"TO SEE TODAY WITH THE EYES OF TOMORROW"*
A HISTORY OF SCREENING MAMMOGRAPHY

Barron H. Lerner, MD, PhD
Associate Professor of Medicine and Public Health
Columbia University

Background Paper for the Institute of Medicine report:
"Mammography and Beyond: Developing Technologies for the Early Detection of Breast Cancer"

March 2001

This paper draws on Barron H. Lerner, *The Breast Cancer Wars: Hope, Fear and the Pursuit of a Cure of Twentieth-Century America* (New York: Oxford University Press, 2001). Go to http://www.oup-usa.org/isbn/0195142616.html

INTRODUCTION

Within months of Wilhelm von Roentgen's 1895 discovery of the x-ray, physicians began to use the new technology to visualize the inside of the body. For the most part, they employed these early radiographs to identify fractures, which appeared as irregularities the dense white bones, and pulmonary tuberculosis, which produced a whitish density within normally blackened lung fields. It was not until 1913 that a German surgeon, Albert Salomon, reported on his efforts to visualize cancer through radiography of the breast. Yet few attempted to replicate Salomon's efforts. Indeed, even as other types of x-rays became familiar diagnostic tools, it was not until the mid-1960s that mammograms began to emerge as an accepted technology.

By the late 1970s, mammography had diffused much more widely but had become a source of tremendous controversy. On the one hand, advocates of the technology enthusiastically touted its ability to detect smaller, more curable cancers. On the other hand, critics asked whether breast x-rays, particularly for women aged 50 and younger, actually caused more harm than benefit. As of the year 2000, despite the publication of hundreds of research studies, this dispute persists.

Mammography well exemplifies how social and cultural factors influence the dissemination of medical technologies into clinical practice. Although the sense persists that better instruments and better data can themselves solve pressing medical dilemmas, the history of mammography reminds us that even the best scientific information is subject to interpretation.

MEDICINE AND TECHNOLOGY

For many years, historians of medical technology, like others studying the history of technology, characterized innovation as the driving force for progress (Howell, 1996:228). That is, the technologies themselves, by producing advances in diagnostics or therapeutics, improved medicine's ability to care for patients. This construct has fallen out of favor. Since the 1960s and 1970s, historians have emphasized the ways in which various individuals and groups in society have influenced the diffusion of medical and other technologies. Moreover, these authors have argued that the information generated by such technologies is not objective but is constructed over time by historical actors (Pickstone, 1992); (Wailoo, 1997); (Stanton, 1999).

Because of the complex process of negotiation that attends the introduction of a new technology, diffusion is rarely linear. For example, as Joel Howell (1996) has demonstrated in his history of x-ray and electrocardiograph (EKG) machines in the early twentieth century, hospitals acquired these new devices before mechanisms existed for introducing them into medical practice. Only when hospitals began to attract paying customers and when physicians trained themselves to operate the new equipment, did use increase.

This discussion should not imply that the quality of the information generated has no influence on the acceptance of a technology. Mammography is a case in point. Between 1930 and 1950, physicians with an interest in radiology, including Stafford L. Warren of Rochester, New York, Jacob Gershon-Cohen of Philadelphia, and Raul Leborgne of Uruguay, spread the gospel of mammography as an adjunct to physical examination for the diagnosis of breast cancer. They introduced several technical innovations, such as double-emulsion film and breast compression, to produce higher-quality images. Yet mammographic films often remained dark and hazy. Moreover, the new techniques, while improving the images, were not easily reproduced by other investigators and clinicians (Gold et al., 1990).

The technical improvements introduced by Houston radiologist Robert L. Egan in the late 1950s had a dramatic impact on the spread of mammography. Egan, by using a high milliamperage-low voltage technique, a fine-grain intensifying screen, and industrial film, generated mammographic images that were clearer and therefore easier to interpret. Physicians across the country proved able to reproduce Egan's methods, which made the technology seem less esoteric. Most importantly, Egan presented data that strongly suggested the value of mammography in diagnosing breast cancer. Between 1956 and 1959, Egan and his colleagues at the M.D. Anderson Cancer Hospital took films on 1000 women evaluated in the breast clinic who did not have obvious cancer on physical examination. Of the 245 breast cancers ultimately confirmed by biopsy, Egan had identified 238 by mammography. Nineteen of these cancers were in women whose physical examinations had revealed no breast pathology. One of the cancers was only eight millimeters in diameter when sectioned at biopsy (Egan, 1960).

While Egan had made important technical improvements, the highly positive response to his work underscores the manner in which social factors influence the reception of medical technologies. For decades, Gershon-Cohen and his colleague Helen Ingleby (1958) had been lonely voices in claiming that mammography could help detect breast cancers that could not be discovered on examination. Relatively few, however, had rallied to the cause. But by the early 1960s, the perception of cancer among the medical profession and the public was dramatically changing. The American Cancer Society (ACS), founded in 1913 as the American Society for the Control of Cancer, had undergone a major reorganization and modernization program after World War II. Increasingly seeking to counter the fatalism that so often accompanied a diagnosis of cancer, ACS literature emphasized that breast and other cancers were highly curable if discovered early in their course (Patterson, 1987).

The ACS's efforts struck a positive chord in American society. The United States had just emerged victoriously from the war, and cancer seemed to be the next logical enemy to conquer (Lerner, 1998). As tuberculosis and other infectious diseases declined as causes of mortality, noncommunicable ailments had taken their place. By 1945, cancer was the second leading cause of death in America, behind only heart disease. Breast cancer was the leading cause of cancer deaths among women. Given the association of the breast with sexuality and intimacy, women particularly dreaded breast cancer. If anything, the country’s cultural fixation on the breast had increased during the war years, when buxom starlets, such as Jane Russell and Marilyn Monroe, replaced the skinny flapper as the country’s feminine ideal (Yalom, 1998:138, 177).

Given the high mortality from breast cancer, the cultural obsession with the breast, and its easy accessibility on the exterior of the body, activists accelerated the "war" on breast cancer inaugurated by the cancer society's "Women's Field Army" in the 1930s. While the Field Army had simply urged women to promptly show any breast lumps to their physicians, by 1950 the ACS was instructing women to perform monthly breast self-examination (BSE). Through BSE and clinical breast examinations in physicians' offices, the ACS believed that smaller and more treatable breast cancers could be discovered (Haagensen, 1950).

