Screening Mammography in Primary Care Settings: Implications for Cost Access and Quality

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Background Paper

Prepared by the Health Program
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Judith Wagner, Study Director

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INTRODUCTION

Until recently, primary care physicians rarely offered screening mammograms as part of their practices. Even today, primary care practices constitute roughly five percent of the total market for mammography units (8). The interest of primary care practices in becoming suppliers of screening mammograms has been growing, however. The American College of Obstetricians and Gynecologists (ACOG) recently endorsed screening mammography in the office setting "when done in accordance with the 1990 technical standards of the American College of Radiology" (5).

The proliferation of equipment in the primary care setting has implications for the volume of services obtained by individual providers and, hence, for the cost and quality of the services provided in all settings of care. This staff paper examines the implications for cost and quality, as well as for access to mammography, of expanding the supply of mammographic services in the primary care setting. The special issues raised by third-party businesses that package mammography services for primary care physicians are also discussed.

VOLUME AND COST

The inverse relationship between the volume of procedures performed and the cost per procedure of mammography services has been well documented (14). Mammography entails high fixed costs, including plant and equipment, setup costs, operator training, and quality control. To break even, a provider must be able to spread these costs across a large enough volume of procedures. The lower the price, the more procedures are required to reach the break even point. Medicare's $55 global limit on screening mammography fees was based on analyses of the full costs (including imaging and interpretation) of screening mammography at

various daily volumes. In 1989, PPRC reported that the average cost per screen was between $45.60 and $61.51, with a best guess of $48.26, for a stationary mammography facility at 20 screening patients per day (14).[1] An earlier OTA review in 1988 of seven high-volume breast cancer screening centers (35-40 patients per day) showed that mammography screening could be provided **together with breast physical examination** for $50 or less in such settings (Table 1).

According to PPRC, a $55 maximum payment rate will induce new providers to offer mammography screening if they can obtain a volume of about 20 patients per day. Those providers who cannot generate such a volume, as is the case for many primary care practitioners, would not be able to operate at $55. (For example, at 5 patients a day, PPRC estimated that the break even price would be about $107).

MAMMOGRAPHY SCREENING CAPACITY

Researchers at NCI and FDA recently estimated that by 1990 there were more than enough mammography machines in the U.S. to handle all potential need for screening, even after taking into account demand for diagnostic mammograms.[2] (OTA concluded the same in its 1987 report on breast cancer screening (19b).) Even assuming full compliance by all American women with the screening guidelines of NCI the supply of dedicated mammography machines is 27 percent greater than the need (3). This capacity is also spread evenly across metropolitan areas in the U.S. -- virtually all of these areas have densities of mammography machines that vastly exceed current demand[3] (4).

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1 OTA did not review the accuracy of the PPRC cost estimates for this staff paper. During the course of this study, however, OTA learned that the PPRC estimates assume that films will be batch processed and did not account for the potiental cost of retakes due to poor technical quality of original films. PPRC is currently updating its cost study and is reexamining its assumptions regarding these and other matters.

2 The analysis assumed an average machine capacity of 25 procedures per day.

3 About 77 percent of the U.S. population lived in metropolitan areas in 1987 (19a).

The high level of mammography capacity relative to current demand, and even to hypothetical need, implies that many facilities must be operating well below capacity. GAO estimated that in 1989 only 11 percent of facilities performed over 100 examinations per week (19). This fact has three implications:

- In the short-run, many providers, particularly those offering diagnostic mammography as well as screening, will be willing to offer mammography screening even when their fully allocated average costs exceed the going price. The variable costs associated with these additional mammography screening procedures are much lower than fully allocated costs (which include fixed costs), so each procedure that brings in enough revenue to meet the variable costs and then some, will contribute at least partially to meeting the fixed costs of the service.

- The placement of new capacity, particularly in areas with excess capacity, will further reduce the volume of existing facilities, through probably only marginally, and will make it more difficult for such facilities to operate within the **$55** cap.

