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MAMMOGRAPHY QUALITY STANDARDS ACT

X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown

Statement of Marsha Lillie-Blanton, Associate Director
Health Services Quality and Public Health Issues
Health, Education, and Human Services Division

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Mammography Quality Standards Act: X-ray Quality Improved, Access Unaffected, but Impact on Health Outcomes Unknown

Mr. Chairman and Members of the Committee:

I am pleased to be here today to discuss the findings of our work over the last several years examining the impact of the Mammography Quality Standards Act (MQSA). Quality mammography services are a key tool in the early detection of breast cancer, significantly increasing the possibility of survival for the estimated 180,000 women who are diagnosed with this devastating disease each year. MQSA was enacted in 1992 in response to the growing incidence of breast cancer and its associated mortality rates. MQSA established minimum national quality standards for the nation's approximately 10,000 mammography facilities, as well as an accreditation and inspection program to help ensure that these standards are met.

The act directed us to study the impact of MQSA's standards on (1) the quality of mammography services, (2) early detection of breast cancer, and (3) women's access to mammography services. Today, I will focus on our findings on these issues, which are drawn from our final report issued last October.[1]

In summary, we found that the overall impact of MQSA on mammography services has been positive, in that it has increased mammography facilities' adherence to accepted quality assurance standards and improved the quality of X-ray images. The impact on early detection of breast cancer is less clear. Improving the quality of mammography images should lead to more accurate interpretation by physicians and, therefore, to improved early detection of breast cancer. However, neither data nor research methodologies are now in place to clearly establish these links. Progress is being made to remedy these problems so that improvements in cancer outcomes can be measured. Regarding concerns that the additional burden of MQSA quality assurance standards could result in facilities deciding to close rather than to upgrade, we found no indication that MQSA has caused access problems.

