictors of women who underutilize mammography services [*10–12*]. Concern that regulatory requirements would reduce access to mammography services, because some facilities would elect to cease operations and would or could not meet quality standards, has prompted the FDA to conduct this early investigation into facility closures, especially in rural, minority, and poverty areas. The study is based on preliminary data of facility closures from October 1, 1993, to October 1, 1994.

METHODS

State radiation control offices inspect and maintain records of users of X-ray-emitting medical devices. The FDA requested that these offices gather information on mammography facilities that had ceased operations by November 1994. Each reply was classified according to the reasons for closure (MQSA, reasons other than MQSA, or unknown reasons). Facilities closed on October 1, 1994, but not supplying a reason were assumed to have closed due to MQSA. Facility identification, reason for closure, and zip code were entered into a database. Geographic coordinates were assigned to facilities using MapInfo software [*13*], which matches facility zip code with longitude and latitude coordinates based on the center of the zip code areas. Facilities were assumed to be located at the center of the zip code regions listed in their address. MapInfo zip codes were linked with county codes, which were matched to the February 1995 Area Resource File (ARF) of the Health Resources and Services Administration [*14*]. County-level data (e.g., population, racial distribution, and poverty status) were obtained from ARF. Because Puerto Rico is not in the ARF, data on this territory were not utilized in analyses. U.S. facilities at other overseas locations, such as military bases, were excluded from the analyses.

A certified, operating facilities listing, based on the number of facilities in the FDA's certification database (which has records of all certified, provisional, reinstated, and extended facilities) as of December 15, 1994, was used in conjunction with facility closure survey data [*15*]. December 15, 1994, was chosen because it represents the time, 2 months past the October 1, 1994, certification deadline, when facility certification approximated steady state.

The U.S. Department of Agriculture's Rural/Urban Continuum Code is based on the Office of Management and Budget's system of defining counties [*16,17*]. In the continuum, counties are described as metropolitan or nonmetropolitan based on population and adjacency to a metropolitan statistical area (MSA). We defined "urban" as large metropolitan central counties (central counties of metropolitan areas of 1,000,000 population or more) to lesser metropolitan counties (counties in metropolitan areas of fewer than 250,000 population). "Rural" is defined as nonmetropolitan counties, ranging from urbanized—adjacent to MSA (urban populations of 20,000 or more, adjacent to a metropolitan area)—to thinly populated—not adjacent to MSA (completely rural or fewer than 2,500 urban population, not adjacent to a metropolitan area).

Using the ARF, we defined "minority" areas as the 20% of counties with highest percentage of nonwhite population and "nonminority" areas as the remaining 80% of counties. "Poverty" areas were defined as the 20% of counties with highest poverty rates and "nonpoverty" areas as the remaining 80%.

Univariate analyses were conducted using Lotus 1-2-3 [*18*]. The χ^2 test was used to assess the significance of facility closures relative to rural, minority, and poverty populations. Baseline facility turnover rates were estimated using data from the 1992 National Cancer Institute's National Survey of Mammography Facilities (NCI NSMF) data, a study using a 10% random sample of mammography facilities nationwide, and the 1992 FDA Nationwide Evaluation of X-ray Trends (NEXT) data, a study of 356 randomly selected mammography facilities stratified by state.

Pre-MQSA facilities were calculated using the sum of facilities listed in the FDA certification database as of December 15, 1994, plus closed facilities from state reports. Post-MQSA facilities were defined as those facilities listed in the FDA certification database as of December 15, 1994. Facilities not included in the analyses were those that (1) closed prior to October 1, 1993, (2) were erroneously categorized as certified, or (3) performed X-ray-guided localization and biopsy procedures only.

