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Breast Cancer Risk Assessment and Screening in Average-Risk Women

Breast cancer is the most commonly diagnosed cancer in women in the United States and the second leading cause of cancer death in American women (1). Regular screening mammography starting at age 40 years reduces breast cancer mortality in average-risk women (2). Screening, however, also exposes women to harm through false-positive test results and overdiagnosis of biologically indolent lesions. Differences in balancing benefits and harms have led to differences among major guidelines about what age to start, what age to stop, and how frequently to recommend mammography screening in average-risk women (2–4).

Breast cancer risk assessment is very important for identifying women who may benefit from more intensive breast cancer surveillance; however, there is no standardized approach to office-based breast cancer risk assessment in the United States. This can lead to missed opportunities to identify women at high risk of breast cancer and may result in applying average-risk screening recommendations to high-risk women. Risk assessment and identification of women at high risk allow for referral to health care providers with expertise in cancer genetics counseling and testing for breast cancer-related germline mutations (eg, BRCA), patient counseling about risk-reduction options, and cascade testing to identify family members who also may be at increased risk.

The purpose of this Practice Bulletin is to discuss breast cancer risk assessment, review breast cancer screening guidelines in average-risk women, and outline some of the controversies surrounding breast cancer screening. It will present recommendations for using a framework of shared decision making to assist women in balancing their personal values regarding benefits and harms of screening at various ages and intervals to make personal screening choices from within a range of reasonable options. Recommendations for women at elevated risk and discussion of new technologies, such as tomosynthesis, are beyond the scope of this document and are addressed in other publications of the American College of Obstetricians and Gynecologists (ACOG) (5–7).

Committee on Practice Bulletins—Gynecology. This Practice Bulletin was developed by the Committee on Practice Bulletins—Gynecology in collaboration with Mark Pearlman, MD; Myrlene Judy, MD; and David Chelmow, MD.

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Background

Incidence

Breast cancer accounts for 30% of all new cases of cancer diagnosed in women (8). In the United States, a woman's lifetime risk of developing breast cancer is approximately 12% (one in eight). It is estimated that 252,710 new cases of breast cancer, resulting in 40,610 deaths, will be diagnosed in women in the United States in 2017 (8). An additional 63,410 new cases of ductal carcinoma in situ also will be diagnosed (8).

Breast cancer mortality rates have decreased substantially during the past 50 years. For example, the current 5-year survival rate is 90%—substantially higher than the 5-year survival rate of 75% in 1975 (1). This decrease has been attributed to early detection and improvements in breast cancer treatment (3). There are currently an estimated 3.5 million women living with breast cancer in the United States (9).

Breast Cancer Risk Factors

The main factors for breast cancer are female sex (more than 99% of cases of breast cancer occur in women) and advancing age. Although other characteristics have been associated with an increased risk of breast cancer (Box 1) (6, 10–13), most women in whom invasive breast cancer is diagnosed do not have identifiable risk factors.

Reproductive Risk Factors

Certain reproductive factors influence breast cancer risk, particularly the risk of hormone receptor-positive breast cancer (Box 1) (6, 10–13). A systematic review indicates that nulliparity and longer intervals between menarche and age at first birth are associated with an increased risk of hormone receptor-positive breast cancer (14). Other less consistently reported reproductive risk factors for breast cancer include older age at first birth, older age at menopause, and younger age at menarche. In contrast, certain reproductive factors appear to decrease the risk of breast cancer. Parity appears to decrease the risk of hormone receptor-positive breast cancer, and breastfeeding is associated with a reduced risk of hormone receptor-positive breast cancer and triple-negative breast cancer (ie, estrogen-receptor negative, progesterone negative, and *ERBB2*-negative [formerly *HER2/Neu*-negative]).

Menopausal Hormone Therapy

Breast cancer risk appears to differ between postmenopausal women who use combined hormonal therapy and those who use estrogen therapy alone. In the Women's

Health Initiative randomized controlled trial, postmenopausal women taking estrogen and progestin had higher breast cancer risk during the intervention and early postintervention parts of the study. In postmenopausal women who previously had a hysterectomy and were randomized to receive estrogen alone or placebo, breast cancer risk did not appear increased (12).