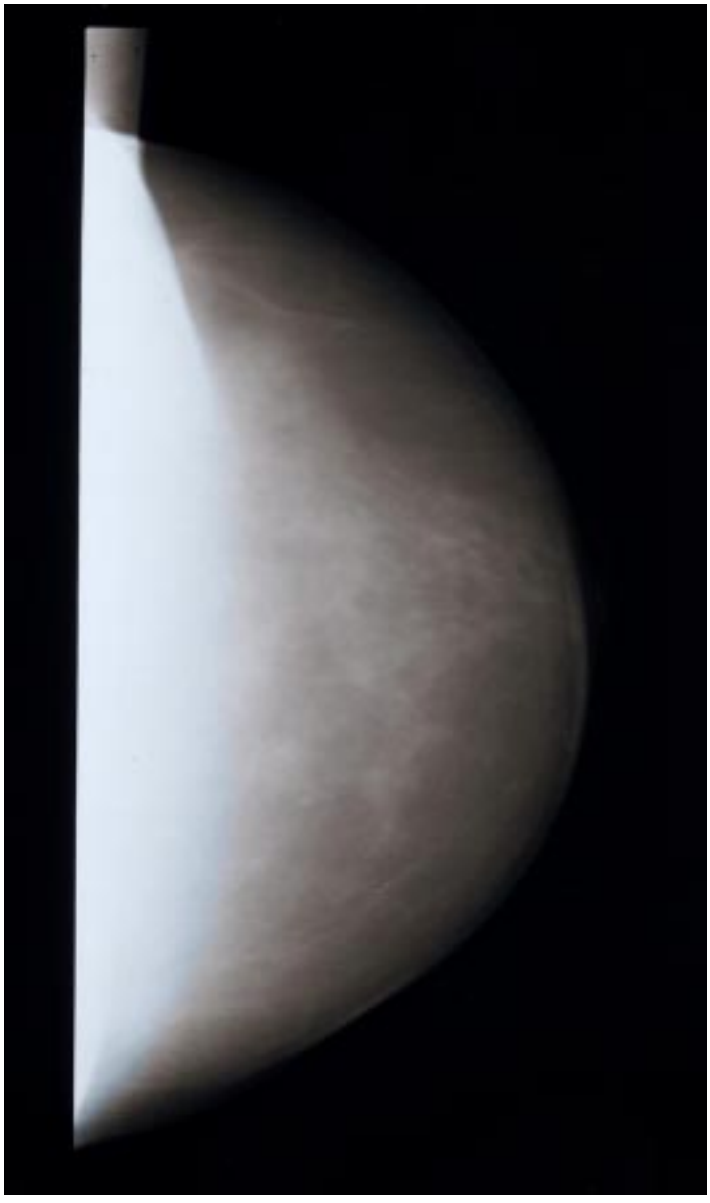
Background

According to the Centers for Disease Control and Prevention, in 1995, almost 60 percent of women over the age of 50 reported having received a mammogram in the past year. The value of mammography in reducing mortality is directly tied to its ability to detect cancer at its earliest stages. Mammography is capable of detecting tumors much smaller than those detected by other means. However, it is one of the most technically

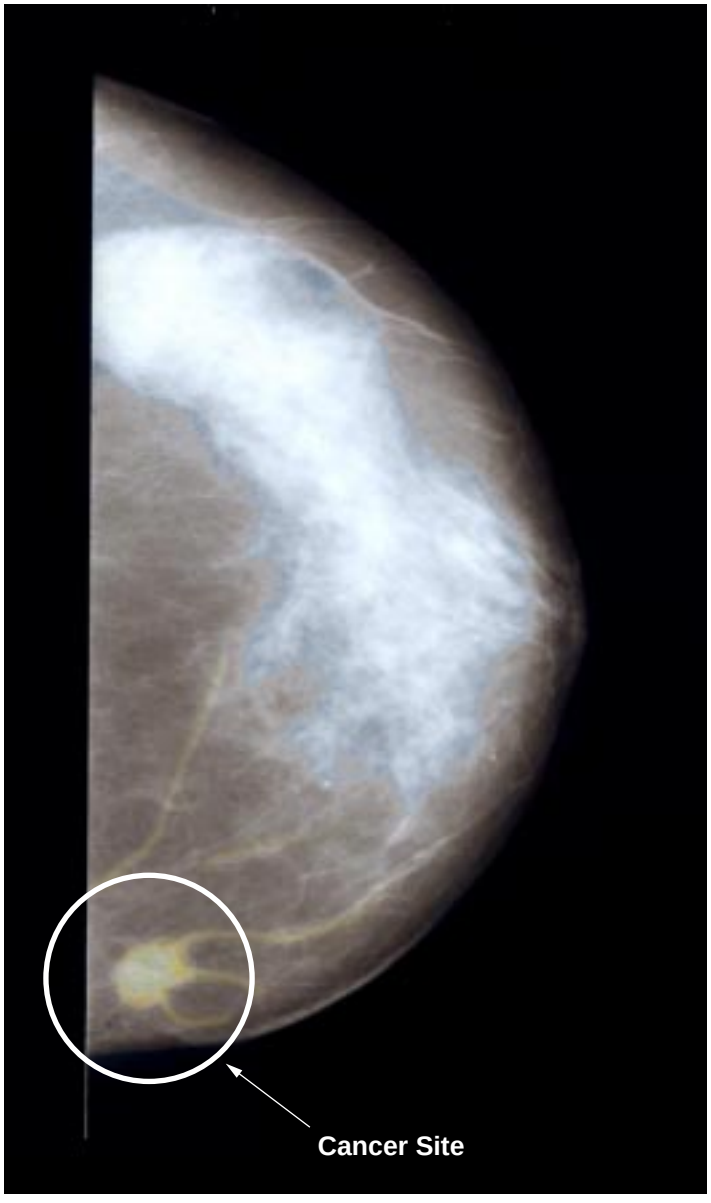
[1]Mammography Services: Impact of Federal Legislation on Quality, Access, and Health Outcomes (GAO/HEHS-98-11, Oct. 21, 1997).

challenging radiological procedures, and ensuring the quality of the image and its interpretation is important in detecting potential tumors. Figure 1 illustrates this point. It shows two mammograms of the same patient who had a cancerous breast tumor. As you can see, the picture on the left is not clear enough to permit detection of the cancer site that is visible in the picture on the right.

Figure 1: Low- and High-Quality Mammography Images of the Same Patient



Tumor Not Visible



Tumor Visible

A mammogram that is of poor quality or incorrectly interpreted can have considerable diagnostic consequences. If the mammogram is incorrectly seen as indicating cancer (that is, a positive test result), a woman may need to endure unnecessary and costly follow-up procedures. A mammogram that is interpreted as normal when an abnormality is actually present could result in the missed diagnosis of early lesions and delayed treatment, which could cost a woman's life.