In this setting, the familiar but previously ignored technology of mammography held growing appeal. Given the potential of breast x-rays to help identify tiny, more curable breast cancers, it is hardly surprising that advocates began to tout mammography as an essential "weapon" in the fight against breast cancer. An additional advantage, they noted, was that the detection of smaller cancers through mammography enabled surgeons to use smaller operations than the highly disfiguring radical mastectomy most often employed.

Yet in order for mammography to gain wider acceptance, radiologists needed to champion it. The radiologic profession dated back to the early twentieth century, when a group of physicians had finally begun to use the x-ray machines lying dormant in hospital basements. Having acquired expertise in both operating these machines and interpreting the films that were generated, these physicians formed the American College of Radiology in 1923. Radiology became increasingly professionalized in the 1930s with the founding of the American Board of Radiology and its administration of the specialty's first qualifying examinations (del Regato, 1973); (Kevles, 1997:85). Over the subsequent decades, this process of professionalization continued with the establishment of numerous subspecialties within radiology.

Mammography emerged as a subspecialty within radiology in the 1960s. Building on the work of Gershon-Cohen and Egan, radiologists such as Herman C. Zuckerman and Philip Strax of New York City acquired significant experience in taking and reading breast x-rays. The laborious nature of this process should not be underestimated. Despite Egan’s recent technical breakthroughs, mammograms still consisted of confluent light and dark shadows that were considerably more difficult to interpret than other types of radiographs.Which images represented normal tissue, benign tumors (such as adenomas) and actual cancers was not immediately apparent. Rather, these mammographic pioneers painstakingly taught themselves the meaning of radiologic findings by comparing them to pathologic specimens obtained through biopsy and autopsy. The mammographers then gathered in groups, first locally and then nationally, "to pool our results, problems and technical improvements" (Zuckerman, 1961).

As a result of this process, breast radiologists obtained increasing authority in the clinical setting. In the 1940s and 1950s, surgeons had been highly skeptical of mammography, refusing to operate if they could not palpate a lesion detected by x-ray. "If I can't feel it on examination," many surgeons opined, "it's not there." But as Egan and others published a growing number of articles claiming that mammography enhanced the detection of small breast cancers, it became more difficult for surgeons to ignore the potential benefits of the new technology as well as the help that radiologists could offer. The power of finding a previously unsuspected cancer on x-ray, and possibly saving a woman's life as a result, was highly dramatic. As Memorial Sloan-Kettering Cancer Center breast surgeon Jerome A. Urban wrote to Zuckerman in 1964, "I think this is an

exciting finding and represents the third carcinoma which we personally did not strongly suspect on clinical examination." Urban closed his letter by stating "More power to you" (Urban, 1964). In addition to increased authority, mammography also provided radiologists with a source of income, especially when they began to use the films to assist with breast biopsies and other invasive procedures.

SEEING IS BELIEVING

Part of the growing enthusiasm for the mammogram stemmed from its visual nature (Stafford, 1992). As is often said, "seeing is believing," and this was most certainly the case for mammography. Once a mammographer had identified a possible cancer on x-ray, surgeons felt increasingly compelled to perform diagnostic biopsies. Indeed, although radiologists frequently reminded one another not to infer an outright diagnosis from a mammogram, the temptation to do so was great, especially as the images improved. Egan (1960), for example, wrote that a particular type of calcium deposit seen on mammograms--known as punctate calcification--was itself practically diagnostic of breast cancer. Over time, mammographers increasingly looked not only for evidence of cancer but for so-called "indirect signs" that merely raised a suspicion that cancer was present (Sickles, 1986).

Meanwhile, discussions of mammography fell into the trap mentioned earlier, where the technology itself was characterized as independently revealing hidden scientific information. "X-Ray Found Able to `See' Early Breast Cancer," read one newspaper headline (Van Buren, 1964). While careful not to use this type of language, even Egan (1969) wrote that mammography had a "certain magic appeal." The patient, he continued, "feels something special is being done for her." Strax (1979) would later write that "[t]he radiologist has become a potential savior of women--and their breasts."

Yet it would be wrong to single out radiologists as the only group that had a tendency to oversell the technically-improved mammogram. The American public was fascinated with visual imagery and had great faith in x-rays to reveal the secrets beneath the body's surface (Kevles, 1997). Women whose cancers had been discovered on a mammogram praised radiologists as heroes who had saved their lives. "As you well know by now, your suspicions were confirmed by a biopsy," wrote one woman to Zuckerman in 1964. "I shudder to think what I might have been doing a year or two from now were it not for you" (A.A., 1964).

But such anecdotal success stories hardly constituted proof of the value of mammography. By the early 1960s, researchers had begun to introduce more sophisticated statistical methodologies to evaluate both diagnostic and therapeutic interventions. Foremost among these strategies was the randomized controlled trial (RCT), which rigorously tested a new modality against either placebo or the existing standard of care. This changing emphasis in biostatistics led Philip Strax to propose that Egan's superior mammographic technique undergo formal evaluation. Strax, a radiologist on the staff of the Health Insurance Plan of Greater New York (HIP), had a personal connection to breast cancer: his first wife had died of the disease.

What Strax proposed was a trial that examined mammography as a screening tool. Until the 1960s, physicians ordered mammograms to help with the diagnosis of complicated cases in which the physical examination was inconclusive. In such an instance, a positive mammogram would encourage a surgeon to perform a diagnostic biopsy while a negative mammogram might render such a procedure unnecessary. While not challenging the value of mammography in these circumstances, Strax firmly believed that the tool's greatest utility was to help diagnose breast cancer in women with entirely normal physical examinations. Such mammographic screening was entirely congruent with the ACS's efforts to lower breast cancer mortality by identifying malignancies at their earliest, incipient stage.

