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Breast Cancer Screening

Breast cancer is the most commonly diagnosed noncutaneous cancer in women in the United States, and the second leading cause of death from cancer in American women—second only to lung cancer (1). Breast cancer mortality can be effectively reduced through screening. The purpose of this Practice Bulletin is to review breast cancer screening guidelines and the evidence used to support the recommendations and highlight new screening modalities and controversies surrounding screening.

Background

Incidence

Breast cancer accounts for 27% of all new cases of cancer diagnosed in women (2). A woman's lifetime risk of developing breast cancer is 12.08%, or 1 in 8 (Table 1) (2, 3). In 2010, approximately 207,090 new cases of invasive breast cancer were diagnosed, and 39,840 deaths were attributable to breast cancer (2). In addition, 54,010 new cases of in situ breast cancer were reported in 2010 (3). There was a 2% per year decrease in the incidence of breast cancer between 1999 and 2006, possibly reflecting decreased use of menopausal hormone therapy and decreased use of screening mammography (3–5). Breast cancer-related mortality has been decreasing steadily since 1990, reflecting both earlier detection of breast cancer and improved treatment (3).

Components of Breast Cancer Screening and Current Guidelines

Breast cancer screening has traditionally included three elements: 1) breast imaging (primarily mammography), 2) clinical breast examination, and 3) patient self-screen-

Table 1. Age-Specific Probabilities of Developing Invasive Female Breast Cancer*

If Current Age Is...	The Probability of Developing Breast Cancer in the Next 10 Years [†]	Or 1 in:
20	0.06%	1,760
30	0.44%	229
40	1.44%	69
50	2.39%	42
60	3.40%	29
70	3.73%	27
Lifetime risk	12.08%	8

*Among those free of cancer at the beginning of the age interval. Based on cases diagnosed 2004–2006. Percentages and "1 in" numbers may not be numerically equivalent because of rounding.

[†]Probability derived using NCI DevCan Software, Version 6.4.0.

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ing (breast self-examination or breast self-awareness). The relative value of each element and appropriate age of initiation, cessation, and frequency of screening remain

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controversial. Table 2 outlines the current screening guidelines of several major medical organizations. The American College of Obstetricians and Gynecologists (the College) continues to endorse inclusion of all three strategies in breast cancer screening.

Screening Mammography

Rationale for Mammographic Screening

Tumors detected at an early stage that are small and confined to the breast are more likely to be successfully treated, with a 98% 5-year survival for localized disease (3). After 18 years of follow-up, one initial study found that 89% of tumors measuring 1 cm or less were cured by primary surgery (mastectomy and axillary dissection) (6). Other studies have confirmed these results, with 90% of patients experiencing 10-year (or longer) disease-free survival periods after tumors measuring 1 cm or less were detected by mammography, indicating the likelihood that the tumors had not yet metastasized before they were diagnosed and treated (7–11).

By mathematical estimation, a typical ductal adenocarcinoma with a constant mean doubling time of 100 days would have been present for more than 11 years before it grew to a generally palpable size of 2 cm (12–14). Mammography screening could potentially identify a nonpalpable mass measuring approximately 1 mm to 1 cm during its preclinical phase, 3 years before it becomes palpable (12–15). This concept is commonly referred to as sojourn time, which is the time interval when cancer may be detected by screening before it

becomes symptomatic. The sojourn time of an individual type of cancer varies, with more biologically aggressive tumors typically having shorter sojourn times. The greatest predictor of sojourn time in breast cancer appears to be age. Estimates of mean sojourn time for breast cancer in women increase with age: for ages 40–49 years, mean sojourn time is 2–2.4 years; 50–59 years, 2.5–3.7 years; 60–69 years, 3.5–4.2 years; and 70–74 years, 4–4.1 years (16).

The mean sojourn time has implications for breast cancer screening because it is desirable to detect tumors during this sojourn period. Individuals who are likely to have types of cancer with shorter sojourn times are more likely to benefit from more frequent screening when compared with those with slow-growing tumors that have a larger preclinical window. Screening strategies should be designed to maximize the likelihood of detecting the cancer during the preclinical window, when treatment options may be greater and outcomes may be improved.

Evaluation of Mammography

A recent meta-analysis conducted for the United States Preventive Services Task Force reviewed eight randomized controlled trials of mammographic screening conducted between 1986 and 2006 (17). Despite some study limitations (all studies were rated of “fair” quality by the United States Preventive Services Task Force), this review reaffirmed a reduction in breast cancer-related mortality for women aged 39–69 years who were invited

Table 2. Breast Cancer Screening Recommendations

	Mammography	Clinical Breast Examination	Breast Self-Examination Instruction	Breast Self-Awareness
American College of Obstetricians and Gynecologists	Age 40 years and older annually	Age 20–39 years every 1–3 years Age 40 years and older annually	Consider for high-risk patients	Recommended
American Cancer Society	Age 40 years and older annually	Age 20–39 years every 1–3 years Age 40 years and older annually	Optional for age 20 years and older	Recommended
National Comprehensive Cancer Network	Age 40 years and older annually	Age 20–39 years every 1–3 years Age 40 years and older annually	Recommended	Recommended
National Cancer Institute	Age 40 years and older every 1–2 years	Recommended	Not recommended	—
U.S. Preventive Services Task Force	Age 50–74 years biennially	Insufficient evidence	Not recommended	—

for screening. This is consistent with the mortality reductions demonstrated in previous meta-analyses (18–22).

