

## **Dangers and Unreliability of Mammography: Breast Examination is a Safe, Effective, and Practical Alternative**

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Mammography screening is a profit-driven technology posing risks compounded by unreliability. In striking contrast, annual clinical breast examination (CBE) by a trained health professional, together with monthly breast self-examination (BSE), is safe, at least as effective, and low in cost. International programs for training nurses how to perform CBE and teach BSE are critical and overdue.

Contrary to popular belief and assurances by the U. S. media and the cancer establishment- the National Cancer Institute (NCI) and American Cancer Society (ACS)- mammography is not a technique for early diagnosis. In fact, a breast cancer has usually been present for about eight years before it can finally be detected. Furthermore, screening should be recognized as damage control, rather than misleadingly as "secondary prevention."

### **DANGERS OF SCREENING MAMMOGRAPHY**

Mammography poses a wide range of risks of which women worldwide still remain uninformed.

#### *Radiation Risks*

Radiation from routine mammography poses significant cumulative risks of initiating and promoting breast cancer (1- 3). Contrary to conventional assurances that radiation exposure from mammography is trivial- and similar to that from a chest X-ray or spending one week in Denver, about 1/ 1,000 of a rad (radiation-absorbed dose)- the routine practice of taking four films for each breast results in some 1,000-fold greater exposure, 1 rad, focused on each breast rather than the entire chest (2). Thus, premenopausal women undergoing annual screening over a ten-year period are exposed to a total of about 10 rads for each breast. As emphasized some three decades ago, the premenopausal breast is highly sensitive to radiation, each rad of exposure increasing breast cancer risk by 1 percent, resulting in a cumulative 10 percent increased risk over ten years of premenopausal screening, usually from ages 40 to 50 (4); risks are even greater for "baseline" screening at younger ages, for which there is no evidence of any future relevance. Furthermore, breast cancer risks from mammography are up to fourfold higher for the 1 to 2 percent of women who are silent carriers of the A-T (ataxia-telangiectasia) gene and thus highly sensitive to the carcinogenic effects of radiation (5); by some estimates this accounts for up to 20 percent of all breast cancers annually in the United States (6).

#### *Cancer Risks from Breast Compression*

As early as 1928, physicians were warned to handle "cancerous breasts with care- for fear of accidentally disseminating cells" and spreading cancer (7). Nevertheless, mammography entails tight and often painful compression of the breast, particularly in premenopausal women. This may lead to distant and lethal spread of malignant cells by rupturing small blood vessels in or around small, as yet undetected breast cancers (8).

#### *Delays in Diagnostic Mammography*

As increasing numbers of premenopausal women are responding to the ACS's aggressively promoted screening, imaging centers are becoming flooded and overwhelmed. Resultingly, patients referred for diagnostic mammography are now experiencing potentially dangerous delays, up to several months, before they can be examined (9).

### **UNRELIABILITY OF MAMMOGRAPHY**

#### *Falsely Negative Mammograms*

Missed cancers are particularly common in premenopausal women owing to the dense and highly glandular structure of their breasts and increased proliferation late in their menstrual cycle (10, 11). Missed cancers are also common in post-menopausal women on estrogen replacement therapy, as about 20 percent develop breast densities that make their mammograms as difficult to read as those of premenopausal women (12).

#### *Interval Cancers*

About one-third of all cancers- and more still of premenopausal cancers, which are aggressive, even to the extent of doubling in size in one month, and more likely to metastasize- are diagnosed in the interval between successive annual mammograms (2, 13). Premenopausal women, particularly, can thus be lulled into a false sense of security by a supposedly negative result on an annual mammogram and fail to seek medical advice.

### *Falsely Positive Mammogram*

Mistakenly diagnosed cancers are particularly common in premenopausal women, and also in postmenopausal women on estrogen replacement therapy, resulting in needless anxiety, more mammograms, and unnecessary biopsies (14, 15). For women with multiple high-risk factors, including a strong family history, prolonged use of the contraceptive pill, early menarche, and nulliparity- just those groups that are most strongly urged to have annual mammograms- the cumulative risk of false positives increases to "as high as 100 percent" over a decade's screening (16).

