

GAO

Testimony

Before the Subcommittee on Health and the Environment
Committee on Energy and Commerce
House of Representatives

For Release on Delivery
Expected at
9:45 a.m.
Friday
June 5, 1992

SCREENING MAMMOGRAPHY

Federal Quality Standards Are Needed

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054597/146839

SUMMARY OF GAO TESTIMONY BY JANET L. SHIKLES
ON NEED FOR FEDERAL QUALITY STANDARDS FOR SCREENING MAMMOGRAPHY

The Congress directed GAO to review the quality of screening mammography, a radiographic test that can detect breast cancer at an early stage, in different types of settings. GAO reported in SCREENING MAMMOGRAPHY: Low-Cost Services Do Not Compromise Quality (GAO/HRD-90-32, January 1990) that many of the screening mammography providers it surveyed lacked the quality assurance programs needed to ensure that women receive safe and accurate mammograms. This finding raises serious concerns because mammograms are more difficult to read than many other types of x-rays. Failure to produce the best possible image or to interpret it correctly can mean the difference between life and death for a woman. Specifically, GAO found that:

- Many of the 1,485 mammography providers surveyed in four states lacked adequate quality assurance programs.
- Those providers reporting the highest rates of compliance with many quality standards were those performing the highest volume of mammography. However, GAO found no consistent relationship between what providers charged for screening mammograms and their compliance with quality standards.
- The association between higher volume and greater quality control is important because high volume screening can permit economies of scale that lower fees. Providing screening in regulated, high-volume settings can help assure the availability of safe and accurate screening mammography at a cost consistent with the Medicare fee limit of \$55.
- Primary care physicians and multispecialty clinics were the screening mammography settings that consistently reported the lowest rates of compliance with quality assurance standards.

Our work also identified a need for strong federal standards to assure the quality of screening mammography. At present, only nine states have laws containing any quality control standards for mammography services.

In creating the new Medicare screening benefit, the Congress required the Secretary of Health and Human Services to establish quality standards for mammography providers serving the Medicare population. Of significant concern, however, are the 30 million women not eligible for Medicare who should obtain regular screening and are not necessarily protected by federal quality standards.

We believe that the Congress should consider setting federal standards that would protect all women receiving screening mammography services.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss GAO's report, SCREENING MAMMOGRAPHY: Low-Cost Services Do Not Compromise Quality (GAO/HRD-90-32, January 1990). The Congress directed us to review the quality of screening mammography,¹ which contributes to early detection of breast cancer, in different types of settings.² Members of Congress were concerned that a new Medicare benefit for screening mammography might lead to the creation of "mammography mills" providing substandard services. Members were also concerned that the \$55 limit on what facilities could charge for Medicare-funded screening might make it difficult for women to obtain safe and accurate mammograms.

In our four-state survey we found that the facilities providing the highest volume of mammography services--the so-called "mammography mills"--were the ones that reported the highest rates of compliance with many quality standards. Moreover, high volume is an important factor in lowering the price of screening mammography, which can result in increased access to screening services.

Our work also identified a need for strong federal standards to assure the quality of screening mammography. At present, only nine states have laws containing any quality control standards for mammography services. Many of the screening mammography providers we surveyed lacked adequate quality assurance programs, which are essential for consistently producing safe and accurate mammograms. This finding raises serious concerns because mammograms are more difficult to read than many other types of x-rays. Failure to produce the best possible image or to interpret it correctly can mean the difference between life and death for a woman.

In creating the new Medicare screening benefit, the Congress required the Secretary of Health and Human Services to establish quality standards for mammography providers serving the Medicare population. Of significant concern, however, are the 30 million women not eligible for Medicare who should obtain regular screening, according to National Cancer Institute guidelines. These women are not necessarily protected by federal quality standards. Therefore we present for congressional consideration an approach to implementing federal standards that will protect all women getting screening mammograms.

¹A radiographic test to detect breast cancer in apparently healthy women.

²Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360), Sec. 204.

BACKGROUND

The American Cancer Society estimates that 46,000 women will die of breast cancer during 1992 and that 180,000 new cases will be diagnosed. Breast cancer incidence has increased dramatically; approximately one in nine American women will develop breast cancer during her life. The Massachusetts Commissioner of Public Health recently declared breast cancer an epidemic in the state and said that immediate action is critical.

The best method we currently have to reduce the number of breast cancer deaths is early detection, and the most effective way to detect breast cancer at the earliest stages is mammography, an X-ray of the breast. The value of mammography for breast cancer screening is that it can detect cancers that are too small for a doctor or the woman herself to feel through physical examination, and these early stage cancers can be 90 to almost 100 percent curable. When detection occurs at a later stage, treatment is both more debilitating and much less effective.

Mammography is performed for two different purposes, screening and diagnosis. Screening mammography is an examination of a woman without breast symptoms, and is done simply to detect breast cancer before a lesion can be felt by her or her physician. Diagnostic mammography is an examination of a woman who already has a symptom, such as a lump, that suggests she may have breast cancer. It is performed to provide as much information as possible about a suspected lesion.