MQSA contained a number of provisions designed to ensure the quality of the image and its interpretation. Among other things, MQSA provided that

- the Food and Drug Administration (FDA) establish quality standards for mammography equipment, personnel, and practices;
- all mammography facilities, regardless of location or setting, be accredited by an FDA-approved accrediting body once every 3 years and obtain a certificate from FDA in order to provide mammography services after October 1, 1994; and
- all mammography facilities have an annual evaluation by a qualified medical physicist and an annual inspection by FDA-approved inspectors that includes a test of image quality.

MQSA Has Had a Positive Effect on the Quality of Mammography Services

MQSA's quality standards and the related accreditation process have had a substantial effect on improving the quality of services. FDA substantially based its standards on an accreditation program developed by the American College of Radiology (ACR), a private, nonprofit professional association of radiologists. When MQSA initially took effect, many mammography units did not meet the standards. For example, between October 1, 1994, and August 1, 1995, about 2,600 (35 percent) of the mammography units that sought ACR accreditation (the main accrediting body used by FDA) initially failed to meet accreditation requirements. While almost all of these units were eventually granted full accreditation, they first had to demonstrate that they had improved their quality assurance activities. The accreditation process continues to result in more facilities meeting quality assurance standards. For example, the percentage of facilities that obtained ACR accreditation on the first attempt increased from 66 percent in 1995 to 82 percent in 1997.

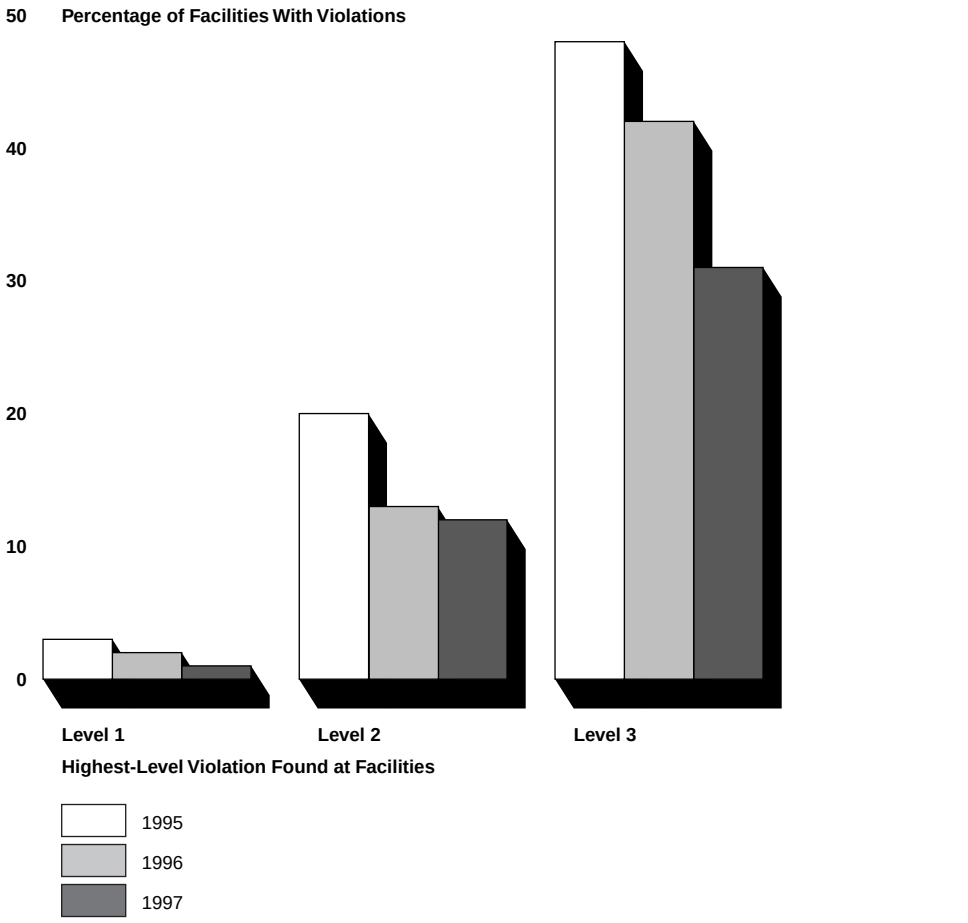
MQSA's inspection requirement gives FDA another means to ensure that facilities comply with standards on a day-to-day operating level. While accreditation is generally based on a review of written application materials, annual inspections are conducted on site, which allows