Relative risk of breast cancer mortality in women invited for screening was 0.85 for women aged 39–49 years; 0.86 for women aged 50–59 years; and 0.68 for women aged 60–69 years. Evidence was insufficient to demonstrate a mortality reduction for women aged 70 years and older (Table 3). However, because of the increasing incidence of breast cancer as women age, more young women (aged 39–49 years) had to be invited for screening to prevent one breast cancer-related death when compared with older women (Table 3). The number needed to invite for screening (over several rounds of screening and at least 11 years of follow-up) to prevent one breast cancer death in women aged 39–49 years was 1,904, compared with 1,339 in women aged 50–59 years. This difference in number needed to invite for screening to prevent one death was a key reason the United States Preventive Services Task Force elected not to recommend routine screening for women aged 40–49 years, despite similar mortality reductions (23).

Because of differences in study design, with most randomized clinical trials evaluating biennial mammographic screening, these randomized controlled trials do not provide meaningful comparisons between different screening strategies in terms of age at initiation, cessation, and frequency. The lack of clear evidence on this issue led the United States Preventive Services Task Force to commission the creation of screening models that could compare different strategies to help guide national screening recommendations. These six models were created by independent investigative groups that are a part of the National Cancer Institute’s Cancer

Intervention and Surveillance Modeling Network. These models were created using a common set of age-specific variables, with the goal of identifying efficient screening strategies (ie, those that produce a gain in mortality reduction or a gain in life years per additional screening mammogram).

Biennial screening was used in seven of eight screening strategies found to be efficient in reducing mortality, and in six of these eight strategies, screening began at age 50 years. A review of the strategies concluded that more lives could be saved by extending screening to women older than 69 years, rather than extending screening to women aged 40–49 years (24). However, when defining benefit as number of life years gained through screening, screening was started at age 40 years in four of eight strategies. Although annual screening was an efficient strategy for reducing breast cancer mortality and increasing life years gained, it was noted by the authors to be more resource intensive (24).

Other Imaging Techniques

Ultrasonography is an established adjunct to mammography in the imaging evaluation. It is useful in evaluating inconclusive mammographic findings, in evaluating young patients and other women with dense breast tissue, in guiding tissue core-needle biopsy and other biopsy techniques, and in differentiating a cyst from a solid mass. It is not recommended as a screening modality for women at average risk of developing breast cancer. Ultrasonography may be an option for additional screening in women at high risk who are candidates for magnetic resonance imaging (MRI) screening but can-

Table 3. Pooled Relative Risks for Breast Cancer Mortality From Mammography Screening Trials for All Ages

Age	Trials Included, n	RR for Breast Cancer Mortality (95% CrI)	NNI to Prevent 1 Breast Cancer Death (95% CrI)
39–49 y	8*	0.85 (0.75–0.96)	1904 (929–6378)
50–59 y	6†	0.86 (0.75–0.99)	1339 (322–7455)
60–69 y	2‡	0.68 (0.54–0.87)	377 (230–1050)
70–74 y	1§	1.12 (0.73–1.72)	Not available

Abbreviations: CrI, credible interval; NNI, number needed to invite to screening; RR, relative risk; y, years.

*Health Insurance Plan of Greater New York, Canadian National Breast Screening Study-1, Stockholm, Malmö, Swedish Two-County trial (2 trials), Gothenburg trial, and Age trial.

†Canadian National Breast Screening Study-1, Stockholm, Malmö, Swedish Two-County trial (2 trials), and Gothenburg trial.

‡Malmö and Swedish Two-County trial (Östergötland).

§Swedish Two-County trial (Östergötland).

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not receive MRI because of gadolinium contrast allergy, claustrophobia, or other barriers.

Magnetic resonance imaging can be a useful adjunct to diagnostic mammography, but cost, duration of the examination, and injection of contrast material prohibit its use as a routine, population-based screening technique. The American Cancer Society has issued guidelines regarding the use of MRI for screening in high-risk women. Based on expert panel review of the evidence, the American Cancer Society recommends MRI screening for women with a 20% or greater lifetime risk of developing breast cancer, including women with the following:

- Have a known *BRCA1* or *BRCA2* gene mutation
- Have a first-degree relative with a *BRCA1* or *BRCA2* gene mutation and have not had any testing themselves
- A lifetime risk of breast cancer of 20% or greater, according to risk assessment tools that are based mainly on family history
- A history of radiation therapy to the chest between the ages of 10 years and 30 years
- Other genetic syndromes, including Li–Fraumeni syndrome, Cowden syndrome, or Bannayan–Riley–Ruvalcaba syndrome or one of these syndromes in a first-degree relative

The panel concluded that there was insufficient evidence to recommend for or against MRI screening for women with a personal history of breast cancer, carcinoma in situ, atypical hyperplasia, and extremely dense breasts on mammography (25). Breast MRI is not recommended for screening women at average risk of developing breast cancer.

Color Doppler ultrasonography, computer-aided detection, positron emission tomography, scintimammography, and digital breast tomosynthesis have shown promise in selected clinical situations or as adjuncts to mammography for breast cancer diagnosis. However, these technologies are not considered alternatives to routine mammography.

Digital Mammography

In 2005, the results of the Digital Mammographic Imaging Screening Trial were reported (26). During the 2-year study period, 49,528 women were recruited to the study from 33 sites in the United States and Canada. All participants underwent both digital mammography and film mammography in random order. The diagnostic accuracy of digital mammography and film mammography was similar across the entire population. Digital mammography was superior to film mammography in women younger than 50 years, women with heteroge-

neously dense or extremely dense breasts, and premenopausal and perimenopausal women.