The process of performing the mammogram is the same in both cases. A diagnostic procedure, however, may require additional breast views and other tests. Because of its more limited purpose, screening mammography can take advantage of certain economies not possible during diagnostic mammography. For example, a radiologist need not be present to immediately interpret a screening mammogram. Instead, the day's films can be read all at one time, allowing greater efficiency in the costly use of a radiologist's time.

The Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) created a new Medicare benefit for screening mammography that went into effect January 1, 1991.³ Previously Medicare covered only diagnostic mammography. To help contain costs, the act generally limited the fee providers may charge for a screening mammogram to

³The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) created such a benefit to go into effect in January 1990. However, on November 22, 1989, the Congress repealed most provisions of the act, including the mammography benefit.

\$55.⁴ Some members of Congress expressed concern that the charge limit could compromise the quality of Medicare-funded screening mammography. To help assure that quality services would be provided, the Congress required the Secretary of Health and Human Services (HHS) to establish quality standards for facilities providing screening mammography to Medicare beneficiaries.

To obtain information about screening mammography practices in a variety of settings, we conducted a mail survey of 1,485 providers in California, Florida, Idaho, and Michigan. These were all the facilities identified as having mammography equipment by those states' radiological health departments. Our questionnaire⁵ requested information about equipment, personnel, quality assurance activities, reporting and record-keeping, volume, and charges. The response rate was 82 percent overall, and, for each state, at least 80 percent.

When analyzing the questionnaire responses, we used the following categories of settings where mammography services are provided: primary care physician, radiology private practice, hospital, hospital breast clinic, breast clinic, health maintenance organization (HMO), multispecialty clinic, mobile van, and other. To gather information about topics not addressed in the questionnaire--such as training and experience of personnel and the physical environment of facilities--we conducted site visits at 15 providers participating in the survey. We also reviewed government regulation and oversight of mammography services in the four states we studied.

MANY PROVIDERS DID NOT MEET STANDARDS
FOR QUALITY ASSURANCE PROGRAMS

Most of the features considered necessary for quality screening mammography contribute to the goal of obtaining good image quality with minimal risk to the patient. Because a mammogram is among the radiographic images most difficult to read, it must have optimal clarity. If image quality is poor or the interpretation faulty, the interpreter may fail to identify a malignancy. This could delay treatment and result in an avoidable

⁴The limit will be updated annually by the percentage increase in the Medicare Economic Index. The current limit is \$56.76.

⁵Questionnaire items were based on the standards and recommendations developed by the American College of Radiology (ACR) for use in its screening mammography accreditation program, the requirements of the Medicare Catastrophic Coverage Act (which were retained in the 1990 Omnibus Budget Reconciliation Act), and factors identified by other experts as associated with quality in screening mammography. The questionnaire was reviewed by officials from ACR and the National Cancer Institute.

death or mastectomy. Problems with images or interpretation also can lead to unnecessary testing and biopsies if normal tissue is misread as abnormal.

We found widespread compliance with certain quality standards, such as using dedicated mammography equipment (equipment specifically designed for mammography)⁶ and employing certified or licensed technologists to perform the mammograms⁷. But many facilities did not comply with professional standards for quality assurance programs, such as annual inspection by a radiological physicist⁸. A comprehensive quality assurance program is essential to evaluate both equipment and staff performance, and includes procedures such as checking the performance of the film processor and using a phantom to evaluate image quality⁹. The lack of such a program can result in problems with image quality and radiation dose.

The importance of ongoing quality feedback for mammography providers is illustrated by the results of the American College of Radiology (ACR) Mammography Accreditation Program. About 30 percent of providers applying for accreditation fail on the first attempt. ACR officials have observed that since the accreditation program is voluntary and applicants probably think they meet ACR standards, the failure rate suggests that improvement is needed even at facilities that believe they are providing good mammography.¹⁰

⁶To obtain the best mammographic image with the smallest dose of radiation, it is essential to use dedicated mammography equipment. Its features enable the operator to obtain high-quality images with much lower radiation exposure than is possible with general X-ray equipment.

⁷The person taking the mammogram plays an essential role in providing quality mammography, as proper positioning of the patient and adjustment of the equipment are vital to producing a good image.

⁸The radiological physicist performs a series of tests on the mammography equipment to ensure that it is safe and functioning properly.

⁹Phantoms simulate breast tissue when exposed. Objects that simulate growths that could be cancerous are embedded in the phantom. When the phantom is exposed with a facility's mammography equipment, the visibility and clarity of these objects provides feedback on the quality of image the system is producing.

¹⁰McLelland, et al., "The American College of Radiology Mammography Accreditation Program," American Journal of Radiology, 157:473-479, September 1991.

In our survey, primary care physicians and multispecialty clinics consistently reported the lowest levels of compliance with quality assurance standards. For example, only 43 percent of primary care physicians reported that a radiological physicist inspected their mammography equipment at least once a year, compared to 85 percent of hospital breast clinics and 91 percent of mobile vans. While over half the HMOs and hospitals said they checked their film processor on a daily basis, only 10 percent of primary care physicians did so.