### *Overdiagnosis*

Overdiagnosis and subsequent overtreatment are among the major risks of mammography. The widespread and virtually unchallenged acceptance of screening has resulted in a dramatic increase in the diagnosis of ductal carcinoma-in-situ (DCIS), a pre-invasive cancer, with a current estimated incidence of about 40,000 annually. DCIS is usually recognized as micro-calcifications and generally treated by lumpectomy plus radiation or even mastectomy and chemotherapy (17). However, some 80 percent of all DCIS never become invasive even if left untreated (18). Furthermore, the breast cancer mortality from DCIS is the same- about 1 percent- both for women diagnosed and treated early and for those diagnosed later following the development of invasive cancer (17). That early detection of DCIS does not reduce mortality is further confirmed by the 13-year follow-up results of the Canadian National Breast Cancer Screening Study (19). Nevertheless, as recently stressed, "the public is much less informed about over-diagnosis than false positive results. In a recent nationwide survey of women, 99 percent of respondents were aware of the possibility of false positive results from mammography, but only 6 percent were aware of either DCIS by name or the fact that mammography could detect a form of 'cancer' that often doesn't progress" (20).

### *Quality Control*

In 1992 Congress passed the National Mammography Standards Quality Assurance Act requiring the Food and Drug Administration (FDA) to ensure that screening centers review their results and performance: collect data on biopsy outcomes and match them with the original radiologist's interpretation of the films (21). However, the centers do not release these data because the Act does not require them to do so. It is essential that this information now be made fully public so that concerns about the reliability of mammography can be further evaluated. Activist breast cancer groups would most likely strongly support, if not help to initiate, such overdue action by the FDA.

## **FAILURE TO REDUCE BREAST CANCER MORTALITY**

Despite the long-standing claims, the evidence that routine mammography screening allows early detection and treatment of breast cancer, thereby reducing mortality, is at best highly questionable. In fact, "the overwhelming majority of breast cancers are unaffected by early detection, either because they are aggressive or slow growing" (21). There is supportive evidence that the major variable predicting survival is "biological determinism- a combination of the virulence of the individual tumor plus the host's immune response," rather than just early detection (22).

Claims for the benefit of screening mammography in reducing breast cancer mortality are based on eight international controlled trials involving about 500,000 women (23). However, recent meta-analysis of these trials revealed that only two, based on 66,000 postmenopausal women, were adequately randomized to allow statistically valid conclusions (23). Based on these two trials, the authors concluded that "there is no reliable evidence that screening decreases breast cancer mortality- not even a tendency towards an effect." Accordingly, the authors concluded that there is no longer any justification for screening mammography; further evidence for this conclusion will be detailed at the May 6, 2001, annual meeting of the National Breast Cancer Coalition in Washington, D. C., and published in the July report of the Nordic Cochrane Centre.

Even assuming that high quality screening of a population of women between the ages of 50 and 69 would reduce breast cancer mortality by up to 25 percent, yielding a reduced relative risk of 0.75, the chances of any individual woman benefiting are remote (18). For women in this age group, about 4 percent are likely to develop breast cancer annually, about one in four of whom, or 1 percent overall, will die from this disease. Thus, the 0.75 relative risk applies to this 1 percent, so 99.75 percent of the women screened are unlikely to benefit.

## **THE UNITED STATES VERSUS OTHER NATIONS**

No nation other than the United States routinely screens premenopausal women by mammography. In this context, it may be noted that the January 1997 National Institutes of Health Consensus Conference recommended against premenopausal screening (24), a decision that the NCI, but not the ACS, accepted (4). However, under pressure from Congress and the ACS, the NCI reversed its decision some three months later in favor of premenopausal screening.

The U. S. overkill extends to the standard practice of taking two or more mammograms per breast annually in postmenopausal women. This contrasts with the more restrained European practice of a

single view every two to three years (4).

### **BREAST EXAMINATION IS A SAFE AND EFFECTIVE ALTERNATIVE TO MAMMOGRAPHY**

That most breast cancers are first recognized by women themselves was admitted in 1985 by the ACS, an aggressive advocate of routine mammography for all women over the age of 40: "We must keep in mind the fact that at least 90 percent of the women who develop breast carcinoma discover the tumors themselves" (25). Furthermore, as previously shown, "training increases reported breast self-examination frequency, confidence, and the number of small tumors found" (26).