In 2007, the follow-up and final results of the Oslo II study were reported. This was a randomized trial of screen-film versus full-field digital mammography in a population-based screening program of women aged 45–69 years. In this trial, women aged 45–69 years were assigned to undergo film mammography (n=16,985) or digital mammography (n=6,944). The group of women aged 45–49 years was monitored for 1.5 years and the group of women aged 50–69 years was monitored for 2 years. There was a significant difference in the cancer detection rate between the digital mammography (0.59%) and film mammography (0.38%) ($P=0.02$) groups (27).

A recent meta-analysis of data from eight large randomized studies found that, overall, digital mammography demonstrated a slightly higher detection rate than film mammography, particularly for women aged 60 years or younger (28).

Clinical Considerations and Recommendations

► *What is the difference between breast self-examination and breast self-awareness, and are these screening methods effective?*

Breast self-examination is the performance of an examination of the breasts in a consistent, systematic way by the individual on a regular basis, typically monthly. Historically, physicians have been encouraged to educate their patients on how to perform these examinations, and public awareness campaigns have focused on this intervention. It still may be appropriate for certain high-risk populations and for other women who choose to follow this approach.

Currently, there is an evolution away from teaching breast self-examination toward the concept of breast self-awareness. The College, the American Cancer Society, and the National Comprehensive Cancer Network endorse *breast self-awareness*, which is defined as women's awareness of the normal appearance and feel of their breasts. This concept has arisen because approximately one half of all cases of breast cancer in women 50 years and older and more than 70% of cases of cancer in women younger than 50 years are detected by women themselves, frequently as an incidental finding (29, 30). In addition, the effectiveness of self-examination was at odds with what was anticipated based on the aforementioned statistics.

Breast self-awareness should be encouraged and can include breast self-examination. Women who desire to perform self-examination as a part of this breast self-

awareness strategy may be instructed in the appropriate technique, although emphasis is not on examination techniques. Women should report any changes in their breasts to their health care providers. Although this patient education strategy has not been studied to date, breast awareness may be of particular importance as part of a screening strategy because some women may falsely assume that negative mammography or clinical breast examination results definitively exclude the presence of breast cancer. New cases of cancer can arise during screening intervals, and breast self-awareness may prompt women not to delay in reporting breast changes based on false reassurance of recent negative screening result. Breast self-awareness aims to capture the importance of self-detection and prompt evaluation of symptoms because it relates to overall breast cancer morbidity and mortality. However, the effect of breast self-awareness education has not been studied.

The United States Preventive Services Task Force has recommended against teaching breast self-examination based on a lack of evidence to show benefit and potential harm resulting from evaluation of false-positive findings (23). A prospective study of 604 patients with breast cancer revealed that only 7.6% of the 448 women who practiced regular breast self-examination had detected their own cancer, and those who did showed no survival advantage (31). The Shanghai breast self-examination trial of 266,000 women aged 39–72 years randomized to receive either breast self-examination instruction plus follow-up or no information on breast cancer screening reported essentially no difference in breast cancer-related deaths between the two groups (135 versus 131, respectively) after 10–11 years of follow-up (32). However, women in the instruction group were more likely to undergo breast biopsy for benign lesions (32).

A Cochrane systematic review published in 2003 included the Shanghai breast trial (32) and another large population-based study from Russia that compared breast self-examination with no intervention. In both trials, almost twice as many biopsies with benign results were performed in the screening group compared with the control group (33). The Canadian Task Force on Preventive Health Care also recommended against teaching breast self-examination based on fair evidence that breast self-examination had no benefit and good evidence that it was harmful. Their review cited additional evidence that patients experience increased worry, anxiety, and depression associated with breast self-examination (34).

Because other screening methods (mammography and clinical breast examination) can have false-negative results and cases of breast cancer can occur in unscreened women, there are clearly situations in which women

will detect cancer themselves. As such, the College, the American Cancer Society, and the National Comprehensive Cancer Network endorse educating women aged 20 years and older regarding breast self-awareness, as a means to play a role in earlier detection (Table 2).

► ***Is clinical (ie, health care provider performed) breast examination effective for breast cancer screening? If so, how frequently should it be performed?***

A study using data from the National Breast and Cervical Cancer Early Detection Program, where 752,081 clinical breast examinations were performed in the community setting in women aged 40 years and older, concluded that clinical breast examination alone has a sensitivity for cancer detection of 58.8%, with a specificity of 93.4%. In this population, five cases of cancer were detected per 1,000 clinical breast examinations performed. When the clinical breast examination finding was abnormal and the mammogram was normal, 7.4 cases of cancer were detected per 1,000 screenings. The authors concluded that the addition of clinical breast examination “modestly improved” early detection (35).

Multiple reviews have supported the combination of clinical breast examination and mammography for breast cancer screening (36–41). A recent study demonstrated improved sensitivity for breast cancer detection (94.6% versus 88.6%) when comparing mammography plus clinical breast examination with mammography alone. However, the false-positive rate was also higher in the group receiving clinical breast examination compared with the mammography-alone group (12.4% versus 7.4%) (41). Based on available evidence, the College, the American Cancer Society, and the National Comprehensive Cancer Network recommend that clinical breast examination should be performed annually for women aged 40 years and older. Although the value of screening clinical breast examination for women with a low prevalence of breast cancer (ie, women aged 20–39 years) is not clear, the College, the American Cancer Society, and the National Comprehensive Cancer Network continue to recommend clinical breast examination for these women every 1–3 years.