HIGH-VOLUME PROVIDERS MORE OFTEN ADHERED TO QUALITY STANDARDS

We found a strong relationship between the volume of mammography performed and the rate of compliance with many quality standards. For example, 87 percent of facilities performing over 100 mammograms per week reported having annual inspections by a physicist, while 58 percent of those doing fewer than 25 weekly mammograms said they had such inspections. Half of the high-volume providers did a daily check of their film processor, compared to 24 percent of the low-volume providers.

Higher charges, however, did not necessarily buy higher quality. We found no consistent relationship between charge and adherence to quality standards. For several standards, we found no correlation between price and degree of compliance with professional standards. For other standards, there was a relationship, but in some cases providers charging the lowest fees had the highest rate of compliance with a quality standard, while in other cases those with the highest fees had the highest rate of compliance.

Our site visits also tended to dispel the concern that quality would be compromised at facilities charging lower fees for screening mammography. This concern was related to the limit the Congress placed on the fee providers may charge for Medicare-funded screening mammograms, currently around \$57. We visited three facilities that reported complying with many important quality standards and that charged \$50 or less for screening mammograms. They employed trained, experienced radiologists; used certified technologists; and had extensive quality assurance programs. All reported volume levels of at least 200 mammograms per week.¹¹

The association between high volume and adherence to quality standards is significant, because high volume is a critical factor in reducing the price of screening mammography. One important way high volume contributes to quality is that it gives radiologists sufficient work to increase the proficiency of their

¹¹One facility used a significant amount of volunteer labor to lower operating costs, but the other two did not.

interpretations. They are then less likely to miss a sign of cancer in a mammogram or cause a woman to undergo an unnecessary procedure by identifying normal breast tissue as abnormal. Providing screening in regulated, high-volume settings can help assure the availability of safe and reliable screening mammography at a cost consistent with the Medicare fee limit.

FEDERAL AND STATE REGULATION OF SCREENING MAMMOGRAPHY LIMITED

At the time of our review, only the states had responsibility for regulating both mammography equipment and services.¹² Of the states we reviewed, only Michigan had a law requiring the use of dedicated mammography equipment and the setting of image quality and radiation dose standards. The lack of such standards in the other three states limited their ability to regulate screening mammography services. Because state requirements were limited, when state inspectors identified image quality problems they could not require mammography providers to correct them. Idaho had no minimum qualifications for the operators of mammography equipment, and the states we visited had varied requirements for persons interpreting mammograms. At present, only nine states have laws containing any quality control standards for mammography services.

In January 1991, the Health Care Financing Administration (HCFA) implemented interim final regulations setting quality standards for providers of Medicare-funded screening mammography services. These standards parallel in most respects those used by ACR and other professional organizations with expertise in screening mammography. They mandate the use of dedicated equipment; set certification, experience and continuing education requirements for technologists performing mammograms and physicians interpreting them; establish reporting and record-keeping requirements; and mandate comprehensive quality assurance programs. One difference is that the HCFA certification program does not include a review of clinical images. HCFA, however, will require annual inspection of facilities and ACR certification lasts for 3 years. The agency has not yet issued final regulations; proposed final regulations are being reviewed in the Department of Health and Human Services.

¹²The Food and Drug Administration (FDA) has responsibility for regulating the manufacture and assembly of mammography equipment. Its standards apply only to the manufacturer and assembler of the equipment, not to the facility using it. FDA has no standards for mammographic image quality or the radiation dose received by the patient. It considers dose a practice-of-medicine issue not within its purview.

CONCLUSIONS AND MATTERS FOR CONSIDERATION

HCFA quality standards should help assure that providers deliver safe and accurate screening mammography services to the Medicare population. However, the National Cancer Institute and other medical organizations recommend that women begin regular screening at the age of 40, and that women have annual screening mammograms starting at age 50. Over 16 million American women not covered by Medicare are candidates for annual screening, and it is recommended that over 14 million additional women be screened every one to two years.

Women not covered by Medicare could obtain mammograms from providers that are not certified by HCFA and that do not comply with federal quality standards. These women would be protected only by state regulations, which in some states are too limited to ensure the provision of safe and reliable screening services.

Because some mammography providers may choose not to be certified for Medicare and because the states, as a rule, do not stringently regulate these providers, the Congress may want to consider adopting federal regulations that would protect all women receiving screening mammograms. One option is to establish a regulatory program similar to that for Medicare supplemental (Medigap) insurance.

Under the Medigap regulatory program, federal law establishes minimum standards that must be met before policies can be sold.¹³ Enforcement of the federal Medigap requirements is delegated to the states as long as their regulatory programs are at least as stringent as the federal standards. Similarly, the federal government could establish minimum quality standards for screening mammography. Enforcement could be delegated to states with regulatory programs meeting these standards.

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Mr. Chairman, this concludes my statement. I would be happy to answer any questions.

¹³The federal standards incorporate by reference the model Medigap regulatory program developed by the National Association of Insurance Commissioners (42 U.S.C. Sec. 1395ss).