Screening for Breast Cancer

Recommendations and Rationale

U.S. Preventive Services Task Force

This statement summarizes the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for breast cancer and the supporting scientific evidence, and it updates the 1996 recommendations contained in the Guide to Clinical Preventive Services, second edition.[1] Explanations of the ratings and of the strength of overall evidence are given in Appendix A and Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is available in the article Breast Cancer Screening: A Summary of the Evidence for the U.S. Preventive Services Task Force[2] (which follows this recommendation) and in the Systematic Evidence Review[3] on this topic. These documents can be obtained through the USPSTF Web site (www.preventiveservices.ahrq.gov), and through the National Guideline Clearinghouse (www.guideline.gov). The summary of the evidence and the recommendation statement are also available in print through the AHRQ Publications Clearinghouse (call 1-800-358-9295 or e-mail ahrqpubs@ahrq.gov).

To update their recommendations on screening for breast cancer, the USPSTF reviewed the evidence regarding the effectiveness of mammography, clinical breast examination, and breast self-examination in reducing breast cancer mortality. The USPSTF did not review the evidence regarding genetic screening, surveillance of women with prior breast cancer, or formal evaluation of new screening modalities that have not been studied in the general population. A meta-analysis using a Bayesian random effects model was conducted for the USPSTF to obtain a summary of relative risk estimates of the effectiveness of screening with mammography, either alone or in combination with clinical breast examination, in reducing breast cancer mortality. Clinical studies that evaluated breast self-examination were included in the review.

Note: These recommendations were first released on February 21, 2002. Subsequent to their release, a 2002 publication provided additional data on outcomes and methods of 4 mammography trials conducted in Sweden.[4] The additional follow-up data have been incorporated into the numeric estimates of the effectiveness of mammography in this statement, which differ minimally from those cited in the February 2002 release. Overall ratings of study quality were not affected.

This was first released on the AHRQ Web site on Septemeber 3, 2002, and an abridged version of this recommendation also appeared in *Ann Intern Med.* 2002;137(5 Part 1):344-346.

Summary of Recommendations

- The U.S. Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1-2 years for women aged 40 and older. **B recommendation.**

The USPSTF found fair evidence that mammography screening every 12-33 months significantly reduces mortality from breast cancer. Evidence is strongest for women aged 50-69, the age group generally included in screening trials. For women aged 40-49, the evidence that screening mammography reduces mortality from breast cancer is weaker, and the absolute benefit of mammography is smaller, than it is for older women. Most, but not all, studies indicate a mortality benefit for women undergoing mammography at ages 40-49, but the delay in observed benefit in women younger than 50 makes it difficult to determine the incremental benefit of beginning screening at age 40 rather than at age 50. The absolute benefit is smaller because the incidence of breast cancer is lower among women in their 40s than it is among older women. The USPSTF concluded that the evidence is also generalizable to women aged 70 and older (who face a higher absolute risk for breast cancer) if their life expectancy is not compromised by comorbid disease. The absolute probability of benefits of regular mammography increase along a continuum with age, whereas the likelihood of harms from screening (false-positive results and unnecessary anxiety, biopsies, and cost) diminish from ages 40-70. The balance of benefits and potential harms, therefore, grows more

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favorable as women age. The precise age at which the potential benefits of mammography justify the possible harms is a subjective choice. The USPSTF did not find sufficient evidence to specify the optimal screening interval for women aged 40-49 (see Clinical Considerations).

- The USPSTF concludes that the evidence is insufficient to recommend for or against routine CBE alone to screen for breast cancer. **I recommendation.**

No screening trial has examined the benefits of CBE alone (without accompanying mammography) compared to no screening, and design characteristics limit the generalizability of studies that have examined CBE. The USPSTF could not determine the benefits of CBE alone or the incremental benefit of adding CBE to mammography. The USPSTF therefore could not determine whether potential benefits of routine CBE outweigh the potential harms.

- The USPSTF concludes that the evidence is insufficient to recommend for or against teaching or performing routine breast self-examination (BSE). **I recommendation.**

The USPSTF found poor evidence to determine whether BSE reduces breast cancer mortality. The USPSTF found fair evidence that BSE is associated with an increased risk for false-positive results and biopsies. Due to design limitations of published and ongoing studies of BSE, the USPSTF could not determine the balance of benefits and potential harms of BSE.