Strax was able to organize and then implement his proposed RCT due to a series of fortunate circumstances. For one thing, HIP, a prepaid group medical insurance program, provided Strax with an identifiable population of women who could be followed over time. Strax also benefited from his collaboration with Sam Shapiro, who was HIP's Director of Research and Statistics. Shapiro designed an RCT which, while generating controversy over the years, successfully stood the test of time. Beginning in 1963, Strax, Shapiro and surgeon Louis Venet randomized 62,000 women aged 40-64 into one of two groups. The intervention group received an annual clinical breast examination and screening mammogram for four years; the control group received its usual care, which included breast cancer screening in some instances but not others.

With the publication of an article in the *Journal of the American Medical Association* in 1971, the HIP investigators appeared to have confirmed their suppositions. Although the relative contribution of mammography versus clinical examination was difficult to ascertain, physicians had clearly discovered earlier-stage breast cancers among women in the intervention group. Seventy percent of these cancers had negative underarm lymph nodes, which increased the likelihood that the disease was localized to the breast. In contrast, only 45 percent of the control group had apparently localized cancers. The most important finding, however, was that the death rate from breast cancer among women in the intervention arm was 40 percent lower than for those in the control group (Shapiro et al., 1971). Later data analysis would place this figure closer to 30 percent.

The HIP data generated tremendous excitement, especially at the American Cancer Society. For the first time since the organization's founding, evidence suggested that screening could lower mortality from the "dread disease," breast cancer. But the HIP study had its limitations. Most notably, if one stratified the data, the decreased death rate had occurred only among women aged 50 or older. For women in their forties, there was no statistically significant difference between those in the intervention and control groups. Given that women under 50 generally have denser breasts that are more poorly seen on mammography, such a result was not especially surprising.

With respect to these younger women, those promoting screening mammography found themselves at a fork in the road. One choice, promoted by a small group of statisticians and clinicians across the United States, was to continue randomized testing in the hope of generating definitive data. But another option was pursued. In 1972, the ACS, working with the National Cancer Institute (NCI), inaugurated the Breast Cancer Detection Demonstration Project (BCDDP), which planned to screen over a quarter of a million American women for breast cancer

with mammography and other modalities. The decision to eschew a controlled study implied a confidence in mammography not borne out by the existing data.

THE BCDDP IS LAUNCHED

The BCDDP emanated out of the Cancer Control Act, which President Richard Nixon had signed into law in December 1971. The act represented a major acceleration in America's war on breast and other cancers. The major beneficiary from the legislation was the NCI, which was to receive a total of $334 million annually to sponsor research designed to find a cure for cancer. But in the case of mammography, the ACS set the agenda (Patterson, 1987).

In the fall of 1971, sensing imminent passage of the cancer act, Arthur I. Holleb, ACS Senior Vice President for Medical Affairs and Research, had decided to act. Holleb, who was trained as a surgeon, began work at the ACS in the late 1940s. At this time, Holleb's predecessor as medical director, Charles S. Cameron, had just inaugurated a campaign to popularize cervical cancer screening with the Pap smear. Cameron's efforts, Holleb believed, had borne fruit. Widespread dissemination of the Pap test in the 1950s and 1960s had produced a decline in mortality from cervical cancer. "[T]he time has come," Holleb announced (1971), "for the American Cancer Society to mount a massive program on mammography just as we did with the Pap test."

Holleb had little doubt that screening mammography, by discovering smaller, more localized breast cancers, could lower breast cancer mortality among women in many age groups. The HIP study had been highly successful, he noted, but the virtues of screening mammography needed to be publicized (Anonymous, 1974a). Using rhetoric that his mentor Cameron might have chosen, Holleb issued his fighting orders (1971): "No longer can we ask the people of this country to tolerate a loss of life from breast cancer each year equal to the loss of life in the past ten years in Viet Nam. The time has come for greater national effort. I firmly believe that time is now."

Although Holleb was utterly sincere in his support of mammography, having a promising screening test available undeniably benefited the ACS as an organization. For decades, the cancer society had issued optimistic messages about the progress supposedly being made in screening for and then treating early cases of cancer. Yet in the case of breast cancer, annual mortality had remained defiantly stable at roughly 26 deaths per 100,000 women (Bailar and Smith, 1986). Routine mammography, it seemed, might finally lower this death rate. By validating the ACS's hopeful message of early detection, this good news about mammography could help the organization raise the funding that it needed in order to exist.

At times, the advocacy of screening mammography by the ACS almost appeared to be an end into itself. Achieving success in screening, chief statistician Herman Seidman noted (1976), "also serves to stimulate further interest in developing still better screening procedures." Indeed, one of the reasons that the ACS would decide to include women as young as 35 in the BCDDP was to inculcate them with "good health habits" (Anonymous, 1973). "One of our major efforts,"

Strax wrote (1979), "must be to make our screenee want to return periodically and to want to act as a missionary to bring other women into the screening process."

The multiple perceived virtues of mammography help to explain the program that Holleb advocated. Rejecting a randomized controlled trial of mammography in younger women, for whom the HIP data were inconclusive, the ACS chose to implement a demonstration project. This type of project, which was a traditional intervention of voluntary health agencies, sought to "demonstrate the feasibility of periodic screening of large numbers of women for breast cancer" (Anonymous, 1977). Over a five year period, enrolled women were to receive free annual mammography, clinical breast examinations and thermography, a technology that measured blood flow in order to detect small cancers.

Originally, the ACS had planned to implement the BCDDP at between eight and 12 clinics across the country. But given the momentum and funding supplied by the War on Cancer act, Holleb reconsidered. In September 1972, he approached Nathaniel I. Berlin, Director of NCI's Division of Cancer Biology and Diagnosis, and asked if the NCI would participate in a larger program. After obtaining approval from NCI Director Frank J. Rauscher, Jr., Berlin agreed, ultimately contributing over $6 million annually and enabling the establishment of 29 detection centers (Greenberg, 1976). The new goal for the BCDDP was to enroll 270,000 women, aged 35-74, beginning in 1973. Special efforts were made to include poor and minority women, who had been underrepresented in the HIP study. Berlin acknowledged that the HIP data had not conclusively shown that screening lowered mortality from breast cancer in younger women. Yet he believed that the BCDDP would demonstrate such an effect, especially given the improvements in mammographic technique that had occurred since the HIP study (Berlin, 1998).