inspectors to verify information provided during the accreditation process. In January 1997 we reported on some initial problems with FDA's inspection program, such as inconsistent approaches in conducting inspections and reporting results, as well as weaknesses in follow-up systems to ensure that facilities were correcting deficiencies in a timely manner.[2] FDA has taken the actions that we recommended in our report to remedy these operational problems.

As FDA entered its third year of annual inspections, inspection results continued to show improvement in facility compliance with MQSA quality standards. As figure 2 shows, the percentage of facilities found to have violations dropped in every violation category during the first 3 years of the inspection program.

[2]FDA's Mammography Inspections: While Some Problems Need Attention, Facility Compliance Is Growing (GAO/HEHS-97-25, Jan. 27, 1997).

Figure 2: Comparison of Mammography Facilities' Inspection Results, Fiscal Years 1995-97



Level 1 violations are those that can have the most detrimental effect on the quality of mammography services—for example, a facility's having personnel who do not meet FDA's minimum qualification standards. Level 2 violations are considered less significant—for example, a facility's not having an evaluation of equipment by a medical physicist during the past 14 months. FDA considers both level 1 and level 2 violations to be significant violations for which it requires the facility to submit written plans for corrective actions. From fiscal year 1995 to fiscal year 1997, the proportion of inspected facilities whose highest-level violation was a level

1 dropped from 3 percent to 1 percent, and the proportion whose highest-level violation was a level 2 dropped from 20 percent to 12 percent.

Level 3 violations are more minor in nature—for example, a facility's not having the required documentation of a quality control test—and do not require a written response. Most facilities with violations had only level 3 violations; these numbers also dropped during the 3-year period. Consistent with the decrease in the number of violations, the proportion of facilities with no violations at all nearly doubled, from about 30 percent in 1995 to about 55 percent in 1997.

While these inspection results relate to the quality of mammography services in general, one particular aspect of inspections can be tied more directly to the quality of the image itself. The quality of the image is tested through a "phantom image test" involving an X ray of a plastic block that contains 16 test objects to determine how many of the objects are visible on the resulting image produced by the facility's mammography equipment.[3] Because FDA was already conducting some phantom image testing before MQSA, it is possible to make general comparisons of image quality before and after the law took effect. In 1992, before the law was implemented, 11 percent of the facilities failed the test. Since 1995, the failure rate has been about 2 percent.

Data and Methodology Problems Prevent Measuring MQSA's Impact on Saving Lives

Although MQSA can be linked to improved quality of mammography images, it is difficult to say to what extent it has helped to improve mammography interpretation or increase the frequency of early detection of cancer which has been shown to save lives. Researchers face several methodological challenges in clearly demonstrating these links.

The first problem is that criteria have not been established to measure how well images are being interpreted by radiologists. Some experts have suggested that some type of peer review or proficiency test would help improve accuracy, but FDA and others have argued that such measures are too difficult and costly to implement and that each facility should instead set up a system to monitor the performance of its interpreting physicians.

The second problem is the overall lack of sufficient clinical data to assess MQSA's contribution to mammography performance and resulting cancer outcomes. For example, while various regional, state, and local cancer

[3]The plastic block, which represents an average-sized compressed breast, contains a wax insert that holds 16 test objects—6 fibrous structures (fibers), 5 embedded microcalcifications (speck groups), and 5 different-sized tumor-like masses that simulate growths that could be cancerous.

registries collect clinical data on breast cancer cases, including stage and tumor size, the data do not indicate whether the cancer was detected by mammography.

A third and overarching problem is that no clear consensus exists on appropriate performance and outcome measures for mammography. Experts we talked with pointed out the following areas of analytical and definitional complications.