- In the long-run, some providers could decide that with low volumes mammography is a losing proposition which cannot be justified, and might close their facilities. To the extent that this occurs, the volume of procedures in remaining facilities will increase, and they will become more economically viable. It is worth noting that most radiology practices have dedicated mammography equipment and that they would probably keep such equipment in order to maintain a full line of radiography services for their referring physicians (7).

To summarize, at present levels of capacity, the existing $55 cap does not appear to be an impediment to the availability of screening mammography services for the women who seek it out in their communities.[4]

COMPLIANCE AND ACCESSIBILITY

Since mammography services are available in most communities, limited supply is not the reason for a current demand that falls well short of the current guidelines for use. For example, in 1987, 25 percent of women between 50 and 75 years of age reported having a screening mammogram within the past year (13). Several recent studies suggest that women do not receive mammograms either because they do not know they should or because their physicians have not recommended them (13). Internists appear to recommend screening mammograms much less frequently than is recommended by expert groups (17). Compliance has recently been rising. Efforts of the American Cancer Society, women's health groups, and even equipment manufacturers to educate consumers and of professional groups to educate physicians are probably responsible for much of the change, but publicity in recent years surrounding the diagnosis of breast cancer in celebrities also raised screening rates (23). The evidence suggests, then, that continued effort must be made to educate both physicians and patients about the importance of breast cancer screening in general, and the role of mammography in that process. There is no information available about how much additional compliance would be expected from general consumer education or from better recommending practices by primary care physicians.

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4 Pockets of underserved areas may exist in rural communities or in particular parts of large metropolitan areas.

Even when mammograms are recommended, and when women are better educated about the value of such services, compliance will still not be perfect. Compliance with screening recommendations may be further enhanced if mammography services are located at the site of primary care. One would expect not only that the physician would be more likely to recommend a mammogram if he or she is the provider of the test[5] but also that the woman would be more likely to comply with the recommendation under these circumstances. There is no information on the additional compliance this would bring forth **over and above** what can be expected from better recommending practices and general consumer education.[6] The high dispersion of Medicare patients among primary care practitioners, however, suggests that for compliance to be much affected in the aggregate, mammography services would have to be placed in thousands of individual practices. Most mammography units in primary care offices today are in obstetrics/gynecology practices, but only 1.6% of all office visits by women 65 years of age and older were to this speciality (20a). Thus, a necessary condition for a big improvement in overall rates of compliance through the primary care route is a major increase in total mammography capacity. This in turn implies not only very low volume in the new services but probably also declining volume in facilities already providing screening mammographies.[7]

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5 Recent studies of referral behavior on the part of physicians suggests that more tests are ordered when the physician has a financial stake in the organization conducting the tests (12).

6 Unpublished data from a 2-week long survey of seven OB-GYN practices with in-office mammography units indicated that roughly 80 percent of women visiting the offices and eligible for a screening examination (according to ACS guidelines) actually received the examination (23).

7 Some of the mammograms performed in primary care offices will substitute for mammograms that would have been done in other screening facilities; other mammograms will be additive. The substitutive procedures will reduce volume in existing providers.

QUALITY

The quality of mammography screening examinations has been of great concern and is behind the 1987 initiation of a voluntary accreditation program for mammography facilities administered by the American College of Radiology (ACR). The period of ACR accreditation is three years with an annual update of equipment and personnel changes and an annual review of quality control procedures. This accreditation program involves tests of image quality and radiation dose as well as requirements for training and ongoing processes of quality control at the facility. Because image quality depends on an interacting complex of factors -- e.g., operator technique, calibration of the equipment, film quality, image receptors, and film processing materials and methods -- ACR requires that a board-certified radiologist be responsible for the quality of the service and for interpretation. In addition to standards relating to personnel, training, equipment, techniques, dosage, record keeping, reporting, etc., the ACR program requires facilities to submit images using a specially designed breast phantom embedded with test objects as well as clinical images from two patients (9). These images are assessed for their quality by a panel of board-certified radiologists and medical physicists who are expert in mammography. As of August, 1991, 5589 facilities had applied or reapplied for accreditation, and 2962 had passed (52 percent) (l). The application process can take as long as a year, so some of the remaining facilities may be in process. The first-time failure rate is 30 percent.