A pooled analysis of several 1993 studies showed that women who regularly performed BSE detected their cancers much earlier and with fewer positive nodes and smaller tumors than women failing to examine themselves (27); BSE would also enhance earlier detection of missed or interval cancers, especially in pre-menopausal women (28). There is a strong consensus that the effectiveness of BSE critically depends on careful training by skilled professionals, and that confidence in BSE is enhanced with annual CBEs by an experienced professional using structured individual training (29). The tactile sensitivity of BSE can be increased by the use of Mammacare techniques to enhance lump detection skills (30, 31), and by the use of FDA-approved and nonprescription thin and pliable lubricant-filled sensor pads (32, 33).

In a joint U. S. and Chinese large-scale trial based on 520 Chinese factories, women in half the factories were trained in and practiced BSE, while the other group of women served as controls (34). The five-year follow up results reported no reduction in breast cancer mortality in women in the BSE group. However, these findings are of little, if any, significance in view of the minimum of a 10-to 13-year period required before the efficacy of mammography is claimed to occur in premenopausal women (24), especially as some of the trial's participants were in their thirties (28).

The critical importance and reliability of CBE has been strikingly confirmed by the recent Canadian National Breast Cancer Screening Study (19). This reported the results of a unique individually randomized controlled trial on some 40,000 women, aged 50 to 59 on entry, followed by record linkage for nine to 13 years, with active follow-up of cancer patients for an additional three years. Half the women performed monthly BSE, following instruction by trained nurses, had annual CBEs (taking approximately ten minutes) by trained nurses, and had annual mammograms, while the other half practiced BSE and had annual CBEs but no mammograms. It should be noted that the CBE performance by trained nurses had been shown to be as good as, if not better than, that of the study surgeons (35), a finding of particular interest in view of the growing perception among women that professional women are more sensitive than men to women's health issues (36). The results of this study provide clear evidence on the reliability of CBE, in association with BSE (19): "In women age 50-59 years, the addition of annual mammography screening to physical examination has no impact on breast cancer mortality." In other words, the mammographic detection of nonpalpable cancers failed to improve survival rates, as "the majority of the small cancers detected by mammography represent pseudo-disease or overdiagnosis" (37); confirmation of this explanation awaits a trial, a protocol of which is available, comparing mammography alone with physical examination alone. It should further be noted that the mammogram group had a three-fold increase in the number of false positives compared with the CBE and BSE group, resulting in unnecessary biopsies.

The effectiveness of CBE is further supported by the results of a new Japanese mass screening study (38). Breast cancer mortality was compared in municipalities with or without "high coverage" by CBE. The age-adjusted breast cancer mortality between 1986- 1990 and 1991- 1995 was reduced by over 40 percent in "high coverage" municipalities, in contrast to only 3 percent in controls. In spite of such evidence, the ACS and radiologists persist in their dismissiveness of CBE and BSE, particularly as "a substitute for screening practices that have a 'proven' benefit such as mammograms" (33). The NCI no longer prints a BSE guide in its breast cancer booklet, claiming that "no studies have clearly shown a benefit of using BSE"; similarly, the ACS no longer distributes information on BSE, such as shower-hanger cards.

There are immediate needs for a large-scale crash program for training nurses in how to perform annual CBE and how to teach BSE. This need is critical for underinsured and uninsured low-socioeconomic and ethnic women in the United States, and even more so for developing countries. Once well trained, women of all social and cultural classes could perform monthly BSE, at no cost or risk apart from false positives, which decrease with increasing practice, along with annual CBE screening. Clinics offering CBE and training in BSE could be established nationwide, and eventually worldwide, in a network of clinics, community hospitals, churches, synagogues, and mosques. These clinics could also act as a comprehensive source of reliable information on how to reduce the risks of breast cancer, about which women still remain largely uninformed by the cancer establishment (2). Besides lifestyle and reproductive risk factors, emphasis should be directed to the massive overprescription of carcinogenic

hormonal drugs and the avoidable and involuntary exposures to petrochemical and radionuclear carcinogens in the totality of the environment (39- 41).

### **COSTS OF SCREENING**

The dangers and unreliability of mammography screening are compounded by its growing and inflationary costs; Medicare and insurance average costs are \$70 and \$125, respectively. Inadequate Medicare reimbursement rates are now prompting fewer hospitals and clinics to offer mammograms, and deterring young doctors from becoming radiologists. Accordingly, Senators Charles Schumer (D-NY) and Tom Harkin (D-IA) are introducing legislation to raise Medicare reimbursement to \$100 (42).