- Researchers do not agree on how to decide when a mammogram is a false negative. For example, under a 12-month follow-up scenario, if a mammogram is interpreted as negative and during the 12 months after the mammogram a cancer is detected, then the negative mammogram is considered a false negative. Some researchers believe the follow-up period should be as little as 7 months, while others believe it should be a year or more. The number of false negatives identified will be affected by the length of the follow-up period that is used.
- Because the ultimate goal of mammography is to reduce breast cancer mortality, some studies have used mortality reduction as a measure of mammography effectiveness. However, because women with breast cancer generally survive longer than 5 years, measuring changes in mortality reduction requires a long follow-up time. Because MQSA has been in effect for only a few years, not enough time has elapsed to permit use of mortality reduction as a measure for assessing MQSA's effect on cancer outcomes.
- As an alternative to mortality reduction rates, some researchers have used the early-stage cancer detection rate as an intermediate measure of the effectiveness of mammography.[4] But using this rate to measure the effectiveness of mammography, also poses methodological difficulties. The most controversial problem concerns whether or not cases of carcinoma in situ (CIS) should be included when measuring mammography effectiveness. While CIS is considered the earliest stage of breast cancer, some experts view CIS as a very slow-growing, noninvasive tumor. They contend that including CIS cases as early-stage cancer overstates the benefit of mammography in reducing mortality. Others argue that some CIS tumors can grow quickly and develop into serious, even fatal, disease and that, therefore, CIS cases should be considered early-stage cancer.

While these methodological problems are formidable, they do not appear to be insurmountable, and, in fact, progress is being made toward

[4]The most widely used approach to categorizing cancers involves the use of staging classifications, with the size of the tumor being one of the most important factors in determining the stage of the cancer.

resolution. As authorized by MQSA, the National Cancer Institute in 1994 established the Breast Cancer Surveillance Consortium, which consists of nine federally funded research projects at sites in most of the major geographical regions of the United States. These projects collect data from affiliated area mammography practices and link mammography data to cancer registry data. The Consortium's goal is to ensure that the data collected can be analyzed to address issues relating to mammography performance and cancer outcomes. The Consortium has spent considerable time developing a consensus on which data elements to collect in order to obtain consistent and reliable data, and it is also working to develop a consensus of common definitions for measurement. By the year 2000, the Consortium expects to have sufficient data to analyze mammography performance and cancer outcomes. Consortium efforts have the potential to greatly strengthen the quality of information about the impact of mammography on improving cancer outcomes. However, they are unlikely to provide substantial information about MQSA's specific effect because data are not available for a pre- and post-MQSA comparison.

MQSA Has Not Limited Access

When MQSA was passed, the Congress was concerned that access to mammography services might be limited because many providers might choose to drop mammography services rather than upgrade facility operations to comply with the standards. Our analysis of data collected by FDA shows that of the approximately 10,000 facilities offering mammography before MQSA, about 4 percent, or 404 facilities, closed during the 12 months preceding MQSA's October 1994 implementation. Data for December 1994 to March 1997 showed a net loss of 163 mammography facilities.

We found no evidence, however, that these closures adversely affected access to mammography services. For example, almost all of the closed facilities were located within 25 miles of another certified mammography facility. Further, state health officials from those states with the greatest numbers of closures generally told us that many of the closed facilities were either low-volume providers that did not generate enough revenue to cover the costs of meeting MQSA requirements or poor-quality providers that could not meet accreditation requirements. Officials in several states said that a sizable number of the facilities identified as closed—more than 40 percent—continued to provide services in some form. For example, some facilities continued to provide services by merging with another facility or consolidating their equipment from satellite clinics. Others

contracted with mobile service providers to continue serving their patients.

Conclusions

As the Congress considers reauthorization of MQSA, two points are clear. First, overall, MQSA has had a positive impact on the quality of mammography services and no adverse effect on women's ability to obtain access to mammography. We believe it is reasonable to attribute a large part of the quality improvement to MQSA processes that enforced accreditation standards that were not previously met by many facilities and to FDA's annual inspection process, which provides a valuable, systematic means of helping ensure that these higher standards are maintained.

Second, quantifying MQSA's effect on the accuracy of mammogram interpretation and on the improvement of cancer outcomes is much more problematic. Although data collection efforts now under way will probably make it easier to monitor the quality of image interpretation and the effects of mammography on cancer outcomes in the future, the absence of pre-MQSA data means that analysts may not be able to fully measure how the act itself has affected these two areas.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of the Subcommittee may have.

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