Familial Risk Factors

Family history of breast cancer, ovarian cancer (including fallopian tube cancer and primary peritoneal cancer), and other types of germline mutation-associated cancer (eg, prostate and pancreatic) are associated with an increased risk of breast cancer. For family members with cancer, breast cancer onset at a young age is associated with an increased risk of the presence of a germline mutation. For more information, see Practice Bulletin No. 103, *Hereditary Breast and Ovarian Cancer Syndrome*, (5) and ACOG's online [Breast Cancer Screening and Treatment Resource Overview](#).

Box 1. Breast Cancer Risk Factors ↵

- Family history of breast cancer, ovarian cancer, or other hereditary breast and ovarian syndrome-associated cancer (eg, prostate cancer, pancreatic cancer)
- Known deleterious gene mutation
- Prior breast biopsy with specific pathology
 - Atypical hyperplasia (lobular or ductal)
 - Lobular carcinoma in situ
- Early menarche
- Late menopause
- Nulliparity
- Prolonged interval between menarche and first pregnancy
- Menopausal hormone therapy with estrogen and progestin (decreased risk with estrogen alone)
- Not breastfeeding
- Increasing age
- Certain ethnicities (eg, increased risk of *BRCA* mutation in Ashkenazi Jewish women)
- Higher body mass index
- Alcohol consumption
- Smoking
- Dense breasts on mammography
- Prior exposure to high-dose therapeutic chest irradiation in young women (10–30 years old)

Breast Disorders

Atypical ductal hyperplasia, atypical lobular hyperplasia, and lobular carcinoma in situ are typically found incidentally upon histologic evaluation of abnormal mammography findings or breast masses (15). Women with these diagnoses have a four-fold risk of subsequent invasive cancer in the affected and contralateral breasts (16), with some studies reporting a cumulative incidence of breast cancer approaching 30% at 25 years of follow-up (17). For more information, see Practice Bulletin No. 164, *Diagnosis and Management of Benign Breast Disorders* (18), and ACOG's online [Breast Cancer Screening and Treatment Resource Overview](#).

Breast Density

Women with dense breasts diagnosed by mammography have a modestly increased risk of breast cancer. Mammography has reduced sensitivity to detect breast cancer in women with dense breasts (19). Breast cancer screening in women with dense breasts is beyond the scope of this document. For more information, see Committee Opinion No. 625, *Management of Women With Dense Breasts Diagnosed by Mammography* (6) and ACOG's online [Breast Cancer Screening and Treatment Resource Overview](#).

Ionizing Radiation

Women treated for Hodgkin lymphoma with therapeutic chest radiation therapy between the ages of 10 years and 30 years (and possibly as late as age 45 years) are at an increased risk of breast cancer (20–22). Girls who are treated between the ages of 10 years and 14 years appear to be at greatest risk of future development of breast cancer.

General Considerations for Screening

The goal of screening for cancer is to detect preclinical disease in healthy, asymptomatic patients to prevent adverse outcomes, improve survival, and avoid the need for more intensive treatments. Screening tests have both benefits (eg, improved health outcomes) and adverse consequences (eg, cost, anxiety, inconvenience, false-positive results, and other test-specific harms such as overdiagnosis and overtreatment).

Breast self-examination, breast self-awareness, clinical breast examination, and mammography all have been used alone or in combination to screen for breast cancer. In general, more intensive screening detects more disease. Screening intensity can be increased by combining

multiple screening methods, extending screening over a wider age range, or repeating the screening test more frequently. However, more frequent use of the same screening test typically is associated with diminishing returns (ie, repeating the test twice as often does not make it twice as effective) and an increased rate of screening-related harms. Determining the appropriate combination of screening methods, the age to start screening, the age to stop screening, and how frequently to repeat the screening tests require finding the appropriate balance of benefits and harms. Determining this balance can be difficult because some issues, particularly the importance of harms, are subjective and valued differently from patient to patient. This balance can depend on other factors, particularly the characteristics of the screening tests in different populations and at different ages.