► ***When should mammography begin, and how frequently should mammography be performed?***

Based on the incidence of breast cancer, the sojourn time for breast cancer growth, and the potential for reduction in breast cancer mortality, the College recommends that women aged 40 years and older be offered screening mammography annually. However, as with any screen-

ing test, women should be educated on the predictive value of the test and the potential for false-positive results and false-negative results. Women should be informed of the potential for additional imaging or biopsies that may be recommended based on screening results. The physician should work with the patient to determine the best screening strategy based on individual risk and values. In some women, biennial screening may be a more appropriate or acceptable strategy. Some average-risk women may prefer biennial screening, which maintains most of the benefits of screening while minimizing both the frequency of screening and the potential for additional testing, whereas other women prefer annual screening because it maximizes cancer detection.

Various groups have offered recommendations on the timing of initiation and frequency of mammography screening. Each group places different values on competing considerations, such as published evidence, cost-effectiveness, efficiency, accuracy, adverse consequences, specificity, sensitivity, false-positive results, false-negative results, positive predictive value, patient adherence, availability of health care resources, conflicting health care needs, and opinions of experts and advocates. A summary of the recommendations can be found in Table 2.

The American Cancer Society and the National Comprehensive Cancer Network recommend annual screening mammography beginning at age 40 years (42, 43). In contrast, the United States Preventive Services Task Force recently changed their guidelines to recommend biennial mammography in women aged 50–74 years. Although routine screening in women aged 40–49 years was not recommended, the Task Force advised that screening in women younger than 50 years should be individualized based on “patient values regarding specific benefits and harms” (23).

The American Cancer Society, the National Comprehensive Cancer Network, and the United States Preventive Services Task Force agree that screening mammography reduces breast cancer-related mortality in women aged 40 years and older based on meta-analyses of available randomized controlled trials on mammographic screening (see Table 3). However, the United States Preventive Services Task Force arrived at a different conclusion regarding routine screening for women aged 40–49 years by placing greater weight on the lower prevalence of disease in this population, which reduces the positive predictive value of mammography and increases the number needed to screen to prevent one breast cancer-related death. In addition, the United States Preventive Services Task Force argues that all women who participate in breast cancer screening may potentially experience a false-positive mammogram (as

high as 49% of women after 10 years of screening), with resultant additional imaging, biopsies, and psychological distress (44). The burden of these additional tests may be perceived as greater on women aged 40–49 years because they are less likely to experience breast cancer and, therefore, less likely to benefit from screening (23).

In response to this argument, experts who support routine screening for women in their 40s note that although the incidence of cancer is less in the 40–49 year age group than in all women older than 50 years, the incidence of cancer in women in their 50s (1 in 38, or 2.60%) is not much higher than in women in their 40s (1 in 69, or 1.44%) (2). In addition, women who undergo routine screening mammography in their 40s have comparable mortality reduction compared with women who undergo routine mammography screening in their 50s (16% reduction versus 15% reduction, respectively) (17). This is of particular importance because each year in the United States breast cancer is diagnosed in approximately 50,000 women younger than 50 years.

Regarding the frequency of screening mammography, the United States Preventive Services Task Force also diverged from what has become common practice in the United States by recommending biennial rather than annual screening for women aged 50 years and older. This decision was based on the National Cancer Institute’s Cancer Intervention and Surveillance Modeling Network screening models, which predicted that 81% of the benefits of screening (ie, mortality reduction) could be maintained by screening every other year (24). This strategy is less resource intensive and is predicted to reduce false-positive results by 50% (23). However, these models demonstrate a greater reduction in mortality and increased number of life years gained by screening annually; therefore, accepting a biennial strategy reduces some (19%) of the potential benefits of screening.

► *What are the potential adverse consequences of screening mammography?*

Potential adverse outcomes of breast cancer screening mammography include false-positive mammograms, false-negative mammograms, and overdiagnosis. Concerns about the risk of radiation exposure (eg, induction of breast cancer from radiation exposure) have largely been decreased by improvements in mammography technique, technology, and clinical experience (45).

False-positive mammograms (ie, those with perceived abnormalities requiring further evaluation to verify that the lesion is not cancer) are a continuing concern (44, 46). False-positive screening mammograms require diagnostic mammography with supplementary views, ultrasonography, and even biopsy in 20–30% of

cases in an attempt to reach an accurate diagnosis (44, 46). Psychosocial consequences of screening mammography, such as anxiety and distress, have been identified, reviewed, and are generally short-lived and not severe (47–50). Studies evaluating the effect of false-positive results suggest that women in the United States are highly tolerant of false-positive mammograms, and that women who experience a false-positive mammogram are more likely than women with a normal result to adhere to routine screening in the future. Women with false-positive results were more likely to have anxiety about developing breast cancer, but not at a demonstrably pathologic level (50, 51).

► **What are the factors that increase a woman’s relative risk of breast cancer?**

Most women in whom invasive breast cancer is diagnosed do not have unique identifiable risk factors; however, women with certain characteristics do have an increased lifetime prevalence of breast cancer compared with the general population (52, 53). The incidence of breast cancer increases with advancing age (2). Because women at high risk need to be appropriately counseled regarding increased surveillance or breast cancer risk reduction, physicians should periodically assess breast cancer risk. The goal of this risk assessment is to categorize the woman’s risk level as average for her age versus elevated or high risk. Risk assessment should not be used to consider a woman ineligible for screening appropriate for her age, but rather to identify those who may qualify for enhanced screening, such as addition of MRI screening or more frequent clinical breast examinations and risk reduction strategies.