With minor exceptions, Medicare's recently published standards for mammography certification mirror ACR's, but the certification process does not include a test of clinical and phantom images. Also, at present, providers seeking Medicare certification must only attest to the fact that they meet all relevant Medicare requirements, and for the time being HCFA plans to initiate further investigation (such as a survey of a facility) only as a result of a complaint (21).

Some aspects of quality are not addressed in the standards. For example, neither ACR nor Medicare require that any films be processed before the patient leaves the screening site, and mobile mammography units often do not include a film processor. Two experts in

mammography (a medical physicist and a radiologist) told OTA that even under the best of circumstances, as many as 5-10 percent of examinations require a retake while the patient is still in the office because the technical quality of the image is poor (6, 10). If women must be recalled for a second examination because of inadequate films, the cost and quality of the entire process is likely to be affected. The decision not to a require on-site film processing in the ACR and Medicare regulations probably resulted from concern for women's access to mammography (10).

As structural and procedural quality criteria, neither the ACR nor Medicare certification standards directly address ultimate health outcomes. A recent study of rates of cancer in patients referred for biopsy on the basis of a suspicious or positive mammogram found a large difference in the rate of positive diagnosis between referrals from a university-based hospital screening clinic and those from community-based radiologists, with the community-based radiologists having a much lower ratio of positive biopsies per referral than the clinic (10, 11). The interpretation of these findings is difficult, because more complete outcome measures, such as cancer mortality rates, would have to be compared to judge whether the community radiologists over-referred or the clinic under-referred. Nevertheless, these findings suggest that there is a high variation in referral rates that has potentially critical impacts on both health outcomes and costs. Whether adherence to the ACR or Medicare quality standards would reduce the observed variation in referral rates is a matter of conjecture. [8]

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8 ACR is developing a mammography reporting and database system which will permit the collection of outcome data and standardize mammography reports.

Primary Care Providers and Quality

In principle, a primary care provider can meet the current requirements for both Medicare and ACR certification if he or she has the appropriate arrangement with a board-certified radiologist who reads the mammograms and carefully oversees the process of quality control. In practice, primary care providers are likely to face two impediments to high quality: low volume and lack of an on site manager of quality of care[9].

A direct relationship between volume and indicators of quality has been documented in two studies. A 1988-1989 survey by GAO found that among screening facilities responding to a survey, substantially fewer low-volume providers (less than 25 procedures per week) met GAO's standards of quality than did high volume providers (more than 100 procedures per week) (19). Data from the ACR on the quality of images produced by centers applying for accreditation show a strong inverse relationship between the volume of procedures and the proportion of sites failing the image quality (9) (Table 2). The reasons for this relationship are not known with certainty, but the importance of high volume in maintaining skills of technologists and radiologists is one possibility.[10] Another reason may be the high cost of quality control. Preliminary estimates by Martin Brown of the National Cancer Institute indicate that the per-patient cost associated with quality control is $12 at 5 tests per day, but only $3 at 20 per day (2).

Because primary care practices are likely to operate at low volume, they are also unlikely to have a radiologist on site or frequently available to oversee the process. Both Medicare and ACR require that a radiologist visit the facility at least once a month to oversee quality. Centers with very high volumes are more likely (but not guaranteed) to be organized

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9 One or the other of these potential threats to quality can also exist in breast cancer screening clinics, radiology practices or even hospitals.

10 The direct relationship between procedure volume and quality has been documented for numerous other medical procedures (20).

with a radiologist on site full-time or much more frequently than once a month. Thus, the benefits of tighter quality control and more frequent feedback among all the participants in the service are easier to attain at high volumes.