Clinical Considerations

- The precise age at which the benefits from screening mammography justify the potential harms is a subjective judgment and should take into account patient preferences. Clinicians should inform women about the potential benefits (reduced chance of dying from breast cancer), potential harms (eg, false-positive results, unnecessary biopsies), and limitations of the test that apply to women their age. Clinicians should tell women that the balance of benefits and potential harms of mammography improves with increasing age for women between the ages of 40 and 70.
- Women who are at increased risk for breast cancer (eg, those with a family history of breast cancer in a mother or sister, a previous breast biopsy revealing atypical hyperplasia, or first childbirth after age 30) are more likely to benefit from regular mammography than women at lower risk. The recommendation for women to begin routine screening in their 40s is strengthened by a family history of breast cancer having been diagnosed before menopause.
- The USPSTF did not examine whether women should be screened for genetic mutations (eg, BRCA1 and BRCA2) that increase the risk for developing breast cancer, or whether women with genetic mutations might benefit from earlier or more frequent screening for breast cancer.
- In the trials that demonstrated the effectiveness of mammography in lowering breast cancer mortality, screening was performed every 12-33 months. For women aged 50 and older, there is little evidence to suggest that annual mammography is more effective than mammography done every other year. For women aged 40-49, available trials also have not reported a clear advantage of annual mammography over biennial mammography. Nevertheless, some experts recommend annual mammography based on the lower sensitivity of the test and on evidence that tumors grow more rapidly in this age group.
- The precise age at which to discontinue screening mammography is uncertain. Only 2 randomized controlled trials enrolled women older than 69 and no trials enrolled women older than 74. Older women face a higher probability of developing and dying from breast cancer but also have a greater chance of dying from other causes. Women with comorbid conditions that limit their life expectancy are unlikely to benefit from screening.
- Clinicians should refer patients to mammography screening centers with proper accreditation and quality assurance standards to ensure accurate imaging and radiographic interpretation.

Clinicians should adopt office systems to ensure timely and adequate follow-up of abnormal results. A listing of accredited facilities is available at http://www.fda.gov/cdrh/mammography/certified.html.

- Clinicians who advise women to perform BSE or who perform routine CBE to screen for breast cancer should understand that there is currently insufficient evidence to determine whether these practices affect breast cancer mortality, and that they are likely to increase the incidence of clinical assessments and biopsies.

Scientific Evidence

Epidemiology and Clinical Consequences

Breast cancer is the most common non-skin malignancy among women in the United States and second only to lung cancer as a cause of cancer-related death. In 2001, an estimated 192,200 new cases of breast cancer were diagnosed in American women, and 40,200 women died of the disease.[5] The risk for developing breast cancer increases with age beginning in the fourth decade of life. The probability of developing invasive breast cancer over the next 10 years is 0.4% for women aged 30-39, 1.5% for women aged 40-49, 2.8% for women aged 50-59, and 3.6% for women aged 60-69.5 Individual factors other than age that increase the risk for developing breast cancer include family history or a personal history of breast cancer, biopsy-confirmed atypical hyperplasia, and having a first child after age 30.[6]

Accuracy and Reliability of Screening Tests

The USPSTF examined the test characteristics of mammography, CBE, and BSE. Precise estimates of sensitivity and specificity of screening are made more difficult by the varied criterion standards in available studies. Estimating the predictive value of positive and negative tests is also difficult because studies have been conducted on populations with a widely varying prevalence of breast cancer.

Mammography

Estimates of the sensitivity of mammography vary with the methods used to calculate it.[2] In a good quality systematic review, the first round of mammography detected 77% to 95% of cancers diagnosed over the following year, but only 56% to 86% of cancers diagnosed over the next 2 years.[3,7] Sensitivity is lower among women who are younger than 50, have denser breasts, or are taking hormone replacement therapy.[3]

In screening trials, the false-positive rate of the initial round of mammography was 3% to 6% (ie, specificity 94% to 97%).[3] Specificity is increased with a shorter screening interval and the availability of prior mammograms.[3] In a large study in a health maintenance organization, the rate of false-positive mammograms (those requiring some additional follow-up) was higher in women aged 40-59 (7% to 8%) than in women aged 60-79 (4% to 5%).[8]

The probability that an abnormal mammogram is due to cancer increases with age. A large study in Northern California estimated positive predictive values for abnormal mammograms at 2% to 4% among women aged 40-49, 5% to 9% among women aged 50-59, and 7% to 19% among women aged 60 and older.[3,9] Positive predictive values were also higher among women with a family history of breast cancer in 2 studies.[3]

Clinical Breast Examination

In a recent good quality review of data from clinical trials, the sensitivity of CBE ranged from 40% to 69%, specificity from 86% to 99%, and positive predictive value from 4% to 50%, using mammography and interval cancer as the criterion standard.[10] In a large community study, only 4% of women with an abnormal CBE were subsequently diagnosed with cancer.[11]

Breast Self-examination

The accuracy of BSE is largely unknown. Available evidence shows sensitivity ranging from 26% to 41% compared with CBE and mammography.[3] Specificity of BSE is largely unknown.