Reproductive Risk Factors

Certain reproductive factors also influence breast cancer risk, including age at menarche, age at first birth, breastfeeding, parity, and age at menopause (Table 4). A greater number of reproductive years, later age at first birth, and lower parity or nulliparity generally increase breast cancer risk.

Familial Risk Factors

Another important consideration in breast cancer risk assessment is family history to identify cases of breast cancer, ovarian cancer, prostate cancer, and other types of cancer in first-degree relatives (parents, sibling, child), second-degree relatives, and third-degree relatives, including the age of onset for the family members with cancer. Based on this family history, women may be eligible for testing for *BRCA* gene mutations or for referral to a genetic counselor for further evaluation and consideration of test-

Table 4. Factors That Increase the Relative Risk of Breast Cancer in Women

Relative Risk	Factor
>4.0	Female Age (65+ vs <65 years, although risk increases across all ages until age 80) Certain inherited genetic mutations for breast cancer (<i>BRCA1</i> and/or <i>BRCA2</i>) Two or more first-degree relatives with breast cancer diagnosed at an early age Personal history of breast cancer High breast tissue density Biopsy-confirmed atypical hyperplasia
2.1–4.0	One first-degree relative with breast cancer High-dose radiation to chest High bone density (postmenopausal)
1.1–2.0	Late age at first full-term pregnancy (>30 years)
Factors that affect circulating hormones	Early menarche (<12 years) Late menopause (>55 years) No full-term pregnancies Never breastfed a child Recent oral contraceptive use Recent and long-term use of estrogen and progestin Obesity (postmenopausal)
Other factors	Personal history of endometrial or ovarian cancer Alcohol consumption Height (tall) High socioeconomic status Ashkenazi Jewish heritage

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ing (see Practice Bulletin No.103, *Hereditary Breast and Ovarian Cancer Syndrome*, April 2009).

Combined Factors

The Gail Model is a risk assessment tool that uses patient age, some reproductive factors, limited family history (breast cancer in first-degree female relatives), and a history of breast biopsies to estimate 5-year and lifetime breast cancer risks. This model has been validated in Caucasian women and studied extensively in African American women. The assessment can be completed in less than a minute, and is available at www.cancer.gov/bcrisktool. Women estimated to have a 5-year breast cancer risk of 1.7% or greater (equivalent to the average

risk for a women aged 60 years) or a lifetime risk of 20% or greater may be offered enhanced screening, including a clinical breast examination every 6–12 months, yearly mammography, and instruction in breast self-examination. The Gail model is not a good risk assessment tool when there is a strong family history of breast cancer in women other than the mother and sisters of the patient or a family history of cancer other than breast cancer (eg, ovarian cancer). Breast MRI is not typically recommended based on the Gail Model.

► ***What screening is appropriate for women at high risk?***

For women who test positive for *BRCA1* or *BRCA2* mutations, enhanced screening should be recommended and risk reduction methods discussed. Enhanced screening for these women includes twice-yearly clinical breast examinations, annual mammography, annual breast MRI, and instruction in breast self-examination. (Details regarding the management of women with *BRCA* mutations are reviewed in Practice Bulletin No.103, *Hereditary Breast and Ovarian Cancer Syndrome*, April 2009.) Women who have first-degree relatives with these mutations but who are untested are generally managed as if they carry these mutations until their *BRCA* status is known.

Women who are estimated to have a lifetime risk of breast cancer of 20% or greater, based on risk models that rely largely on family history (such as BRCAPRO, BODACEA, or Claus), but who are either untested or test negative for *BRCA* gene mutations, can be offered enhanced screening as described previously for carriers of the *BRCA* mutation. Risk-reduction strategies also may be considered for these women.

Other women considered at high risk of development of future cases of breast cancer are those who received thoracic irradiation (typically as a treatment for lymphoma) between the ages 10 years and 30 years. These women should be advised to receive annual mammography, annual MRI, and screening clinical breast examination every 6–12 months beginning 8–10 years after they received treatment or at age 25 years, whichever occurs last.

Women with a personal history of high-risk breast biopsy results, including atypical hyperplasia and lobular carcinoma in situ are at increased risk of future breast cancer. These women should receive enhanced screening, including annual mammography, clinical breast examination every 6–12 months, and instruction in breast self-examination. Yearly breast MRI also has been recommended for women with a history of lobular carcinoma in situ by some organizations (43). Women with a personal history of ductal carcinoma in situ or invasive

breast cancer should be monitored similarly, although MRI is not routinely recommended in this population.

► ***Is there an upper age range at which the risks of mammography outweigh the benefits?***

A consensus of recommendations on this issue does not exist. Medical comorbidity and life expectancy should be considered in a breast cancer screening program for women aged 75 years or older because the benefit of screening mammography decreases compared with the harms of overtreatment with advancing age. Women aged 75 years or older should, in consultation with their physicians, decide whether or not to continue mammographic screening (17).

Figure 1 illustrates the progressively increasing incidence and mortality rates of invasive breast cancer by race and age up to 84 years (3). Most of the screening mammography clinical trials had an upper age limit criteria ranging from 64 years to 74 years. However, a meta-analysis concluded that screening mammography in women aged 70–79 years is moderately cost-effective and yields a small increase in life expectancy (54).