Primary care practitioners may have an advantage over other kinds of providers in other aspects of quality. Patient satisfaction and comfort, for example, are legitimate dimensions of quality (20). The continuity of care associated with followup and monitoring may also be enhanced when the provider of the service is a primary care provider. Would a woman choose a provider on these criteria if she had information that the provider is not ACR accredited or that the provider operated a low volume facility? The answer to this question is unknown.[11]

To summarize, there is no absolute barrier to high quality mammography in the primary care setting, but low volume and the lack of an on site quality control manager make maintaining quality a greater challenge and a more costly effort in this setting. Furthermore, when the service is owned by the primary care practice, the person ultimately responsible for maintaining quality --the radiologist -- has neither the operational authority nor financial control to effect the change.

Leasing Arrangements and Quality

Leasing arrangements are fairly common for diagnostic imaging equipment and are essentially financial agreements that have little to do with cost or quality of care. The real question is whether "turnkey" services like those offered by Spectrascan Imaging, Inc., (15) are compatible with high-quality mammography services in the primary care setting.

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11 Research underway at the University of Washington under the sponsorship of NCI will explore how women make tradeoffs between access, convenience, and cost (18).

Spectrascan will sell or lease equipment to providers of mammography services (23) and in that respect is no different from other equipment leasing companies. But Spectrascan's services can and often do go further than simple leases. Spectrascan packages the various components of a screening mammography service together for the primary care physician. The company will manage the installation of equipment (which consists of a fully diagnostic mammographic unit, a film processing unit, and patient education and tracking material and equipment), hire and train a qualified radiologic technologist[12], provide ongoing repairs and needed service, provide annual inspection and documentation by a physicist, make a contractual arrangement with a radiologist[13] to read and consult with the provider, provide film and supplies, and transport films between the provider and the interpreting radiologist. Spectrascan as an integral part of the equipment package provides a proprietary computerized patient information system that allows for automatic tracking of patient status and manages periodic patient recalls together with patient education and communication materials (16). The primary care physician must provide space for the service and manage the technologist and the patient's treatment. The company bills the provider for its own services and for those of the radiologist. The primary care provider bills the patient or third-party payer for the screening examination.[14]

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12 The technologist is officially an employee of Spectrascan but is under the supervision and operational control of the primary care physician at all times she is in the physician's office (23).

13 The radiologist is generally but not always located in the same metropolitan area as the primary care physician.

14 Some Medicare carriers require that the radiologist bill separately for the professional component, and the provider bills only for the technical component. Where this happens. Medicare's allowed payment for the technical component in approximately $35.00, but according to PPRC, the technical cost of a facility at 20 examinations per day is $38.00. Non participating providers may bill the patient for a higher amount.

Under Spectrascan's agreement with the radiologist, the radiologist is responsible for reading images and reporting examination results in a timely fashion. In the most recent radiologist agreement form, the radiologist must also agree to support the practice **if** it applies for Medicare certification or ACR accreditation and to meet the Medicare and/or ACR requirements for on-site visits, quality control, and surveys (23).

It is, of course, impossible to compare the quality of mammographic services in practices that use Spectrascan's services with other facilities without detailed information about the accreditation status (and even outcome studies) of those practices vs. other services. Because it offers a set of services and procedures that are consistent with the ACR accreditation guidelines, Spectrascan may enable primary care physicians to offer a higher quality of mammography services than they would provide if they had to develop such services "from scratch." Spectrascan also universally includes film processing on site and therefore offers a higher quality in this dimension than those provided in offices or mobile vans that do not have this capacity. Also, as the number of primary care sites in a community increases, a service like Spectrascan might be able to achieve some economies of scale in maintaining quality standards. Thus, if a primary care provider has decided to engage in on-site mammography screening, a third-party service such as Spectrascan could make it easier and more efficient to meet the quality standards of ACR and Medicare. On the other hand, the introduction of a third party into the relationship between the primary care physician and radiologist -- a participant who employs the technical personnel but who is not responsible for the quality of the service and has little authority over the primary care provider -- may further complicate the question of who is in charge of quality assurance. Finally, by making it convenient and easy (with little or no required capital investment) for a primary care practice to install and operate a dedicated mammography unit, such a business may encourage the further proliferation of low-volume facilities, with potentially negative consequences for quality.