Beyond women, radiologists and anticancer organizations, another group stood to benefit from the dissemination of mammography: the companies that manufactured the materials involved in x-ray production. With the promising findings of the HIP study and the launching of the BCDDP, these companies began to produce x-ray machines and film designed specifically for imaging the breast. Not surprisingly, such products were actively marketed (Kevles, 1997:253). Advertisements in medical journals, such as one for Kodak mammographic film, offered "a hopeful message from industry on a sober topic" (Anonymous, 1976a). Playing on the familiar notion that mammography itself revealed cancer, the Picker company claimed that its new Mammorex II device "can see it before she can feel it" (Anonymous, 1976b). Early news from the BCDDP was highly favorable. In October 1974, based on data from 42,000 women, the NCI reported that 77 percent of detected breast cancers--an even higher percentage than in the HIP study--contained no positive underarm lymph nodes (Anonymous, 1974b). But it was other events in September and October 1974 that transformed the BCDDP. When First Lady Betty Ford and Margaretta (Happy) Rockefeller, the wife of Vice President-Designate Nelson Rockefeller, announced that they had been diagnosed with breast cancer, women eagerly sought screening at demonstration project clinics. The rise in age-adjusted breast cancer incidence among women between 1973 and 1974--from 82.6 to 94.9 per 100,000 population--reflected this surge of interest (http://seer.cancer.gov/Publications/CSR1973-1997).

The message of the BCDDP was exactly what women wanted to hear given the news about Ford and Rockefeller: there was something they could do in the face of a terrifying disease.

As one woman later wrote, "I was one of the many thousands of women who tore, and I mean literally, over to [New York City's] Guttman Institute to commence a yearly mammogram and thermogram program" (E.R., 1978). Screening mammography played into two important cultural attributes of Americans. First, having a mammogram enabled women to take personal responsibility for their health, a duty that American public health campaigns had long encouraged. Second, having a mammogram became seen as a way to improve one's odds against breast cancer, and thus fit well with the risk-aversive response of Americans to the threat of disease (Lerner, 2001). "Every woman," Strax wrote in 1974, "carries within her body a built-in hazard--the risk of breast cancer." Ignoring such a risk, he warned, might produce "disastrous results to herself and her family" (Strax, 1974). Strax reiterated this theme in 1977, stating that women "harboring breast cancer in a curable stage" who did not undergo screening were "playing Russian roulette with their lives" (Anonymous, 1977a). Choosing mammography, according to this logic, was the least risky choice in an uncertain situation (Press et al., 2000).

Within two years of the BCDDP's inauguration, the media was trumpeting the apparent successes of the project. To some degree, this process was promoted by the ACS, which hosted a Science Writers' Seminar in conjunction with its annual meeting. Such events educated reporters on breast and other cancers but also placed a positive spin on ACS activities. "Breast project is saving lives," announced the San Antonio Evening News (Anonymous, 1975). "Mammography makes the difference," reported an article on the Guttman Institute, one of the BCDDP sites. "It is truly a life saver" (Bernstein, 1975). Yet if certain members of the media accentuated the BCDDP's accomplishments, others chose to castigate the project once questions about its utility and ethics were raised.

A WHISTLE IS BLOWN

The individual most responsible for the heated debates over mammography in the mid-1970s was John C. Bailar, III. Bailar was a physician who pursued further training in biostatistics and epidemiology rather than becoming a practicing clinician. In the early years of the BCDDP, Bailar was the NCI's Deputy Associate Director for Cancer Control. On October 1, 1975, Washington D.C. journalist Jack Anderson printed excerpts from an article that Bailar would eventually publish in the *Annals of Internal Medicine* in January 1976. In questioning the risk-benefit assessment that had induced the ACS and the NCI to proceed with the BCDDP, Bailar inaugurated a line of critique that has continued to have a dramatic influence on the spread of mammography.

The HIP study, Bailar wrote, had not definitively determined the benefits of screening mammography. In support of this claim, he cited lead-time and length biases, two statistical phenomena that potentially led observers to exaggerate the value of screening tests. Routine mammography, Bailar feared, was apt to detect many slow-growing lesions unlikely to ever become clinically significant breast cancers. These included ductal and lobular carcinoma in situ, which were collections of cancer-like cells that had not actually invaded the breast tissue. Although Bailar initially challenged screening mammography in all age groups, he eventually focused his concerns on women under 50.

Meanwhile, Bailar argued, the risks of mammograms "may be greater than are commonly understood." Citing "experimental and clinical evidence ... that ionizing radiation can cause breast cancer," he wondered (1976) "why questions about the effects of radiation used in mammography have not been investigated more actively." It is worth emphasizing that Bailar's doubts about mammography, as with those subsequently raised by other critics, pertained to screening studies. Physicians agreed that breast x-rays remained appropriate for women with identifiable breast problems who needed testing for diagnostic purposes.

Bailar's challenge to the BCDDP was especially devastating because he was employed by one of the cosponsoring agencies. Yet Bailar had not blindsided his colleagues. Since the earliest days of the program, he had voiced numerous concerns to Rauscher, Berlin and others (Greenberg, 1976). In addition to Bailar's questions about benefit and risk, he had also objected to the BCDDP's methodology. Having rejected an RCT in favor of an uncontrolled demonstration project, Bailar wrote, the ACS and NCI were nevertheless planning to collect research data regarding the value of screening mammography (as well as thermography and clinical breast examination). Bailar cautioned that such uncontrolled data would not permit any meaningful conclusions. Although others at NCI and across the country shared Bailar's reservations, those in charge of the BCDDP concluded that it should proceed as planned.

Yet, once Bailar's concerns became public, the NCI commissioned a series of internal reports to study his claims. One of these reports, completed by University of California at Los Angeles Public Health School Dean Lester Breslow and colleagues, concluded that the HIP study did not support the use of screening mammography in women aged 40 to 50. Breslow's group recommended that the BCDDP discontinue mammography among these younger women. Another study, from a group headed by Arthur C. Upton of the State University of New York at Stony Brook, concluded that the radiation from low dose mammograms posed only a "very, very small risk to the individual" (Culliton, 1976). But in light of Breslow's data, Upton, too, expressed reluctance regarding routine mammographic screening in women under 50.