Summary of Recommendations and Conclusions

The following recommendations are based on limited and inconsistent scientific evidence (Level B):

- Based on the incidence of breast cancer, the sojourn time for breast cancer growth, and the potential reduction in breast cancer mortality, the College recommends that women aged 40 years and older be offered screening mammography annually.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Clinical breast examination should be performed annually for women aged 40 years and older.
- For women aged 20–39 years, clinical breast examinations are recommended every 1–3 years.
- Breast self-awareness should be encouraged and can include breast self-examination. Women should report any changes in their breasts to their health care providers.
- Women should be educated on the predictive value of screening mammography and the potential for false-positive results and false-negative results. Women should be informed of the potential for

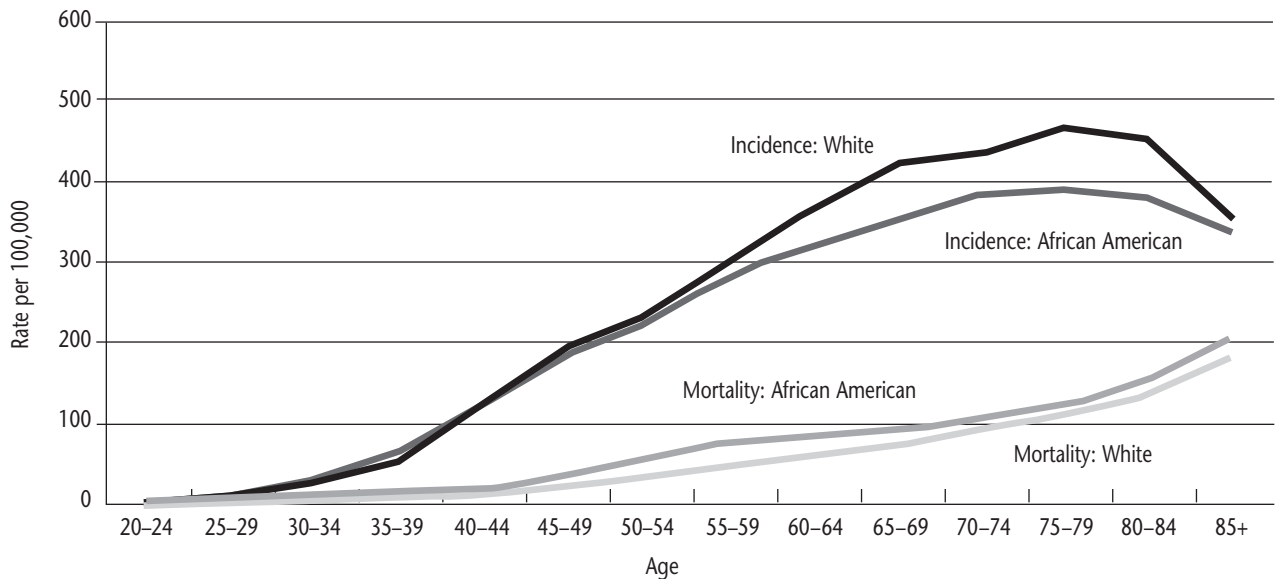


Fig. 1. Female Breast Cancer—Incidence and Mortality Rates by Age and Race, United States, 2002–2006. Data from Incidence—North American Association of Central Cancer Registries, 2009. Mortality—National Center for Health Statistics, Centers for Disease Control and Prevention, 2009. Reprinted with permission from American Cancer Society. Breast Cancer Facts & Figures 2009–2010. Atlanta: American Cancer Society, Inc.

additional imaging or biopsies that may be recommended based on screening results.

- ▶ Women who are estimated to have a lifetime risk of breast cancer of 20% or greater, based on risk models that rely largely on family history (such as BRCA1, BRCA2, or Claus), but who are either untested or test negative for *BRCA* gene mutations, can be offered enhanced screening.
- ▶ Breast MRI is not recommended for screening women at average risk of developing breast cancer.
- ▶ For women who test positive for *BRCA1* and *BRCA2* mutations, enhanced screening should be recommended and risk reduction methods discussed.

References

1. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Thun MJ. Cancer statistics, 2009. *CA Cancer J Clin* 2009;59:225–49. (Level II-3)
2. Altekruse SF, Kosary CL, Krapcho M, Neyman N, Aminou R, Waldron W et al, editors. SEER cancer statistics review, 1975–2007. Bethesda (MD): National Cancer Institute; 2011. Available at: http://seer.cancer.gov/csr/1975_2007. Retrieved February 17, 2011. (Level II-3)
3. American Cancer Society. Breast cancer facts & figures: 2009–2010. Atlanta (GA): ACS; 2009. Available at: <http://www.cancer.org/acs/groups/content/@nho/documents/document/f861009final90809pdf.pdf>. Retrieved February 17, 2011. (Level II-3)
4. Ravdin PM, Cronin KA, Howlander N, Berg CD, Chlebowski RT, Feuer EJ, et al. The decrease in breast-cancer incidence in 2003 in the United States. *N Engl J Med* 2007;356:1670–4. (Level III)
5. Glass AG, Lacey JV Jr, Carreon JD, Hoover RN. Breast cancer incidence, 1980–2006: combined roles of menopausal hormone therapy, screening mammography, and estrogen receptor status. *J Natl Cancer Inst* 2007;99:1152–61. (Level II-3)
6. Rosen PP, Groshen S, Kinne DW. Survival and prognostic factors in node-negative breast cancer: results of long-term follow-up studies. *J Natl Cancer Inst Monogr* 1992;(11):159–62. (Level III)
7. Tabar L, Chen HH, Duffy SW, Yen MF, Chiang CF, Dean PB, et al. A novel method for prediction of long-term outcome of women with T1a, T1b, and 10–14 mm invasive breast cancers: a prospective study [published erratum appears in *Lancet* 2000;355:1372]. *Lancet* 2000;355:429–33. (Level II-3)
8. Tabar L, Dean PB, Kaufman CS, Duffy SW, Chen HH. A new era in the diagnosis of breast cancer. *Surg Oncol Clin N Am* 2000;9:233–77. (Level III)
9. Joensuu H, Pylkkanen L, Toikkanen S. Late mortality from pT1N0M0 breast carcinoma. *Cancer* 1999;85:2183–9. (Level II-3)
10. Lopez MJ, Smart CR. Twenty-year follow-up of minimal breast cancer from the Breast Cancer Detection Demonstration Project. *Surg Oncol Clin N Am* 1997;6:393–401. (Level II-3)
11. Arnesson LG, Smeds S, Fagerberg G. Recurrence-free survival in patients with small breast cancer. An analysis of cancers 10 mm or less detected clinically and by screening. *Eur J Surg* 1994;160:271–6. (Level I)

