Impact of the Mammography Quality Standards Act on Access in Minnesota

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SYNOPSIS

Objectives. The Minnesota Department of Health surveyed registered mammography facilities to assess their accreditation status prior to full implementation of the Federal Mammography Quality Standards Act (MQSA), which mandated accreditation of all mammography facilities by October 1994; to strategize on the steps that might be taken to avoid closure of facilities; and to evaluate the ultimate impact of the law on the availability of mammography in Minnesota.

Methods. Mammography facilities registered with the Radiation Control Section of the state health department were surveyed five months prior to and four months after the October 1994 deadline. Data collected included accreditation status, plans for continuing service, number of mammograms performed, and areas in which technical assistance was needed. In October 1995, the number and distribution of facilities were determined from the Radiation Control Section registration database.

Results. The pre-MQSA survey of 182 respondents found that 96% planned to continue mammography services but only 49% were accredited. The remaining 51% had applications in progress. In the post-MQSA survey, 70% of 182 facilities were found to be accredited, and 30% were operating under provisional certification. As of October 1995, although six facilities had closed, there was a net gain of four mammography facilities providing on-site service.

Conclusions. Despite fears to the contrary, access to mammography in the state of Minnesota was not adversely affected by full implementation of the Mammography Quality Standards Act.

Over the last two decades, mammography has become widely accepted as the most sensitive method to screen for early stage breast cancer. Randomized controlled trials conducted in the United States and Europe have demonstrated that the use of screening mammography every one to two years for women ages 50 to 69 reduces breast cancer mortality by up to 35%.[1] This level of benefit, however, depends on mammography of high technical quality.[2] In fact, the failure of the Canadian National Breast Screening Study to demonstrate a significant reduction in mortality among women ages 40 to 49 has been attributed, at least in part, to the fact that the quality of mammography in the early

part of the study failed to meet modern standards.[3]

In the 1980s, tremendous growth in the number of facilities performing mammography in the United States was accompanied by substantial variability in the quality of the services provided.[2] Some states enacted legislation to address mammography quality, although these efforts were by no means universal.[4] A uniform set of quality standards for all mammography facilities in the nation was established for the first time with passage of the Mammography Quality Standards Act (MQSA) by Congress in 1992.

All facilities were mandated under MQSA to obtain certification by the Food and Drug Administration (FDA) by October 1, 1994, which included accreditation by an FDA-approved accrediting body.[5] The states of California, Arkansas, and Iowa received FDA approval to accredit facilities within their states. The American College of Radiology (ACR), which had had a voluntary mammography accreditation program in place since 1987, became the first and only national accreditation body approved by FDA.

Accreditation Process

Mammography accreditation through the ACR entailed a number of steps including (*a*) completion of a site survey questionnaire; (*b*) assessment of phantom images; (*c*) measurement of average glandular dose; (*d*) clinical image evaluation; and (*e*) assessment of film processing. At the time MQSA was enacted, it was not uncommon for facilities throughout the country to fail at one or more of these steps, requiring remediation of deficiencies and resubmission of materials to ACR for review. Most facilities eventually obtained accreditation.[6] The long turnaround time required by ACR for the step involving peer review of clinical images and the time involved in resubmitting materials often resulted in accreditation taking many months to complete.

Mammography in Minnesota

In 1993, fewer than half of Minnesota's mammography facilities were accredited by the ACR, according to unpublished ACR data, but information on the number of facilities with applications in progress or on where they stood in the application process was not readily available. As full implementation of MQSA approached, concern grew at the Minnesota Department of Health (MDH) that a large number of facilities were at potential risk for temporary or permanent closure for failure to complete accreditation by the October 1994 deadline.

Anecdotal reports of facilities in Minnesota taking more than a year to gain accreditation raised additional concerns about the quality of the mammograms at such facilities. Access to mammography in rural areas was felt to be particularly vulnerable; 36% of Minnesota's rural mammography sites were serviced by a small number of mobile providers, most of which were not yet ACR-accredited. Cessation of service by even one of these mobile providers would severely reduce access in rural communities. Consequently, MDH conducted a study to (*a*) assess facilities' status with regard to ACR accreditation, (*b*) determine what steps might be taken to avert facility closure, and (*c*) evaluate the impact of MQSA on the availability of mammography in Minnesota.

Methods

In Minnesota, all facilities that provide mammography services within the state, including those based in neighboring states, must register with the Radiation Control Section of the MDH.[7] Registered facilities fall into three categories: (*a*) those that own stationary mammography equipment and offer mammography on-site, (*b*) those that are mobile service providers with mobile mammography equipment and provide mammography at hospitals and clinics without mammography equipment, and (*c*) those hospitals and clinics without mammography equipment that are served by mobile units. Our data are limited to facilities with stationary equipment and those providing mobile mammography service, that is, those required under MQSA to obtain certification.