Effectiveness of Early Detection

The USPSTF reviewed 8 randomized controlled trials (RCTs) of mammography (4 of mammography alone and 4 of mammography plus CBE) that have reported results with 11- 20 years of follow-up.[4,12-21] The USPSTF found important methodological limitations in each trial, but rated only one trial as "poor" based on established criteria used by the USPSTF to evaluate the quality of evidence for screening tests.[22] The most serious problems concerned the assembly and maintenance of comparable groups, methods for ascertaining outcomes, and generalizability to routine practice. The USPSTF concluded that the flaws were problematic but unlikely to negate the reasonably consistent and significant mortality reductions observed in these trials.

Imperfections in these mammography trials have been recognized and discussed in the literature and by the original investigators for many years. Recently, a 2001 Cochrane Collaboration review[23] of the same trials concluded that 6 of the 8 trials were "flawed" or of "poor" quality and that the pooled results from the remaining 2 better quality trials did not support a benefit from mammography. Although the USPSTF was concerned about many (but not all) of the flaws identified in the Cochrane review, it did not consider the presence of flaws sufficient reason in itself for rejecting trial results. Instead, it examined whether observed mortality reductions in the trials were likely to be explained by the biases potentially introduced by such flaws. Studies rated to be of "fair" quality by the USPSTF contained flaws that were considered unlikely to account for observed benefits (or lack of benefits).

The trials[4,12-21] reported mortality reductions ranging from no significant effect to a 32% reduction in breast cancer mortality. The meta-analysis performed for the USPSTF on the most current published data found that the pooled effect size of the combined trials was sizable and statistically significant. After excluding data from one trial rated as poor quality by the USPSTF,[17] the summary relative risk (RR) of breast cancer death among women of all ages randomized to screening in the remaining 7 trials was 0.84 (95% CI, 0.77-0.91).

Earlier subgroup analyses from these mammography trials raised questions about whether screening is effective in women younger than 50. Seven trials enrolled women aged 40-49. Six of these were rated by the USPSTF to be of at least "fair" quality, but only 1 of these was designed to specifically address the benefits of screening in this age group: it reported no reduction in breast cancer mortality with annual mammography and CBE.[18,20] Of the remaining 5 fair-quality trials that included women younger than 50, 1 trial has reported significant mortality reduction with screening in this age group,[4,13] 3 have reported non-significant mortality reductions,[4,12,15,16] and 1 found no benefit.[14] In a meta-analysis performed for the USPSTF pooling results for women aged 40-49 in the 6 fair-quality trials, the summary relative risk of breast cancer mortality was 0.85 (95% CI 0.73-0.99) among screened women after 13 years of observation.[2] These results are similar to prior meta-analyses based on older data.

Because these data represent a subgroup analysis of trials not designed to test the benefits of beginning screening at a specific age, questions remain about the additional benefits of beginning screening before age 50. On average, the time until mortality benefits begin to be observed in these trials is longer in women younger than 50 than in older women (8 years vs 4 to 6 years) and some of the observed benefits could be due to screening after age 50.[3,4] Analyses of individual studies suggest that at least some of the mortality reduction is due to early detection of tumors before age 50, but definitive estimates of the proportion of benefits due to early screening cannot be made.[3,24]

Clinical Breast Examination

No study has compared CBE to no screening. The reductions in breast cancer mortality in studies using mammography alone are comparable to those using mammography plus CBE.[3]

Breast Self-examination

The role of BSE in reducing breast cancer mortality has been evaluated in 1 Chinese[25] and 1 Russian[26] RCT and 1 non-randomized controlled trial of BSE education in the United Kingdom.[27]

None of the 3 trials has demonstrated a reduction in breast cancer mortality or significant improvements in the number or stage of cancers detected, with follow-up ranging from 5 to 14 years; follow-up is continuing in 1 trial that observed a slight non-significant reduction in mortality in the BSE group at 9 years.[26] In a good-quality nested case-control analysis from a Canadian screening study, the overall practice of BSE was not associated with a reduction in mortality.[28] Although none of these studies provides support for BSE, the USPSTF concluded that these studies did not exclude a possible benefit, due to their limited duration of follow-up and questions about whether results from other countries are generalizable to women in North America.

When To Stop Screening

Although there are no trial data directly evaluating screening in women older than 74, 2 RCTs suggest benefits among women enrolled in screening trials up to ages 70 and 74.[15,16] Because risk for breast cancer is high after age 70, the benefits of mammography could be important. However, this is offset by the fact that some older women (especially the very old and those with comorbid illness) will die from other causes before they observe any benefits from early detection.