12. Macdonald I. The natural history of mammary carcinoma. *Am J Surg* 1966;111:435–42. (Level III)
13. Gullino PM. Natural history of breast cancer. Progression from hyperplasia to neoplasia as predicted by angiogenesis. *Cancer* 1977;39:2697–703. (Level III)
14. Wertheimer MD, Costanza ME, Dodson TF, D’Orsi C, Pastides H, Zapka JG. Increasing the effort toward breast cancer detection. *JAMA* 1986;255:1311–5. (Level III)
15. Walter SD, Day NE. Estimation of the duration of a pre-clinical disease state using screening data. *Am J Epidemiol* 1983;118:865–86. (Level III)
16. Smith RA, Duffy SW, Gabe R, Tabar L, Yen AM, Chen TH. The randomized trials of breast cancer screening: what have we learned? *Radiol Clin North Am* 2004;42:793–806; v. (Level III)
17. Nelson HD, Tyne K, Naik A, Bougatsos C, Chan BK, Humphrey L. Screening for breast cancer: an update for the U.S. Preventive Services Task Force. U.S. Preventive Services Task Force. *Ann Intern Med* 2009;151:727–37; W237–42. (Level III)
18. Humphrey LL, Helfand M, Chan BK, Woolf SH. Breast cancer screening: a summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med* 2002;137:347–60. (Level III)
19. Kerlikowske K, Grady D, Rubin SM, Sandrock C, Ernster VL. Efficacy of screening mammography. A meta-analysis. *JAMA* 1995;273:149–54. (Meta-analysis)
20. Hendrick RE, Smith RA, Rutledge JH, 3rd, Smart CR. Benefit of screening mammography in women aged 40–49: a new meta-analysis of randomized controlled trials. *J Natl Cancer Inst Monogr* 1997;(22):87–92. (Meta-analysis)
21. Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography [published erratum appears in *Lancet* 2006;367:474]. *Lancet* 2001;358:1340–2. (Level III)
22. Nystrom L, Andersson I, Bjurstam N, Frisell J, Nordenskjold B, Rutqvist LE. Long-term effects of mammography screening: updated overview of the Swedish randomised trials [published erratum appears in *Lancet* 2002;360:724]. *Lancet* 2002;359:909–19. (Level III)
23. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. US Preventive Services Task Force [published errata appear in *Ann Intern Med* 2010;152:199–200; *Ann Intern Med* 2010;152:688]. *Ann Intern Med* 2009;151:716–26;W-236. (Level III)
24. Mandelblatt J, Saha S, Teutsch S, Hoerger T, Siu AL, Atkins D, et al. The cost-effectiveness of screening mammography beyond age 65 years: a systematic review for the U.S. Preventive Services Task Force. Cost Work Group of the U.S. Preventive Services Task Force. *Ann Intern Med* 2003;139:835–42. (Level III)
25. Saslow D, Boetes C, Burke W, Harms S, Leach MO, Lehman CD, et al. American Cancer Society guidelines for breast screening with MRI as an adjunct to mammography. American Cancer Society Breast Cancer Advisory Group [published erratum appears in *CA Cancer J Clin* 2007;57:185]. *CA Cancer J Clin* 2007;57:75–89. (Level III)
26. Pisano ED, Gatsonis C, Hendrick E, Yaffe M, Baum JK, Acharyya S, et al. Diagnostic performance of digital versus film mammography for breast-cancer screening. Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group [published erratum appears in *N Engl J Med* 2006;355:1840]. *N Engl J Med* 2005;353:1773–83. (Level II-3)
27. Skaane P, Hofvind S, Skjennald A. Randomized trial of screen-film versus full-field digital mammography with soft-copy reading in population-based screening program: follow-up and final results of Oslo II study. *Radiology* 2007;244:708–17. (Level I)
28. Vinnicombe S, Pinto Pereira SM, McCormack VA, Shiel S, Perry N, Dos Santos Silva IM. Full-field digital versus screen-film mammography: comparison within the UK breast screening program and systematic review of published data. *Radiology* 2009;251:347–58. (Level III)
29. Coates RJ, Uhler RJ, Brogan DJ, Gammon MD, Malone KE, Swanson CA, et al. Patterns and predictors of the breast cancer detection methods in women under age 45 years of age (United States). *CCC cancer causes & control* 2001;12(5):431–42. (Level II-2)
30. Newcomer L, Newcomb P, Trentham-Dietz A, Storer B, Yasui Y, Daling J, et al. Detection method and breast carcinoma histology. *Cancer* 2002;95(3):470–7. (Level II-3)
31. Auvinen A, Elovainio L, Hakama M. Breast self-examination and survival from breast cancer: a prospective follow-up study. *Breast Cancer Res Treat* 1996;38:161–8. (Level II-2)
32. Thomas DB, Gao DL, Ray RM, Wang WW, Allison CJ, Chen FL, et al. Randomized trial of breast self-examination in Shanghai: final results. *J Natl Cancer Inst* 2002;94:1445–57. (Level I)
33. Kusters JP, Gotzsche PC. Regular self-examination or clinical examination for early detection of breast cancer. *Cochrane Database of Systematic Reviews* 2003, Issue 2. Art. No.: CD003373. DOI: 10.1002/14651858.CD003373. (Meta-analysis)
34. Baxter N. Preventive health care, 2001 update: should women be routinely taught breast self-examination to screen for breast cancer? Canadian Task Force on Preventive Health Care. *CMAJ* 2001;164:1837–46. (Level III)
35. Bobo JK, Lee NC, Thames SF. Findings from 752,081 clinical breast examinations reported to a national screening program from 1995 through 1998. *J Natl Cancer Inst* 2000;92:971–6. (Level II-3)
36. Shen Y, Zelen M. Screening sensitivity and sojourn time from breast cancer early detection clinical trials: mammograms and physical examinations. *J Clin Oncol* 2001;19:3490–9. (Level III)
37. Jatoi I. Breast cancer screening. *Am J Surg* 1999;177:518–24. (Level III)
38. Primic-Zakelj M. Screening mammography for early detection of breast cancer. *Ann Oncol* 1999;10(suppl 6):121–7. (Level III)
39. Fletcher SW, Black W, Harris R, Rimer BK, Shapiro S. Report of the International Workshop on Screening for Breast Cancer. *J Natl Cancer Inst* 1993;85:1644–56. (Level III)
40. Miller AB, To T, Baines CJ, Wall C. Canadian national breast screening study-2: 13-year results of a random-