Data collection. A brief pre-MQSA survey was mailed to the chief radiologic technologist at each facility registered with the Radiation Control Section in May 1994. The survey contained items regarding ACR accreditation status, plans for continuing to offer mammography after October 1, 1994 (when MQSA was to be fully implemented), qualifications of the technologists performing mammography, and the number of mammograms performed per year by the facility. In addition, data were collected about areas specifically related to accreditation in which technical assistance might be needed. A follow-up post-MQSA survey containing similar questions was sent to the same facilities in January 1995. An updated list of all registered facilities was obtained from the Radiation Control Section at MDH in October 1995.

Results

Response to the pre-MQSA survey is summarized in the Table. Of the 185 facilities surveyed in May 1994, 182 (98%) responded. Almost all (96%) of the facilities planned to continue providing mammography. Two (1.1%) facilities indicated plans to discontinue mammography services, five (2.7%) were not sure, and for one there was no response to this questionnaire item. A total of 90 facilities (49%) were fully accredited by ACR. Among those not accredited (n=92), 76 (83%) had initiated the accreditation process. Of those with applications in progress, 49 (64%) had submitted applications within the preceding six months, and eight (10%) had begun the process more than one year prior to the survey. The majority of the 92 non-accredited facilities requested technical assistance from MDH in one or more areas—clarification of credential requirements (63%), film processing (52%), quality control procedures (58%), and

Table. American College of Radiology accreditation status of radiology facilities in Minnesota before enactment of the Mammography Quality Standards Act (May 1994) and after enactment of the Act (January 1995)

Status	Before enactment of MQSA		After enactment of MQSA	
	Number	Percent	Number	Percent
Total facilities surveyed	185	100	182	100
Surveys returned	182	98	182	100
Facilities closed	...	...	4	2
Facilities active	...	...	178	98
Accredited				
Yes	90	49	125	70
No	92	51	53	30
Applied for accreditation	76	83	...	...
Images submitted				
Yes	36	47	46	87
No	40	53	7	13

assistance in evaluating the quality of phantom images (56%). Seventy-five percent requested review and critique of their clinical images prior to submission.

The post-MQSA survey results are also shown in the Table. In January 1995, 178 (98%) of the facilities that participated in the first survey were still providing service. Of these, 125 (70%) were fully accredited, for an absolute increase of 21%. The remaining 53 (30%) were not fully ACR-accredited but were operating under provisional certification from FDA, which functionally extended the deadline and allowed them to continue operating while completing accreditation. Many of the provisionally certified facilities still had substantial requirements to fulfill to become fully accredited, and 41% were resubmitting images for clinical review after failing on their first attempt.

In October 1995, one year after full implementation of MQSA, there were 189 stationary and mobile mammography facilities registered in Minnesota. A total of six facilities, including two that did not respond to the pre-MQSA survey, closed between May 1994 and January 1995. Together, these facilities performed 0.4% of the total number of mammograms reported in 1994. No appreciable change in the distribution of facilities around the state was noted, with the exception of one rural county that lost its only facility (see Figure). That facility had reported performing 200 to 300 mammograms per year prior to closure.

Discussion

Prior to enactment of MQSA, regulation of mammography was highly variable around the country. Although a few states had quality assurance standards similar to those mandated by MQSA, others had none.[4] Minnesota's 1991 Rules of Ionizing Radiation contained requirements in most, but not all, of the areas identified by a national group of experts as essential to a mammography quality assurance program.[8] These rules included many quality assurance requirements addressing the quality of clinical images. Annual inspections had been in place since 1988, coordinated with an annual cancer screening program sponsored by the American Cancer Society.

