

Position Statement on Screening Mammography March 2003

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Position

NBCC believes that there is insufficient evidence to recommend for or against screening mammography in any age group of women. Women who have symptoms of breast cancer such as a lump, pain or nipple discharge should seek a diagnostic mammogram. The decision to undergo screening must be made on an individual level based on a woman's personal preferences, family history and risk factors. Mammography does not prevent or cure breast cancer, and has many limitations. Women are told that mammography screening saves lives, but the evidence of a mortality (death rate) reduction from screening is conflicting and continues to be questioned by some scientists, policy makers and members of the public. Ultimately, resources must be devoted to finding effective preventions and treatments for breast cancer and tools that detect breast cancer truly early.

Background

A mammogram is an x-ray of the breast that can reveal abnormalities, such as a tumor, inside the breast. The procedure involves compressing the breast horizontally between two metal plates and then applying a small dose of radiation to produce an x-ray image. Mammograms can be used for screening and for diagnosis.

- Diagnostic Mammogram—is performed if a woman has symptoms of breast cancer, such as a lump that can be felt in her breast.
- Screening Mammogram— is performed to attempt to detect breast cancer before symptoms occur in women without symptoms of breast cancer.

In a mammography screening program, screening mammograms are administered to large populations of women who have no symptoms of breast cancer. Unfortunately, detecting a woman's breast cancer before symptoms occur does not guarantee that she will have a better chance of survival. In addition, mammograms are not risk free and may have harmful consequences. Mammography screening programs should only be initiated if well designed, high quality randomized trials prove that such programs save lives, and that the benefits outweigh the risks.

Potential Risks of Mammography Screening

Screening mammography is often inaccurate, and many women receive false-positive or false-negative results. A false-positive occurs when a woman's mammogram shows a suspicious lump, but she actually does not have breast cancer. A false-negative occurs when a woman's mammography results are normal, but she actually has breast cancer. After 10 years of annual screening, up to 50% of all women screened would get at least one false-positive result. More than 80% of women who receive suspicious mammogram results do not have breast cancer. When mammograms find lumps that are not breast cancer, women often undergo unnecessary biopsies (surgery to remove a suspicious lump). Although breast biopsies are relatively simple surgeries, they can still cause distress, scarring and disfigurement.

Another potential risk of mammography is overtreatment. There are some types of early breast cancers that will never spread to other parts of the body, and mammograms probably find many of these breast cancers. Detecting and removing breast cancers that would never have spread to other parts of the body does not save any lives. Unfortunately, doctors have not figured out how to tell which breast cancers will eventually spread and which will not. The result is that many women get treated for breast cancer when they may not need to be treated at all. Breast cancer

treatments, such as chemotherapy and radiotherapy, are toxic and should not be given to women who do not need them. Finally, mammography may harm women in ways that are not yet known.

Research on Mammography Screening

There are seven published randomized trials of mammography screening. Four of the trials were conducted in Sweden, one was conducted in Canada, one was conducted in the United Kingdom, and one was conducted in the United States. The seven trials are known as:

- The New York trial or HIP trial - enrolled women ages 40-64
- The Malmo trial - enrolled women ages 45-69
- The Two-County trial - enrolled women over age 40
- The Edinburgh trial - enrolled women ages 45-64
- The Canadian trial (parts 1 and 2) - enrolled women ages 40-59
- The Stockholm Trial - enrolled women ages 40-64
- The Goteborg trial - enrolled women ages 39-59

Many scientists have critiqued these trials. NBCC believes that the most thorough evaluation to date was conducted by Drs. Gotzsche and Olsen, two Danish scientists affiliated with the well-respected Cochrane Collaboration.¹ These scientists set out to review and evaluate all seven of the mammography trials to determine the quality of each. Using standard criteria, Gotzsche and Olsen rated each randomized trial's quality with one of the following marks: high, medium, poor or flawed. Based on these criteria, they found that no trial was high quality; the Malmo and Canadian trials were medium quality; the Two-County, Stockholm and Goteborg trials were poor quality; and the New York and Edinburgh trials were flawed.

The two trials with the best quality data - the Malmo and Canadian trials - *did not* show that mammography screening benefits women. In these trials, the women who were offered mammography screening had the same breast cancer mortality (death rate) as the women who were not offered mammography screening. The other five trials found that mammography did benefit women and reduced breast cancer mortality by about 30% on average. But these trials had poor quality data and serious problems that call into question the reliability of their results. None of the seven trials found that mammography screening reduced overall mortality (deaths from all causes combined). Finally, data from all of the trials indicate that mammography screening leads to more false-positives, more unnecessary surgeries, and more use of aggressive breast cancer treatments.

The seven trials of mammography screening included few women over the age of 70 and very few women of color. None of the trials examined women younger than 39 years old, and only one trial -- the Canadian trial (part 1) -- was specifically designed to examine mammography in women ages 40 to 49. In this trial, after an average of 13 years of follow-up, the women who were offered mammography screening had the same breast cancer mortality (death rate) as the women who were not offered this screening.²

For a more detailed explanation of the research on mammography screening and the controversy surrounding this research, see NBCC's Fact Sheet entitled [The Mammography Screening Controversy: Questions and Answers](#).