RESULTS

Forty-five states submitted data on closed facilities. Alaska, Colorado, the District of Columbia, Delaware, Montana, and Oklahoma did not reply. The responding jurisdictions represent 96.3% of all mammography facilities (9,986). On December 15, 1994, there were

TABLE 1

Characteristics of Closed and Certified Mammography Facilities as of October 1, 1994

Facilities	Reason for Closure (10/1/93–10/1/94)			All closures	Certified
	MQSA	Other	Unknown		
Urban	92 (69%)	46 (85%)	151 (83%)	289 (78%)	7,919 (77%)[a]
Rural	41 (31%)	8 (15%)	31 (17%)	80 (22%)	2,322 (23%)[a]
Minority	43 (32%)	19 (35%)	95 (52%)	157 (43%)	3,413 (33%)
Nonminority	90 (68%)	35 (65%)	87 (48%)	212 (57%)	6,857 (67%)
Poverty	18 (14%)	1 (2%)	21 (12%)	40 (11%)	814 (8%)
Nonpoverty	115 (86%)	53 (98%)	161 (88%)	329 (89%)	9,456 (92%)
All	133	54	182	369	10,270

[a] Values of urban/rural certified facilities do not add up to 10,270 because of missing values in the rural–urban continuum codes for metro and nonmetro counties.

10,142 certified facilities. The estimated number of facilities prior to MQSA was 10,511 (10,142 operating facilities plus 369 closed facilities).

A total of 369 of 10,511 facilities (3.5%) were identified as closed in October 1994. Reasons provided were 36% (133) closed due to MQSA, 15% (54) closed due to other reasons (financial—10, low patient volume—9, equipment—13, personnel—5, state requirements—4, other—13), and 49% (182) closed for unknown reasons and no follow-up was possible.

Table 1 shows characteristics of closed and certified operating facilities as of December 15, 1994. Seventy-seven percent of all facilities were located in urban areas, and of facilities that closed, 78% (289) were in urban areas. Total rural area closings were few (80 facilities); relative access to facilities for the rural populations was not appreciably changed. About 43% of closed facilities were located in minority areas, compared with 33% of all certified facilities ($P = 0.0002$). Nearly 36% of the population resided in the top 20% of nonwhite counties and 64% lived in the remaining 80% of counties. The two populations were serviced by mammography facilities in nearly the same proportions as the population (33 and 67% of certified facilities were located in minority and nonminority areas, respectively).

Approximately 11% (40/369) of closed facilities were located in poverty areas. Nearly 8% (814) of all certified mammography facilities were located in poverty areas ($P = 0.04$). Roughly 9% of the population resided in poverty areas while 91% of the population resided in nonpoverty areas. Because the absolute number of closings in poverty areas was small (40 facilities), there was no change in relative access to mammography facilities by population in these areas after MQSA.

Table 2 shows that 97% of closed facilities were within 25 miles of a certified facility. Facilities that closed in rural counties (80, 22%) were more likely to be 10 or more miles from a certified facility than closed urban facilities. Only 10 of the 369 closed facilities were located 25 miles or farther from a certified facility.

Using 1992 NCI NSMF data, the baseline turnover rate of facilities for that year was estimated. About 3% of facilities surveyed had gone out of business and 7% had ceased performing mammography or "had never performed mammography" although they had been identified as a mammography facility. The 1992 FDA NEXT data revealed 2.5–4.5% of facilities had ceased mammography operations. An 1985 NEXT survey revealed 7% of facilities "no longer in business" at the time of the survey [*19*]. These data suggest that the 3.5% facility closure rate surrounding the October 1994 certification deadline was not significantly different from previous years' rates.

DISCUSSION

On October 1, 1994, the United States did not see a significant change in the number of facilities providing mammography services due to the implementation of MQSA. Of the nation's pre-MQSA mammography facilities, 96.5% remained operational and were granted full or provisional certification by the effective date of the law. Of the remaining 3.5% of facilities that closed, 36–85% of these closures were due to MQSA. (This range is presented because "unknown reason" for closure accounted for the majority of closings.) This closure rate is comparable to the market turnover as estimated in previous years (2.5–10%), thus, MQSA's contribution to this rate seems minimal. There were more closures

TABLE 2

Distance in Miles from Closed Mammography Facility to Nearest Certified Facility as of October 1, 1994

Closed facility location	<1 mile	1–9 miles	10–24 miles	>25 miles
Urban ($n = 289$)	189 (65%)	94 (33%)	6 (2%)	0
Rural ($n = 80$)	29 (36%)	5 (6%)	36 (45%)	10 (13%)
All closed facilities ($n = 369$)	218 (59%)	99 (27%)	42 (11%)	10 (3%)

in minority and poverty areas, relative to their proportions in the United States; however, because the absolute number of closings was small, there was no change in the relative access to facilities for populations in these areas. Roughly 97% of closures were within 25 miles of a certified operating facility.