The NCI was not the only organization to investigate the issues that Bailar had raised. For example, through a Freedom of Information Act (FOIA) request, Sidney Wolfe of Ralph Nader's Health Research Group learned the results of internal testing of 57 BCDDP mammography machines. Sixteen exposed women to more than the acceptable level of one to two rads that Upton's group had used in its calculations of radiation risk. One machine even registered 6.5 rads per mammogram (Culliton, 1976).

But it was the media--particularly print reporters in Washington, D.C.--that most eagerly pursued the BCDDP controversy. Of particular note was an article written by the journalist Daniel S. Greenberg in the September 23, 1976 issue of the prestigious New England Journal of Medicine. Through another FOIA, Greenberg had obtained a series of internal documents detailing the initial reservations of NCI staff members regarding the BCDDP. Charging that these legitimate concerns had been ignored, Greenberg (1976) concluded that "there is more than a bit to be appalled about in the archives of the Breast Cancer Demonstration Project." To Greenberg and his fellow investigative reporters, the BCDDP provided an excellent opportunity to challenge more broadly the assumptions and programs of the anticancer establishment.

In response to these charges, officials at the ACS and the NCI made a series of changes in the BCDDP. For example, they revised the original consent form to indicate to potential enrollees that mammography carried potential risks. They also accelerated efforts to standardize radiation dosages at the various BCDDP sites, a process that radiologists had initiated but had never been completed. Most notably, in August 1976, the ACS and the NCI decided to offer mammography only to those women under 50 who were at "high risk" (Anonymous, 1976c).

But this latter decision resolved little. Arthur Holleb and the ACS chose to define "high risk" extremely broadly, including younger women who had chronic breast cysts; personal breast cancer histories or past diagnostic breast surgery; family breast cancer histories; early menstrual histories; no pregnancies; a first full-term pregnancy at age 30 or older; or an unusual fear of breast cancer. Holleb estimated that roughly 80 percent of women aged 35 to 50 fell into one of these high-risk categories, thus making them eligible for screening mammography (Cohn, 1976).

This extensive delineation of risk factors drew on familiar American cultural beliefs. Emphasizing the great risk of breast cancer--and then offering a meliorative technological intervention--enabled women to take action in order to avoid a bad health outcome. The ACS's effort at risk assessment also highlighted what would become perhaps the most fundamental tension in the subsequent debates over screening mammography. The newer population-based methods used by Bailar and other epidemiologists, which assessed the value of the interventions among large numbers of individuals, directly threatened the more traditional patient-centered approach taken by clinicians. The ACS was dominated by physicians, such as Holleb, all of whom could recall patients who had apparently died because their breast cancers had been detected too late. "I don't see how you can say there is no benefit [to mammography]," protested the NCI's Rauscher. "To those individual women whose cancer is detected, there certainly is a benefit" (Culliton, 1976).

But it was precisely this claim, however intuitively appealing, that Bailar and others questioned. Just because a mammogram helped to detect an abnormality that was subsequently treated did not in and of itself prove the value of this series of interventions. Such cancers might never have killed the women, for example, or might have been detected later with a comparable outcome. Bailar also termed "mathematically absurd" the notion that 80 percent of young women could be at high risk for breast cancer. "We simply cannot have everybody, or even a majority, at risks that are significantly above average" (Anonymous, 1977b:49).

In an effort to help resolve the increasingly contentious debates about the use of mammography in younger women, the National Institutes of Health (NIH) scheduled a consensus conference for September 1977. This meeting would become the first of a series of NIH conferences that sought to evaluate the appropriate use of emerging health care technologies in the clinical setting. The conferences involved the convening of an expert panel that heard testimony from scientists and interested laypersons and then reached a consensus about the current status of the technology in question (Mullan and Jacoby, 1985). As one of the planning steps for the September 1977 meeting, the NCI asked University of Utah pathologist Robert W. McDivitt to review the pathology of 506 so-called "minimal" breast lesions of less than one centimeter in diameter that had been discovered during the BCDDP. These lesions included both cancer and carcinoma in situ.

ACS and NCI officials viewed the ability to unearth and treat these ostensibly early, highly curable cancers as the BCDDP's greatest achievement. Yet McDivitt's preliminary report, presented at the consensus conference, once again generated controversy as opposed to agreement. McDivitt reported that 66 of the 506 pathological specimens--53 of which had resulted in some type of mastectomy--had contained neither cancer nor carcinoma in situ (Greenberg, 1978). These apparently unnecessary mastectomies were not really the fault of the BCDDP, McDivitt emphasized. Because the clinicians and mammographers associated with the project had merely identified abnormalities that required evaluation, physicians at hospitals across the country had actually performed the biopsies, made the diagnoses, and then treated the patients.

The NCI had anticipated that the BCDDP would lead to the discovery of a significant number of biologically ambiguous specimens, and in 1974 had convened a meeting of eminent pathologists to discuss the problem. As with other concerns about the BCDDP, however, this issue did not induce either the NCI or the ACS to alter the structure of the project. Predictably, reporters seized on this issue as further evidence of the overzealousness of the BCDDP organizers. William Hines, for example, compared the "surgical mutilation" suffered by the 53 BCDDP enrollees to the previous year's swine flu vaccine debacle (Hines, 1977). More sedately, the New York Times editorial page questioned the "indiscriminate use of [early diagnosis] on younger women before research has determined whether it causes more harm than good" (Anonymous, 1977c:22).

The debate over the 66 cases was never formally resolved. A subsequent working group, chaired by Mayo Clinic surgeon Oliver Beahrs, obtained more complete pathological material and concluded that only three women, at most, had undergone improper mastectomies. McDivitt disagreed, claiming that the diagnosis of at least 48 of the cases remained unclear. Another maelstrom ensued when the NCI decided not to directly inform the 66 women of the possible misdiagnoses but to leave this responsibility to the physicians who had treated them. Breast cancer activists, such as Rose Kushner, found this situation deplorable. "I wonder," she remarked (1977) at the consensus conference, "if anyone has told these lucky women that they no longer have to worry about recurrences and metastases."

