

Frank words about breast screening

CORNELIA J. BAINES

Cornelia J. Baines, MD, MSc, Fellow of the American College of Epidemiology, is Professor Emerita at the Dalla Lana School of Public Health, University of Toronto, Toronto, ON Canada.

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Correspondence: cornelia.baines@utoronto.ca

A GROWING BODY OF EVIDENCE SUGGESTS THAT THE benefits achieved by screening for breast cancer are small, that the harm from the over-diagnosis of breast cancer arising from screening is substantial, and that, where screening is available, the observed reductions in breast cancer mortality arise largely from increased awareness and improved chemo- and hormone therapy.¹ In spite of these new insights, screening advocacy continues in full crescendo. For example, in 2010 the Canadian Breast Cancer Foundation Ontario (CBCFO) released a report on its recent consensus conference, “It’s About Time,” focusing on the earlier detection and diagnosis of breast cancer. The CBCFO is a not-for-profit organization; its conference scientific advisory committee consisted of five members, of whom three are active in breast imaging and a fourth is the director of cancer screening at the American Cancer Society. The breast cancer screening recommendations for women at average risk that emerged from the conference are that screening should be done within an organized program and should begin at “approximately” age 40. (“Approximately” may leave wiggle room for women in their 30s to participate.) The “preferred” modality described is annual digital mammography, and if it is not available, film mammography is the alternative.

The CBCFO’s campaign for women in their 40s to be included in the Ontario Breast Screening Program is less than convincing given the current evidence. Furthermore, vested interests from the imaging industry are a major factor associated with screening advocacy.² Despite the lack of compelling evidence, the recently released 2011 budget for the Government of Ontario has

earmarked \$10 million to screen high-risk women aged 30–49 for breast cancer. Such an initiative is compatible with the generally held *belief* that the earlier detection achieved by screening makes cure more likely. It is not compatible with current evidence.

Commitment and funding for breast screening for women aged 40–49 without compelling evidence of benefit is not unique to Canada. An uproar among screening advocates was unleashed in November 2009 with the publication of the United States Preventive Services Task Force (USPSTF) Guidelines for Breast Screening.³ The task force concluded that 1904 women aged 39 to 49 needed to be invited for annual screening for 10 years to prevent one breast cancer death (leaving 1903 women at substantial risk of over-diagnosis). Corresponding figures for women aged 50–59 and 60–69 were 1339 and 377 respectively. The guidelines are outlined in Textbox 1. The USPSTF also recognized over-diagnosis as one of the harms of screening.⁴

The recommendations “were widely and loudly denounced by radiologists, breast cancer survivors, media doctors, gynecologists and politicians. Medical experts called the task force ‘idiots’ and conservatives lined up to denounce the report as an Obama administration plot.”⁵ The American College of Radiology (ACR) declared that “two decades of decline in breast cancer mortality could be reversed and countless American women may die needlessly from breast cancer each year” and that the recommendations were “flawed,” “shocking” and “unconscionable.”⁶ These protestations conveniently ignored evidence from Italy, Denmark, Norway and the World Health Organization that, primarily as a result of

Textbox 1: Summary of United States Preventive Services Task Force (USPSTF) recommendations on screening for breast cancer³

The USPSTF:

- “recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take into account patient context, including the patient’s values regarding specific benefits and harms.”
- “recommends biennial screening mammography for women between the ages of 50 and 74 years.”
- “concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older.”
- “concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination beyond screening mammography in women 40 years or older.”
- “recommends against clinicians teaching women how to perform breast self-examination.”
- “concludes that the current evidence is insufficient to assess additional benefits and harms of either digital mammography or magnetic resonance imaging instead of film mammography as screening modalities for breast cancer.”

increased breast cancer awareness and improved therapy, breast cancer mortality has in fact declined in the absence of screening in screening-eligible women and also in women too young to be screened.^{7–10}

It is of interest that the ACR received donations of at least \$1 million each from GE Healthcare and Siemens AG, both companies that make mammography equipment and MRI scanners. The lobbyists leading the charge against the USPSTF 2009 guidelines in Washington included GE, Siemens and the ACR.⁶ A US radiologist and screening advocate not only assailed the 2009 USPSTF Guidelines but also wrote that those disagreeing with him were wrong: “They distort data, rely on weak science, but refuse to defend when challenged.”¹¹ The claim was also made that “Many European countries as well as Canada do not support, or at any rate do not encourage, screening before the age of 50 and have lied to their populations.”¹¹