If all U. S. premenopausal women, about 20 million according to the Census Bureau, submitted to annual mammograms, minimal annual costs would be \$2.5 billion (4). These costs would be increased to \$10 billion, about 5 percent of the \$200 billion 2001 Medicare budget, if all postmenopausal women were also screened annually, or about 14 percent of the estimated Medicare spending on prescription drugs. Such costs will further increase some fourfold if the industry, enthusiastically supported by radiologists, succeeds in its efforts to replace film machines, costing about \$100,000, with the latest high-tech digital machines, approved by the FDA in November 2000, costing about \$400,000. Screening mammography thus poses major threats to the financially strained Medicare system. Inflationary costs apart, there is no evidence of the greater effectiveness of digital than film mammography (43), as confirmed by a study reported at the November 2000 annual meeting of the Radiological Society of North America (44). In fact, digital mammography is likely to result in the increased diagnosis of DCIS.

The comparative cost of CBE and mammography in the 1992 Canadian Breast Cancer Screening Study was reported to be 1 to 3 (45). However, this ratio ignores the high costs of capital items including buildings, equipment, and mobile vans, let alone the much greater hidden costs of unnecessary biopsies, specialized staff training, and programs for quality control and professional accreditation (46). This ratio could be even more favorable for CBE and BSE instruction if both were conducted by trained nurses. The excessive costs of mammography screening should be diverted away from industry to breast cancer prevention and other women's health programs.

### **CONFLICTS OF INTEREST**

The ACS has close connections to the mammography industry (39). Five radiologists have served as ACS presidents, and in its every move, the ACS promotes the interests of the major manufacturers of mammogram machines and films, including Siemens, DuPont, General Electric, Eastman Kodak, and Piker. The mammography industry also conducts research for the ACS and its grantees, serves on advisory boards, and donates considerable funds. DuPont also: is a substantial backer of the ACS Breast Health Awareness Program; sponsors television shows and other media productions touting mammography; produces advertising, promotional, and information literature for hospitals, clinics, medical organizations, and doctors; produces educational films; and, of course, lobbies Congress for legislation promoting availability of mammography services. In virtually all its important actions, the ACS has been and remains strongly linked with the mammography industry, while ignoring or attacking the development of viable alternatives (39).

ACS promotion continues to lure women of all ages into mammography centers, leading them to believe that mammography is their best hope against breast cancer. A leading Massachusetts newspaper featured a photograph of two women in their twenties in an ACS advertisement that promised early detection results in a cure "nearly 100 percent of the time." An ACS communications director, questioned by journalist Kate Dempsey, admitted in an article published by the Massachusetts Women's Community's journal *Cancer*, "The ad isn't based on a study. When you make an advertisement, you just say what you can to get women in the door. You exaggerate a point. . . . Mammography today is a lucrative [and] highly competitive business" (39).

### **NEEDED REFORMS**

Mammography is a striking paradigm of the capture of unsuspecting women by run-away powerful technological and pharmaceutical global industries, with the complicity of the cancer establishment, particularly the ACS, and the rollover mainstream media. Promotion of the multibillion dollar mammography screening industry has also become a diversionary flag around which legislators and women's product corporations can rally, protesting how much they care about women, while studiously avoiding any reference to avoidable risk factors of breast cancer, let alone other cancers.

Screening mammography should be phased out in favor of annual CBE and monthly BSE, as an effective, safe, and low-cost alternative, with diagnostic mammography available when so indicated. Such action is all the more critical and overdue in view of the still poorly recognized evidence that screening mammography does not lead to decreased breast cancer mortality (18, 21, 23).

Networks of CBE and BSE clinics, staffed by trained nurses, should be established internationally, including in developing nations. These low-cost clinics would further empower women by providing them with scientific evidence on breast cancer risk factors and prevention, information of particular importance in view of the continued high incidence of breast cancers, with an estimated 192,200 new U. S. cases predicted for 2001 (47), exceeding the number for any previous years. The multibillion dollar U. S. insurance and Medicare costs of mammography, besides those in other nations, should be diverted to outreach and research on prevention of breast and other cancers and on other women's health programs.

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