Nearly lost in the acrimonious atmosphere of the consensus conference was the fact that compromise had been reached on several aspects of the BCDDP. The consensus panel, chaired by Yale University Professor of Medicine Samuel Thier, recommended further revision of the BCDDP consent form to encourage women to obtain opinions from multiple pathologists if the screening process led to the diagnosis of borderline or non-infiltrating cancers of uncertain biological significance. It also advocated that women and consumer representatives participate in the design of future studies (Anonymous, 1978). The panel agreed that annual mammographic screening of women over 50 remained appropriate but recommended that women aged 40 to 49 receive testing only if they had previous breast cancer or a strong family history of breast cancer. Women aged 35 to 39 needed mammograms only if they themselves had had the disease.

Over the next two decades, consensus would persist in many areas. For example, relying on statistics that consistently demonstrated a 30 percent reduction in mortality, the ACS, American College of Radiology and other organizations continued to recommend annual

mammography for women aged 50 to 69 (Leitch, 1999). The development of film-screen mammography, commentators agreed, had lowered the amount of radiation used to much safer levels. The Mammography Quality Standards Act of 1992 further ensured the safety and efficacy of mammographic equipment (Bassett, 1996). But as more data from the BCDDP and a series of RCTs conducted outside of the United States became available in the 1980s and 1990s, whatever agreement existed regarding screening mammography for women under 50 would disappear.

MORE DATA, FEWER ANSWERS

The American Cancer Society broke ranks with the National Cancer Institute and other organizations in 1980, advocating that women aged 35 to 39 receive a baseline mammogram. In 1983, the ACS recommended that women aged 40 to 49 have a screening mammogram every one to two years. This decision drew in part on the BCDDP, which had concluded screening in 1980 but continued to generate data. Ninety-one percent of younger women diagnosed with breast cancer or carcinoma in situ during the BCDDP had survived five years--an even better rate than that of older women diagnosed during the project. Moreover, physicians had detected 35 percent of the cancers in the younger women by mammography alone (Baker, 1982). Even though the methodology of the BCDDP limited its value as a research tool, the ACS had nevertheless concluded that "screening including mammography detects breast cancer at favorable stages and saves lives" (Anonymous, 1982), both for older women and those in their forties.

In another attempt to create consensus, the NCI, the American College of Radiology and eleven other medical organizations joined the ACS in 1988 in recommending routine screening mammograms for younger women. But dissent reemerged in 1993, when the NCI withdrew its support for this policy. The major impetus for the NCI's change of heart was its analysis of the growing amount of data available from a series of randomized controlled trials of mammography that included women in their forties. By 1993, there were eight such trials, one of which was the HIP study. Based on a meta-analysis of these trials, Suzanne Fletcher and her copanelists at the International Workshop on Screening for Breast Cancer had concluded that mammography had demonstrated no benefit (Leitch, 1999). As a result, the NCI had withdrawn its support of routine mammograms for women under 50.

The schism between those who favored and opposed screening mammography became even more apparent in January 1997, when NCI Director Richard D. Klausner convened yet another consensus conference on the topic. Klausner had acted in large part because he believed that additional data from the eight RCTs now definitively indicated that women in their forties should receive regular screening. Klausner attempted to obtain as objective an assessment as possible by appointing a 13-member panel of physicians, epidemiologists and others whose particular expertise was not in breast cancer. After reading hundreds of papers and hearing testimony from 32 experts, the panel, chaired by Johns Hopkins University epidemiologist Leon Gordis, issued its majority conclusion: there was not enough evidence to support routine screening mammography for women in their forties (Anonymous, 1997).

The panel's judgment, and the vitriolic reaction that ensued, offer an excellent opportunity to revisit the themes discussed throughout this essay. The growing dissemination of

mammography beginning in the 1960s did not simply result from improvements in technology. Rather, it drew on a reinvigorated national war against breast cancer; the interests of anticancer activists, radiologists and other physicians in fighting such a war; and the persistent belief that mammographic images revealed the hidden "truth." Similarly, opposition to mammography did not only reflect its technical deficiencies but the desire of journalist and physician “skeptics” to challenge conventional wisdom and the growing role of more sophisticated population-based statistics in guiding medical care.

Given the great social, cultural and professional issues at stake in the debates over mammography, it is hardly surprising that the consensus panel's decision to reject routine screening would incite protest. Still, the degree of animosity was striking. Daniel B. Kopans, a Harvard Medical School radiologist who has become the country's fiercest advocate for screening, called the panel's conclusion "fraudulent" (Kolata, 1997b). New Mexico mammographer Michael Linver stated that withholding mammography from women in their forties was "tantamount to a death sentence" (Kolata, 1997a). One reporter covering the imbroglio dubbed it the "Breast Screening Brawl." Ultimately, the United States Senate, eager to please voters and the increasingly powerful breast cancer lobby, got into the act, voting 98-0 to encourage the NCI's National Cancer Advisory Board (NCAB) to reject the consensus panel's conclusions.

In retrospect, the notion that a group of scientists would use the available data to dispassionately reach a consensus was problematic. While such a process may be possible when statistics are straightforward, mammography in women under 50 was a screening initiative in a low-risk population. As a result, any benefit discovered was likely to be small. In this setting, panel members were likely to interpret the statistics in light of their scientific, professional and personal backgrounds. Perhaps the consensus panel might more profitably have been comprised of 13 anthropologists or social scientists, who could have pointed out the multiple sociocultural factors that inevitably influence the interpretation of supposedly "objective" data.

This last point was driven home by several commentators, who pointed out that the experts on opposing sides of the screening debate had not really disagreed about what the data showed. Rather, they had interpreted and then presented the statistics differently (Ransohoff and Harris, 1997); (Sox, 1998). Thus, those in favor of mammography pointed out that screening women in their forties reduced deaths from breast cancer by 16 to 18 percent, at least half as much as it did in older women. Without disputing this seemingly impressive drop in mortality, opponents argued that 2,500 healthy women under 50 would have to receive regular screening in order to extend one life. Such a strategy, they added, would result in many unnecessary interventions--such as additional x-rays, doctors' appointments and biopsies--in women without any actual breast disease (Elmore et al., 1998); (Dickersin, 1999). Opponents of screening mammography in younger women also raised the issue of cost, claiming that every year of life saved would require $108,000. The fact that the same data could be presented in so many different ways interfered with efforts to quantify the benefits and risks of mammography (Press et al., 2000).