Over-diagnosis is now recognized as a major harm of screening.^{4,12–14} Over-diagnosis, according to the US National Cancer Institute website, is the diagnosis of “a neoplasm that would never become clinically apparent prior to a patient’s death without screening. An example is a tumor that is found by mammographic screening that would never be evident otherwise.”¹⁵ It has been estimated that 25% or more of screen-detected breast cancers are over-diagnosed.^{4,12–14} How is this puzzling conclusion reached? When screening trials were being planned, it was predicted that screening would initially result in an increased incidence of early cancer. With screening bringing forward the date of diagnosis compared to later clinical detection (lead time), the numbers of early breast cancers diagnosed were increased. This led to the assumption that later there would be a corresponding decline in the incidence of invasive cancer in the screened population. In fact, US SEER data reveal that the expected correlation between an initial increase in early cancers and a later decline in invasive cancers did not occur in the period 1983–2005. The early increase occurred, but there was no subsequent decline in advanced cancers.¹³ Similar observations have been made in Europe,¹⁴ leading to the conclusion that there is a substantial risk of over-diagnosis arising from screening programs. In contrast to the transitory disadvantages of false-positive screens, the downside of over-diagnosis is that its consequences are life-long.¹² Not only is treatment unpleasant, but its long-term consequences (pain, deformity, and increased risk of cardiac complications) are significant.

After many years of follow-up, combining data from screening trials demonstrates a significant 15%–16%

reduction in overall breast cancer mortality.^{16,17} However, looking specifically at screening benefit for women aged 40–49, the Swedish Overview revealed a 9%,¹⁸ the UK Age trial a 17%¹⁹ and the USPSTF a 15% reduction,¹⁶ none of which were statistically significant. When that “benefit” is balanced against the 25% or more increased risk of screen-detected cancers that are over-diagnosed,^{12–14} in addition to the recognized efficacy of current therapy,¹ mammography screening benefits are diminished.

Perhaps even more compelling are the data relating breast cancer mortality to the presence or absence of screening programs. A 2010 Danish study compared breast cancer death rates over the period 1971 to 2005 in 20% of the Danish population living in counties where breast screening was offered for about 17 years, to death rates in the 80% of the population in counties where no screening occurred. Surprisingly, breast cancer deaths decreased as much in screened as unscreened populations up to the age of 74. Even more surprising was the finding that breast cancer deaths declined even in younger women who were ineligible for screening and thus did not undergo routine screening to detect their cancers. No decline was observed in women over age 74, another group ineligible for screening in Denmark.⁷

In addition, a recent overview of 30 European countries using WHO data has shown that breast cancer mortality dropped 37% in women under 50 years, who are generally ineligible for screening, while the drop was only 21% in women aged 50–69 years, who were most commonly screened.⁹ Improvement in therapy (such as chemo- and hormone therapy) since the 1980s, when many screening trials were conducted, have undoubtedly contributed to the breast cancer mortality reduction observed in both screened and unscreened women.

It’s time to recognize that screening benefits in younger women are small in relation to the risks of over-diagnosis. Screening advocates have used *ad hominem* attacks that, although inappropriate, have been very successful in dominating the screening controversy.^{5,6,11,20} Survivors’ testimony in support of mammography screening has been powerful, even though it is incompatible with the reality that most women with breast cancer do not die of breast cancer. Their testimony is also incompatible with the reality that women who have been over-diagnosed never will die of their “cancer.” In addition, what the early breast cancer survivors may not be aware of is the sad fact that breast cancer can kill 20 years after diagnosis.²¹

As recently observed in the *New England Journal of Medicine*, we should “work to prevent vested interests from being granted the loudest voices in health care.”²²

The vested interests in what has been termed “the mammography wars”²² are clearly those in the imaging industry, those involved directly in screening programs, and even those in the not-for-profit sector, whose fundraising capacity is enhanced by a public committed to fighting breast cancer.

It is reasonable for women to choose to be screened, but only if they are completely informed about the probability of benefit versus the probability of harm. For 2000 women aged 40–49 who undergo screening for 10 years, the benefit is much smaller in terms of avoiding death from breast cancer than is the harm arising from over-diagnosis and unnecessary treatment for breast cancer, to say nothing of the increased rates of mastectomy associated with screening.^{22,23} These issues are not widely known to the general public. After over 20 years of involvement in the screening controversy, I can only conclude that this is information few want to hear and many want to suppress.

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