Spectrascan Imaging Services, Inc., is not the only third-party business marketing mammography service packages to primary care physicians. OTA has not reviewed the services offered by other groups and cannot comment on their implications for quality. If such businesses do not offer services that are compatible with ACR and Medicare standards, then they may have negative effects on quality by encouraging primary care physicians to rely on services that are substandard.

CONCLUSIONS

- The supply of mammography facilities is already more than adequate to meet the needs for screening and diagnostic mammography.
- Raising the Medicare fee to allow primary care practices to offer mammographic screening will probably raise the cost of providing screening in all settings because average volumes of existing units are likely to decline (all other things held equal).
- As volumes decline, maintaining high standards of quality becomes more costly and difficult. Most primary care providers will have low volumes and therefore will find it more difficult to assure quality.
- Primary care settings may have even greater difficulties in maintaining quality than other low-volume settings because the radiologist responsible for technical quality may be more remote than at other settings.
- The impact on quality-of-care of third party businesses that package services for primary care settings is unclear -- it could be positive or negative, depending on the nature of the business and its commitment to meeting or exceeding existing quality standards. By making it easier for primary care practices to engage in mammographic screening, these businesses encourage the proliferation of units.

- The education of physicians and consumers has increased compliance with screening mammography recommendations. Putting mammography facilities in physicians offices may further increase compliance, but the net additional effect is unknown. To have a very large impact on total compliance in the Medicare population would require a very large increase in the number of screening mammography sites.

Table 1.--Charges for Breast Cancer Screening at Low Cost Centers and Attributes of the Programs that Keep Costs Low

Service and Center	Screening Component Covered (Cost) BPE[a]	Mammogram	BSE[b]	Total	Factors Contributing to Low Costs
Mammography only					
Providence (Charlotte, NC)	No[c]	Yes ($29)	No	$29	No BPE on site; volume
UCSF (San Francisco, CA)	No[d]	Yes ($40)	No	$40	No BPE on site; volume
Breast Consultation Center Mobile Program (Cincinnati, OH)[e]	No	Yes ($40)	Group[f]	$40	No BPE; volume
Full service screening					
Breast Consultation (Cincinnati, OH)[e]	Yes ($8)	Yes ($42)	Yes	$50	Nurse does BPE; volume
Strax (Ft. Lauderdale, FL)[e]	Yes	Yes	Yes	$45	Volunteers and philanthropic resources used; very high volume
Guttman (New York, NY)[e]	Yes	Yes	Yes	$≥5	Same as Strax

a Breast physical examination by a professional
b Instruction in breast self-examination
c Physician referral encouraged.
d Physician referral required.
e Self-referral.
f The group instruction in BSE is done at a "brown bag" lunch sponsored by the employer. The lunch is part of a "wellness clinic."

Source: Dougherty et al., internal staff memorandum, March 7, 1988

Table 2: Number of Applications and Failure Rates by Volume of Facility

No. of Mammographic Studies/Month	No. of Applicants	No. of Completed Applications	No. of Failures (%)
0-50	525	291	76(26)
51-100	904	520	113(22)
101-200	1492	949	118(12)
201-300	768	510	62(12)
301-400	457	345	26 (8)
401-500	253	180	16 (9)
501 or more	318	238	9 (4)
Total	4717	3033	420(14)

Note: Failures result from phantom or clinical image evaluations or both.

SOURCE: McLelland, et al., table, 1991.

REFERENCES

1. American College of Radiology, Mammography Accreditation Program, August 31, 1991.

2. Brown, M., "Quality Assurance and Related Activities in Mammography: Economic Issues" presented to NCI Breast Imaging Workshop: State-of-the-Art and New Technologies, Bethesda, MD, September 4, 1991.