Further complicating the debate were issues of insurance coverage, class and race. The consensus panel's recommendation, that individual women in their forties discuss the pros and

cons of mammography with their providers, potentially gave insurance companies a justification for refusing to pay for such tests. This consequence was of particular concern to poor and minority women, who had long had lower rates of mammography than white, more affluent women. Many feminist groups felt torn by the controversy, on the one hand favoring increased access to mammography for those in need but also appreciating the panel's stance that women should be empowered to make their own decisions about undergoing screening. Finally, concerns that omitted mammograms might make them vulnerable to malpractice lawsuits induced many physicians to favor a blanket recommendation of screening.

In short order, many groups turned against the NIH consensus panel's decision. In March 1997, the ACS changed its recommendation, advising women in their forties to have screening mammography every year. The American College of Radiology soon issued the same recommendation. Also in March 1997, the NCAB followed the Senate's advice and adopted the old ACS policy that favored screening women between 40 and 50 at least every other year. This decision effectively reversed the conclusion of the January consensus conference and brought the NCI close to the position of the ACS (Leitch, 1999). Despite these developments, other organizations, including the U.S. Preventive Services Task Force, continue to oppose routine screening in favor of individualized case assessment.

CONCLUSION

The history of mammography demonstrates how the dissemination of medical technologies depends on the social, political and ideological context into which they are introduced. Mammography languished for decades after it was first attempted. Technical improvements contributed to its growing use after 1970. Yet a series of other factors--such as the acceleration of America’s war on breast cancer and the professional interests of mammography advocates--played a more important role. At the same time, opposition to mammography in younger women provided a mechanism for questioning the anticancer establishment and promoting the use of epidemiological studies in the clinical setting. The production of better data alone cannot eliminate the role that economics, authority and ideology play in the assessment of mammography and other early detection technologies.

Sociocultural factors not only influence the answers to questions about cancer screening, but also the questions themselves. We need to examine why so much of the mammography literature (this article included) has focused on the debates over screening women in their forties. Why has proving or disproving the value of this intervention taken on such great cultural significance? As some commentators have argued, a much larger dent in breast cancer mortality could likely be made by improving access to and compliance with mammography among women aged 50 to 69 (Aronowitz, 1995). Others have begun to stress the possible benefits of promoting breast cancer screening among women aged 70 and older, who have typically been overlooked by researchers and clinicians (American Geriatrics Society, 2000).

The need to revisit what questions we ask has never been more important. Increasingly sophisticated breast cancer screening modalities have arrived (Office on Women's Health, 1996). One of these is digital mammography, which uses computer technology to produce much more

distinct images than conventional x-rays. Advocates of digital mammography, including manufacturers and radiologists, argue that it will help detect even smaller breast cancers and cut down on the number of false-positives.

This claim may well turn out to be true. Mammography pioneers such as Robert Egan and Philip Strax successfully demonstrated how technical improvements and better evaluative techniques could help to disseminate a useful medical technology. Yet the history of mammography cautions us that technology itself is unlikely to provide a "quick fix" for breast cancer screening. More sophisticated and "lifelike" visual images are no more "real" than their mammographic counterparts; their meanings must also be constructed. And more data, even those generated in randomized clinical trials, will not necessarily answer questions about what screening technologies can accomplish (Fletcher, 1997). Indeed, there is no screening test as thoroughly evaluated as mammography, yet difficult quandaries persist. The evaluation and subsequent dissemination of digital mammography and other new screening tools will continue to depend on how health care providers, patients and society respond to the promises and pitfalls of these technologies.

ACKNOWLEDGMENTS

* This phrase is from Edward F. Lewison, "Changing Concepts in Breast Cancer," *Cancer* 46 (1980):859-864. Joel D. Howell and H. Gilbert Welch read earlier drafts of this manuscript.

REFERENCES

A.A., 1964. Letter to Herman C. Zuckerman, September 11. Courtesy of Herman Zuckerman.

American Geriatrics Society Clinical Practice Committee. 2000. Breast cancer screening in older women. *Journal of the American Geriatrics Society* 48:842-844.

Anonymous. 1973. Changing concepts in managing cancer of the breast. Audio-Digest. *Surgery* 20:2, January 31, 1973.

Anonymous. 1974a. Minutes of special meeting for discussion of project protocol, January 9. Courtesy of John Bailar.

Anonymous. 1974b. A hectic week for breast cancer researchers. *Medical World News*, October 25, 19-22.

Anonymous. 1975. Breast project is saving lives. *San Antonio Evening News,* November 7.

Anonymous. 1976a. About breast cancer and x-rays. *Science.* 193:back cover.

Anonymous. 1976b. Mammorex II. *Radiology* 121:140A-141A.

Anonymous. 1976c. Cancer institute proposes limits on breast x-rays. *The New York Times,* August 23, 12.

Anonymous. 1977a. Re: ACS Breast Cancer Task Force Meeting--June '77, unpublished document. Courtesy of Philip Strax.

Anonymous. 1977b. *Consensus development meeting on breast cancer screening, September 14-16, 1977.* Washington, DC: Department of Health, Education and Welfare.

Anonymous. 1977c. From the editor. *New York Times*, October 8.

Anonymous. 1978. National Institutes of Health/National Cancer Institute consensus development meeting on breast cancer screening. *Journal of the National Cancer Institute* 60:1519-1520.

Anonymous. 1982. End Results: The Breast Cancer Detection Demonstration Project, unpublished document, ACS Media Division, New York, NY. Folder: Breast Cancer Demonstration Projects.

Anonymous. 1997. Breast cancer screening for women ages 40-49. *NIH Consensus Statement* 15:1-35.

Aronowitz, R. 1995. To screen or not to screen: what is the question [Editorial]? *Journal of General Internal Medicine* 10:295-297.

Bailar, J.C., III. 1976. Mammography: a contrary view. *Annals of Internal Medicine* 84:77-84.

Bailar, J.C., III, and E.M. Smith. 1986. Progress against cancer? *New England Journal of Medicine* 314:1226-1232.

Baker, L.H. 1982. Breast cancer detection demonstration project: five-year summary report. *Ca* 32:194-225.