Screening Interval

In clinical trials, mortality reductions occurred in programs with screening intervals ranging from 12-33 months, with no clear difference due to interval.[3] Data suggest that breast cancer grows more rapidly in women younger than 50, and the sensitivity of mammography is lower in this age group; thus, shorter screening intervals have been advocated for women aged 40-49. Among the trials showing or suggesting a benefit of screening in women younger than 50, screening intervals that ranged from 12-33 months appeared to achieve comparable results, providing no direct evidence of incremental benefits over annual screening.[3]

Potential Harms of Screening

Similar to other cancer screening tests, the large majority (80% to 90%) of abnormal screening mammograms or CBEs are false-positives.[3] These may require follow-up testing or invasive procedures such as breast biopsy to resolve the diagnosis, and can result in anxiety, inconvenience, discomfort, and additional medical expenses.[3] In 1 large community study, 6.5% of screening mammograms required some additional follow-up and, over a 10-year period, 23% of all women had experienced at least 1 abnormal mammogram.[8] The cumulative risk for a false-positive result after 10 mammograms was estimated to be 49%.[8] The proportion of false-positive results that lead to biopsy varies substantially in different settings.[29] In screening trials, 1% to 6% of all women screened underwent biopsy, and the proportion of biopsies that revealed cancer ranged from 12% to 78%.[3] In 2 RCTs, BSE education resulted in a nearly 2-fold increase in false-positive results, physician visits, and biopsies for benign disease.[25,26]

The consequences of false-positive mammograms are uncertain. Most, but not all, studies report increased anxiety from an abnormal mammogram.[2] At the same time, some studies report that women in the United States may be willing to accept a relatively high number of false-positive results in the population in return for the benefits of mammography.[2,30] Studies do not indicate that false-positive results diminish adherence to subsequent screening.[3]

False-negatives also occur with mammograms and CBE. Although false-negative results might provide false reassurance, the USPSTF found no data indicating these led to further delays in diagnosis.[3]

Some experts view the over-diagnosis and treatment of ductal carcinoma in situ (DCIS) as a potential adverse consequence of mammography. Although the natural history of DCIS is variable, many women in the United States are treated aggressively with mastectomy or lumpectomy and radiation.[2] Given the dramatic increase in the incidence of DCIS in the past 2 decades (750%) and autopsy series suggesting that there is a significant pool of DCIS among women who die of other causes,[3] screening may be increasing the number of women undergoing treatment for lesions that might not pose a threat to their health.

A final potential concern about mammography is radiation-induced breast cancer, but there are few data to directly assess this risk. A 1997 review, using risk estimates provided by the Biological Effects of Ionizing Radiation report of the National Academy of Sciences, estimated that annual mammography of 100,000 women for 10 consecutive years beginning at age 40 would result in up to 8 radiation-induced breast cancer deaths.[31]

Recommendations of Others

Nearly all North American organizations support mammography screening, although groups vary in the recommended age to begin screening, the interval for screening, and the role of CBE. The American Medical Association (AMA),[32] the American College of Obstetricians and Gynecologists (ACOG),[33] the American College of Radiology (ACR),[34] and the American Cancer Society (ACS),[35] all support screening with mammography and CBE beginning at age 40. The Canadian Task Force on Preventive Health Care (CTFPHC),[36] the American Academy of Family Physicians (AAFP),[37] and the American College of Preventive Medicine (ACPM)[38] recommend beginning mammography for average-risk women at age 50. AAFP and ACPM recommend that mammography in high-risk women begin at age 40, and AAFP recommends that all women aged 40-49 be counseled about the risks and benefits of mammography before making decisions about screening.[37,38] A 1997 Consensus Development Panel convened by the National Institutes of Health concluded that the evidence was insufficient to determine the benefits of mammography among women aged 40-49. This panel recommended that women aged 40-49 should be counseled about potential benefits and harms before making decisions about mammography.[39] In 2001, the CTFPHC concluded there was insufficient evidence to recommend for or against mammography in women 40-49.[40]

Organizations differ on their recommendations for the appropriate interval for mammography. Annual mammography is recommended by AMA, ACR, and ACS.[32,34,35] Mammography every 1-2 years is recommended by AAFP, ACPM, and the CTFPHC.[36-38] ACOG recommends annual mammography every 1-2 years for women aged 40-49 and annually for women aged 50 and older.[33]

In their 2001 report, the Canadian Task Force on Preventive Health Services recommends against teaching BSE to women aged 40-69.[41] The AMA, ACOG, ACS, and AAFP support teaching BSE.

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Appendix A
U.S. Preventive Services Task Force - Recommendations and Ratings

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. *The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.*

B. The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. *The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.*

C. The USPSTF makes no recommendation for or against routine provision of [the service]. *The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.*

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. *The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.*

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. *Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

Appendix B
U.S. Preventive Services Task Force - Strength of Overall Evidence

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

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