3. Brown, M. L., Kessler, L. G., Rueter, F. G., "Is the Supply of Mammography Machines Outstripping Need and Demand?" Annuals of Internal Medicine 113(10): 547-552, 1990.

4. Brown, M. L., Kessler, L. G., "The geographical distribution of screening mammography resources, NCI working paper, December 1989.

5. Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists, "Office Mammography" ACOG Committee Opinion, No. 95-August 1991, (Washington, DC: American College of Obstetricians and Gynecologists).

5a. Dougherty, D., Gluck, M., Power, E., Office of Technology Assessment, U.S. Congress, "Charges for Breast Cancer Screening and Effectiveness of Biennial Screening," internal staff memorandum, March 7, 1988.

6. Hendrick, R. E., Ph. D., University of Colorado Health Sciences Center, personal communication, September 25, 1991.

7. Kopans, Daniel, M. D., Massachusetts General Hospital, personal communication, September 20, 1991.

8. LaValle, D., General Electric Company, personal communication, September 23, 1991.

9. McLelland, R., Hendrick, R. E., Zinninger, M. D., et al., "The American College of Radiology Mammography Accreditation Program, " American Journal of Roentgenology 157(9): 473-479, 1991.

10. Meyer, J. E., M. D., Women's & Brigham Hospital, Boston, Massachusetts, personal communication, September 25, 1991.

11. Meyer, J. E., Eberlin, T.J. Somper, P. C., Sonnefeld, M. R., "Biopsy of occult breast lesions: analysis of 1261 abnormalities, " Journal of the American Medical Association 263:2341-2343, 1990.

12. Mittan, J. Barry (cd.), Florida Department of Health and Rehabilitative Services, Office of Comprehensive Health Planning, 1991 Florida Health Care Atlas (Tallahassee, FL: HRS Office of Comprehensive Health Planning, 1991).

13. The NCI Breast Cancer Screening Consortium, "Screening Mammography: A Missed Clinical Opportunity, " Journal of the American Medical Association 264: 54-58, 1990.

14. Physician Payment Review Commission, The Costs of Providing Screening Mammography, Report to Congress No.98-2, (Washington, DC: U.S. Government Printing Office, June 1989).

15. Spectrascan Imaging Services, Inc., "Benefits for Your Patient's and Practice," 1988.

16. Spectrascan Imaging Services, Inc., sales literature, 1991

17. Schwartz, J. S., Lewis, C. E., Clancy, C. et al., "Internists' Practices in Health Promotion and Disease Prevention," Annuals of Internal Medicine 114: 46-53, 1991.

18. Urban, Nicole, Fred Hutchinson Cancer Center, Seattle, Washington, personal communication, September 23, 1991.

19. U.S. Congress, General Accounting Office, Screening Mammography: Low-Cost Services Do Not Compromise Quality, GAO/HRD-90-32 (Washington, DC: January 1990).

19a. U.S. Congress, Office of Technology Assessment, Chartbook on Health Care in Rural America (background paper), (Washington, DC: Office of Technology Assessment, October 1990).

19b. U.S. Congress, Office of Technology Assessment, Breast Cancer Screening for Medicare Beneficiaries: Effectiveness. Costs to Medicare and Medical Resources Requires-Staff Paper, (Washington, DC: Office of Technology Assessment, U.S. Congress, November 1987).

20. U.S. Congress, Office of Technology Assessment, The Quality of Medical Care: Information for Consumers, OTA-H-386 (Washington, DC: U.S. Government Printing Office, June 1988).

20a. Nelson, Cheryl, National Center for Health Statistics, unpublished data from the National Ambulatory Care Survey, October 11, 1991.

21. U.S. Department of Health and Human Services, Health Care Financing Administration, State Operations Manual, HCFA-Pub.7, (Baltimore, MD: January 1991)

22. U.S. Department of Health and Human Service, Public Health Service, Centers for Disease Control, Morbidity and Mortality Weekly Report, 38: 137-140, 1989.

23. Ware, Alan, Spectrascan Imaging Services, Inc., personal communication, September 25, 1991.