Bassett, L.W. 1996. The regulation of mammography. *Seminars in Ultrasound, CT and MRI* 17:415-423.

Berlin, N.I. 1998. Interview with the author, November 3.

Bernstein, P. 1975. Mammography: it's a tool that can save lives. *New York Post*, March 4, 44.

Cohn, V. 1976. Women avoiding breast cancer test. *Washington Post*, November 23, A3.

Culliton, B.J. 1976. Breast cancer: second thoughts about routine mammography. *Science* 193:555-558.

del Regato, J.A. 1973. The American College of Radiology: fiftieth anniversary. *Radiology* 107:1-13.

Dickersin, K. 1999. Breast screening in women aged 40-49 years: what next? *Lancet* 353:1896-1897.

E.R., 1978. Letter to Betty Rollin, May 7. Betty Rollin Papers, State Historical Society of Wisconsin, Madison WI. Box 6, Folder 7.

Egan, R.L. 1960. Experience with mammography at a tumor institution. *American Journal of Roentgenology* 75:894-900.

Egan, R.L. 1969. Roles of mammography in the early detection of breast cancer. *Cancer* 24:1197-1200.

Elmore, J.G., M.B. Barton, V.M. Moceri, S. Polk, P.J. Arena, and S.W. Fletcher. 1998. Ten-year risk of false positive screening mammograms and clinical breast examinations. *New England Journal of Medicine* 338:1089-1096.

Fletcher, S.W. 1997. Whither scientific deliberation in health policy recommendations. *New England Journal of Medicine* 336:1180-1183.

Gershon-Cohen, J., and H. Ingleby. 1958. Roentgenography of unsuspected carcinoma of breast. *Journal of the American Medical Association* 166:869-873.

Gold, R.H., L.W. Bassett, and B.E. Widoff. 1990. Highlights from the history of mammography. *Radiographics* 10:1111-1131.

Greenberg, D.S. 1976. X-ray mammography--background to a decision. *New England Journal of Medicine* 295:739-740.

Greenberg, D.S. 1978. A cancer controversy: did doctor know best? *Washington Post*, April 4.

Haagensen, C.D. 1950. *Carcinoma of the breast*. New York: American Cancer Society.

Hines, W. 1977. Breast surgery cases probed. *Pittsburgh Press*, September 25.

Holleb, A.I. 1971. Toward better control of breast cancer, American Cancer Society press release, October 4. ACS Media Division, Folder: Breast Cancer Facts.

Howell, J.D. 1996. *Technology in the hospital: transforming patient care in the early twentieth century*. Baltimore: Johns Hopkins University Press.

Kevles, B.H. 1997. *Naked to the bone: medical imaging in the twentieth century*. New Brunswick, NJ: Rutgers University Press.

Kolata, G. 1997a. Mammogram talks prove indefinite. *New York Times*, January 24, A1, A15.

Kolata, G. 1997b. Stand on mammograms greeted by outrage. *New York Times*, January 28, C1, C8.

Kushner, R. 1977. Addendum to earlier submission to the consensus committee regarding the BCDDPs, September 13. Rose Kushner Papers, Schlesinger Library, Cambridge, MA. Box 1, unmarked manila folder.

Leitch, A.M. 1999. Breast cancer screening: success amid conflict. *Surgical Oncology Clinics of North America* 8:657-672.

Lerner, B.H. 1998. Fighting the war on breast cancer: debates over early detection, 1945 to the present. *Annals of Internal Medicine* 129:74-78.

Lerner, B.H. 2001. *The breast cancer wars: hope, fear and the pursuit of a cure in twentieth-century America*. New York: Oxford University Press.

Mullan, F., and I. Jacoby. 1985. The town meeting for technology: the maturation of consensus conferences. *Journal of the American Medical Association* 254:1068-1072.

Office on Women's Health, U.S. Public Health Service. 1996. *From Missiles to Mammograms: A Capitol Hill Briefing*. Washington, DC: Department of Health and Human Services.

Patterson, J.T. 1987. *The dread disease: Cancer and modern American culture*. Cambridge, MA: Harvard University Press.

Pickstone, J.V., ed. 1992. *Medical innovations in historical perspective*. New York: St. Martin's Press.

Press, N., J.R. Fishman, and B.A. Koenig. 2000. Collective fear, individualized risk: the social and cultural context of genetic testing for breast cancer. *Nursing Ethics* 7:237-249.

Ransohoff, D.F, and R.P. Harris. 1997. Lessons from the mammography screening controversy: can we improve the debate? *Annals of Internal Medicine* 127:1029-1034.

Seidman, H. 1976. Letter to Arthur I. Holleb, February 12. Courtesy of John Bailar.

Shapiro, S., P. Strax, and L. Venet. 1971. Periodic breast cancer screening in reducing mortality from breast cancer. *Journal of the American Medical Association* 215:1777-1785.

Sickles, E.A. 1986. Mammographic features of 300 consecutive nonpalpable breast cancers. *American Journal of Radiology* 146:661-663.

Sox, H.C. 1998. Benefit and harm associated with screening for breast cancer [Editorial]. *New England Journal of Medicine* 338:1145-1146.

Stafford, Barbara M. 1992. *Body criticism: imaging the unseen in Enlightenment art and medicine*. Cambridge, MA: MIT Press.

Stanton, J. 1999. Making sense of technologies in medicine. *Social History of Medicine* 12:437-448.

Strax, P. 1974. *Early detection: breast cancer is curable*. New York: Harper & Row.

Strax, P. n.d. Radiologist's role in screening mammography, unpublished document. Courtesy of Philip Strax.

Urban, J.A. 1964. Letter to Herman C. Zuckerman, November 4. Courtesy of Herman Zuckerman.

Van Buren, J. 1964. X-ray found able to `see' early breast cancer. *Rochester (N.Y.) Democrat and Chronicle*.

Wailoo, K. 1997. *Drawing blood: technology and disease identity in twentieth-century America*. Baltimore & London: The Johns Hopkins University Press.

Yalom, M. 1998. *A history of the breast*. New York: Alfred A. Knopf.

Zuckerman, H.C. 1961. Letter to Jacob Gershon-Cohen, December 28. Courtesy of Herman Zuckerman.