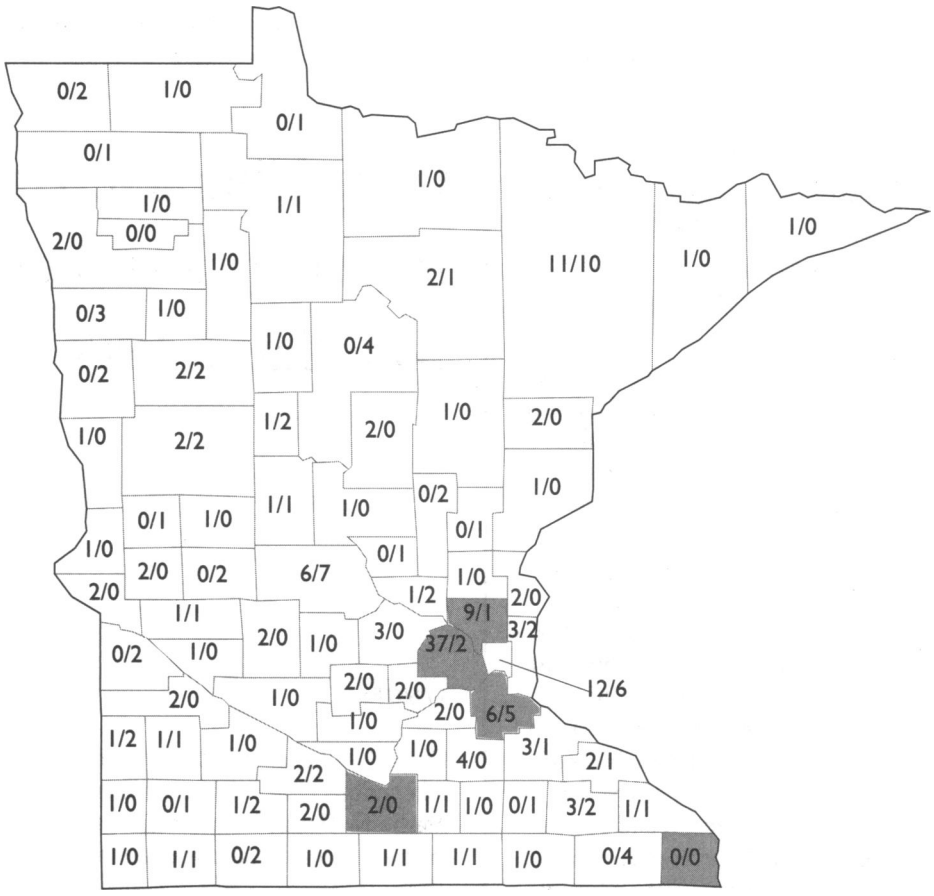
In 1992 MDH began actively promoting voluntary accreditation of mammography facilities by ACR through the Minnesota Breast and Cervical Cancer Control Program (MBCCCP), a program funded through a cooperative agreement with the Centers for Disease Control and Prevention (CDC). CDC required ACR accreditation from participating facilities. Because facilities' participation in MBCCCP was voluntary, however, and the number of patients served under MBCCCP at any given facility was low, there was little incentive for facilities to become accredited. Some smaller facilities cited the cost of accreditation as a barrier. The lengthy review process and requests for additional documentation or materials by ACR added to local frustration with the accreditation process.

Through informal contacts with facilities through the MBCCCP, it became apparent that many facilities were unclear about ACR's expectations for accreditation and the MQSA requirements. This was confirmed in the pre-MQSA survey—many facilities requested technical assistance in areas related to MQSA and accreditation. MDH took a proactive role in providing that assistance in the hope that it would ease or speed the process, or both, for those going through the accreditation process for the first time. Five one-day workshops were developed and conducted around the state in conjunction with the Minnesota Society of Radiologic Technologists to provide technologists with more in-depth understanding of accreditation and certification requirements as well as one-on-one assistance with clinical images and positioning. On the post-MQSA survey, far fewer facilities raised questions and concerns related to MQSA, suggesting that efforts at both the state and Federal level to clarify the requirements of the new law had succeeded.

Nationally, 47% of facilities failed to complete accreditation by the original deadline of October 1, 1994.[9] The experience in Minnesota was not dissimilar. Although there was

an absolute increase of 21% in the number of Minnesota facilities fully accredited between May 1994 and January 1995, 30% of the state's facilities were not fully accredited and certified by January 1995. Many had initiated applications to ACR within months of the MQSA deadline. Some were slow to resubmit materials after failing a step, and others simply postponed resubmission until equipment was upgraded. Had FDA not granted provisional certification to the majority of facilities with accreditation in process, the initial impact of MQSA on access to mammography in Minnesota would have been far more consequential.

Only six facilities in Minnesota closed. Three of the four urban facilities that closed had been performing mammograms of marginal quality, according to Radiation Control Section inspectors. Although two rural facilities closed, all mobile mammography providers continued to operate. Thus, access in rural areas remained, for the most part, unaffected. During the same time period, some new facilities opened. One year after full implementation of MQSA, there was a net gain in the number of facilities registered with the state.



Distribution of mammography facilities registered with the Radiation Control Section, Minnesota Department of Health, in October 1995. For each county, the number of facilities owning mammography equipment and providing on-site services is followed by the number of facilities served by mobile units. The shaded counties are those in which facilities closed between May 1994 and January 1995.

By holding mammography facilities in Minnesota to higher standards, MQSA undoubtedly raised the overall quality of mammography without negatively affecting access. These changes should enhance our capability to detect early stage cancers and to achieve further reductions in morbidity and mortality associated with breast cancer.

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