ized trial in women aged 50–59 years. *J Natl Cancer Inst* 2000;92:1490–9. (Level I)

41. Chiarelli AM, Majpruz V, Brown P, Theriault M, Shumak R, Mai V. The contribution of clinical breast examination to the accuracy of breast screening. *J Natl Cancer Inst* 2009; 101:1236–43. (Level II-2)
42. Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP 3rd, et al. American Cancer Society guidelines for breast cancer screening: update 2003. American Cancer Society High-Risk Work Group; American Cancer Society Screening Older Women Work Group; American Cancer Society Mammography Work Group; American Cancer Society Physical Examination Work Group; American Cancer Society New Technologies Work Group; American Cancer Society Breast Cancer Advisory Group. *CA Cancer J Clin* 2003;53:141–69. (Level III)
43. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™: breast cancer. Fort Washington (PA): NCCN; 2011. (Level III)
44. Elmore JG, Barton MB, Mocerri VM, Polk S, Arena PJ, Fletcher SW. Ten-year risk of false positive screening mammograms and clinical breast examinations. *N Engl J Med* 1998;338:1089–96. (Level II-3)
45. Armstrong K, Moye E, Williams S, Berlin JA, Reynolds EE. Screening mammography in women 40 to 49 years of age: a systematic review for the American College of Physicians. *Ann Intern Med* 2007;146:516–26. (Level III)
46. Harris R. Variation of benefits and harms of breast cancer screening with age. *J Natl Cancer Inst Monogr* 1997;(22):139–43. (Level III)
47. Rimer BK, Bluman LG. The psychosocial consequences of mammography. *J Natl Cancer Inst Monogr* 1997;(22):131–8. (Level III)
48. Lerman C, Trock B, Rimer BK, Boyce A, Jepson C, Engstrom PF. Psychological and behavioral implications of abnormal mammograms. *Ann Intern Med* 1991; 114:657–61. (Level III)
49. Brett J, Bankhead C, Henderson B, Watson E, Austoker J. The psychological impact of mammographic screening. A systematic review. *Psychooncology* 2005;14:917–38. (Level III)
50. Brewer NT, Salz T, Lillie SE. Systematic review: the long-term effects of false-positive mammograms. *Ann Intern Med* 2007;146:502–10. (Meta-analysis)
51. Schwartz LM, Woloshin S, Sox HC, Fischhoff B, Welch HG. US women's attitudes to false positive mammography results and detection of ductal carcinoma in situ: cross sectional survey. *BMJ* 2000;320:1635–40. (Level III)
52. Overmoyer B. Breast cancer screening. *Med Clin North Am* 1999;83:1443–66;vi–vii. (Level III)
53. Agency for Healthcare Research and Quality. Diagnosis and management of specific breast abnormalities. Evidence Report/Technology Assessment 33. Rockville (MD): AHRQ; 2001. AHRQ publication no. 01-E046. (Level III)
54. Kerlikowske K, Salzman P, Phillips KA, Cauley JA, Cummings SR. Continuing screening mammography in women aged 70 to 79 years: impact on life expectancy and cost-effectiveness. *JAMA* 1999;282:2156–63. (Level III)

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1990–February 2011. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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