A major limitation of this study is the assessment capability of a macrolevel analysis. While the national impact has been minimal, particular areas of the country may have encountered availability problems. However, any decrease in availability must be weighed relative to improvements in quality and preventing access to poor quality mammography services. In addition, five states and the District of Columbia did not participate in this study; however, these areas have not reported any unusual impact of MQSA to FDA. Finally, no data are available to characterize the volume of patients seen nor the quality of mammography at the closed sites, especially in minority and poverty areas. However, using NCI NSMF data from 1992, there was no difference in the distribution of facilities with respect to patient volume between minority and nonminority areas and between poverty and nonpoverty areas. Using ACR voluntary accreditation by 1992 as an indicator of quality, the likelihood of accreditation was lower in poverty areas than in nonpoverty areas (25% of facilities were ACR voluntary accredited in 1992 in poverty areas, compared with 49% of facilities in nonpoverty areas); there was no difference in proportions of facilities accredited in minority and nonminority areas. If these characteristics were constant in 1994, MQSA's effect may have been to force poorer quality facilities out of service, particularly in poverty areas.

Moreover, a preliminary study by the General Accounting Office concludes, "Early indications are that the Act has had a positive effect on the quality of mammography services . . . Before the Act, States varied widely in the standards they imposed, and only a few States had standards comparable to those established under MQSA" [*19*].

In areas where mammography facilities have closed, there is usually an FDA-certified facility nearby. Ninety-seven percent of closed facilities are within 25 miles of a certified facility. However, since reported distances between facilities are distances between zip code centers, mileage calculations are estimations of distance, not actual distance. While straight-line distance (measured distance between two points on a map) is a commonly used geographic methodology, it does not factor in terrain, road systems, or public transportation routes. Patient insurance status also affects travel distance. Health maintenance organizations require patients to see specific service providers that may not be the nearest available provider. Finally, the patient's preferred facility for usual source of care may not be the closest facility [*20–22*].

The vast majority of facilities have elected to participate in the accreditation and certification process, demonstrating a commitment to achieving or maintaining a high level of quality mammography according to national performance criteria. The FDA, in turn, has been committed to providing a framework of reasonable, attainable goals within which facilities have been able to elevate the quality of mammographic imaging without interruption of services or undue financial hardship. For example, the FDA granted initial certification to those 46% of mammography facilities that had achieved and maintained active status under ACR's voluntary accreditation program. Facilities that applied for accreditation, but had not completed the process by October 1, 1994 (about 47% of the 10,030 facilities in operation), were given 6-month provisional certificates to allow them an opportunity to demonstrate quality performance. The FDA's inspection policy has been geared to providing and monitoring criteria that will bring facilities into compliance with national standards as opposed to terminating operations. As part of an extensive outreach program, the FDA, the states, and the accreditation bodies have dedicated significant resources to mailings detailing accreditation and certification processes. The careful adoption of appropriate public policies and regulations in program implementation can preserve access to mammography.

The goal of MQSA is to improve the quality of mammography services. Facilities closing because of MQSA may have done so to avoid the cost of compliance with regulations. However, a level of attrition is not unexpected when national standards of quality assurance are mandated and suboptimal or noncompliant facilities are eliminated from the health care system [*23*, *24*]. Thus, availability of services must be counterbalanced with cost of higher image quality. The FDA will examine the distribution of facilities after the end of the 6-month provisional period and the 90-day extension for provisional facilities, June 29, 1995, and correlate availability to mammography utilization. The FDA will also study the impact of MQSA on quality indicators, such as phantom image scores, dose, and, ultimately, medical outcomes data as the program is implemented. The FDA will continue policies to promote high-quality mammography with efforts to encourage access to services for all women.

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