The Swedish Mammography Trials

Many scientists and researchers believe that if the individual patient data from all of the trials can be independently audited and analyzed, we will get clearer answers. Unfortunately, the researchers who conducted the four Swedish randomized trials have refused to divulge their data to the public, despite being called to do so repeatedly. In response to the criticism of their trials,

the Swedish researchers conducted their own review by compiling and analyzing the raw data from their four trials.³ Half of the data from the Two-County trial was omitted from this analysis because the author of that study, Dr. Laszlo Tabar, refused to cooperate. The review did clarify some inconsistencies, and it provided some new information that was previously missing. The Swedish researchers were able to correct or refute some, but not all, of the flaws that were cited by Olsen and Gotzsche.

The combined data from the four studies suggested that mammography screening of 100,000 women (ages 40-74) prevents a total of 136 breast cancer deaths after 18 years. However, the breast cancer mortality reduction occurred only in women ages 55 to 69 -- breast cancer mortality was reduced by 24%, 32%, and 31% in women ages 55-59, 60-64, and 65-69 years, respectively. The researchers also reported that their data suggest that mammography reduced overall mortality by 2.3%. However, this number was not statistically significant (e.g. the margin of error was too large to conclude that there definitely was an overall mortality reduction).

The National Breast Cancer Coalition applauds the efforts of the Swedish researchers to address the growing concerns about the design and conduct of their trials. However, NBCC believes that the Swedish trials must be audited and analyzed by an independent and unbiased panel of people who did not take part in the design, funding, or conduct of the four trials. In addition, any analysis of mammography screening must include the results of the Canadian randomized trial.

The Swedish researchers must release all of the data and documentation from their four trials. The researchers who conducted the other three trials of screening mammography have already agreed to do this. NBCC is calling for an independent review committee, such as the UK based group, MedicoLegal Investigations, to conduct a thorough audit of all of the trials.

Mammography Quality Care

Health insurance and third-party payers should cover the costs of appropriate screening and diagnostic mammography, and all women should have access to high-quality mammography. Qualified staff must perform the mammogram, and all equipment must comply with the standards set out in the Mammography Quality Standards Act (MQSA).⁴

Women receiving a mammogram should be treated with respect throughout the process. Some women experience more discomfort than others; health care providers should make every effort to reduce discomfort. Results of mammograms should be provided within 30 business days as required by the MQSA. The FDA has interpreted MSQA to require mammogram results that are *positive or suspicious* to be reported to the referring physician and/or the patient as soon as possible. Although it is impossible to establish a precise time frame, it is expected that such communication could ordinarily be accomplished within 5 business days.

Most importantly, women who get mammography screening must have access to treatment. No detection method will save lives unless followed by appropriate treatment.

Conclusion

Recommendations on breast cancer screening must be based on evidence from high-quality randomized trials. Thus far, the randomized trials with the highest quality data do not show that mammography benefits women in any age group. Women should be informed about the uncertainty regarding mammography and decisions should be made on an individual basis. Mammography may provide benefits for some women, but it may also harm others.

Women deserve to know the truth -- and the truth is that there is no evidence of a mortality reduction in women under the age of 50 and the evidence for women over 50 is currently unclear. Broad public health recommendations should only be made when it is clear that the potential benefits of the recommended intervention will outweigh the potential harms. NBCC believes that women are capable of educating themselves so they can make their own individual decisions about screening.

NBCC has long questioned the limitations of mammography screening. For years, NBCC has said that mammography is not the answer to the breast cancer epidemic. At best, mammography screening may offer only very small benefits to certain age groups of women. NBCC believes that there are public health interventions that could save more lives and use fewer health care resources than mammography screening programs. One such intervention would be to ensure that all women diagnosed with breast cancer have access to quality health care.

It is vital that women know the truth about breast cancer screening, including its potential benefits, risks, and limitations. As breast cancer activists, the Coalition welcomes the discussion of the effectiveness of existing breast cancer screening methods. We must accept that we do not know how to detect breast cancer truly early, how to prevent or cure this disease, and focus our attention on getting those answers.

The goal is to focus research efforts on true prevention – stopping breast cancer from occurring altogether – and on new, more effective ways to detect and treat breast cancer.

About NBCCF

The National Breast Cancer Coalition Fund is a grassroots organization dedicated to ending breast cancer through the power of action and advocacy. The Coalition's main goals are to increase federal funding for breast cancer research and collaborate with the scientific community to implement new models of research; improve access to high quality health care and breast cancer clinical trials for all women; and expand the influence of breast cancer advocates in all aspects of the breast cancer decision making process.

Footnotes

¹Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography. *Lancet* 2001;358(9290):1340-2.

²Miller AB, To T, Baines CJ, Wall C. The Canadian National Breast Screening Study-1: Breast cancer mortality after 11 to 16 years of follow-up. *Ann Intern Med* 2002;137:305-312.

³Nystrom L, Andersson I, Bjurstam N, et al. Long-term effects of mammography screening: updated overview of the Swedish randomised trials. *Lancet* 2002;359(9310):909-19.

⁴Congress enacted the Mammography Quality Standards Act (MQSA) in 1992 to ensure that all women have access to quality mammography. In the fall of 1998, Congress reauthorized MQSA, extending the program to 2002. Under this act, The Food and Drug Administration (FDA) is responsible for developing, implementing, and enforcing quality standards for mammography.