Varying judgments about the appropriate balance of benefits and harms have led to differences among the major guideline group recommendations for breast cancer screening (Table 1) (3, 4, 23). The American College of Obstetricians and Gynecologists has reviewed these guidelines, their supporting evidence and rationale, and the recommendations for shared decision making embedded within them. The American College of Obstetricians and Gynecologists' recommendations for breast cancer screening presented in this document reflect that screening decisions should incorporate patient values regarding relative benefits and harms. The American College of Obstetricians and Gynecologists' recommendations emphasize shared decision making in choosing between the range of options encompassed within the U.S. Preventive Services Task Force, American Cancer Society (ACS), and National Comprehensive Cancer Network guidelines. The next few sections of this Practice Bulletin present data on overall benefits and harms of mammography screening. Data for other screening modalities and the differences among benefits and harms of mammography at different ages and screening intervals are presented in "[Clinical Considerations and Recommendations](#)" later in this document.

Benefits of Mammographic Screening

To update its screening recommendations, the U.S. Preventive Services Task Force and the ACS recently conducted separate systematic reviews of the evidence for breast cancer screening in average-risk women (2, 24). Studying the effect of mammography on mortality is methodologically challenging because of the large number of women needed and long follow-up periods involved. Randomized and observational studies provide

Table 1. Recommendations for Breast Cancer Screening in Average-Risk Women ↵

	American College of Obstetricians and Gynecologists	U.S. Preventive Services Task Force	American Cancer Society	National Comprehensive Cancer Network
Clinical breast examination	May be offered* every 1–3 years for women aged 25–39 years and annually for women 40 years and older.	Insufficient evidence to recommend for or against.†	Does not recommend‡	Recommend every 1–3 years for women aged 25–39 years. Recommend annually for women 40 years and older.
Mammography initiation age	Offer starting at age 40 years.§ Initiate at ages 40–49 years after counseling, if patient desires. Recommend by no later than age 50 years if patient has not already initiated.	Recommend at age 50 years.¶ Age 40–49 years: The decision to start screening mammography in women before age 50 years should be an individual one.¶	Offer at ages 40–45 years.¶ Recommend at age 45 years.¶	Recommend at age 40 years.
Mammography screening interval	Annual or biennial§	Biennial¶	Annual for women aged 40–54 years‡ Biennial with the option to continue annual screening for women 55 years or older‡	Annual
Mammography stop age	Continue until age 75 years. Beyond age 75 years, the decision to discontinue should be based on a shared decision-making process that includes a discussion of the woman's health status and longevity.	The current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women 75 years and older.†	When life expectancy is less than 10 years‡	When severe comorbidities limit life expectancy to 10 years or less

*Offer in the context of a shared, informed decision-making approach that recognizes the uncertainty of additional benefits and harms of clinical breast examination beyond screening mammography.

†Category I recommendation

‡Qualified recommendation

§Decision between options to be made through shared decision making after appropriate counseling

¶Category B recommendation

¶Category C recommendation. The Task Force notes that “Women who place a higher value on the potential benefit than the potential harms may choose to begin screening between the ages of 40 and 49 years.”

#Strong recommendation

Data from National Comprehensive Cancer Network. Breast cancer screening and diagnosis. Version 1.2016; Oeffinger KC, Fontham ET, Etzioni R, Herzig A, Michaelson JS, Shih YC, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society [published erratum appears in JAMA 2016;315:1406]. *JAMA* 2015;314:1599–614; and Siu AL. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. U.S. Preventive Services Task Force [published erratum appears in Ann Intern Med 2016;164:448]. *Ann Intern Med* 2016;164:279–96.

important information but have different limitations. Both systematic reviews combined randomized and observational studies and agreed that mammography generally decreases breast cancer mortality. The ACS systematic review noted that the magnitude of the mortality reduction varied across study types and duration of follow-up (2). The ACS systematic review reported that screening mammography was associated with a decreased risk of breast cancer mortality in randomized controlled trials (relative risk [RR], 0.80–0.82); in cohort studies (RR, 0.75; 95% CI, 0.69–0.81); and in modeling

studies (median RR, 0.85; ranging from 0.77 to 0.93) (2). The U.S. Preventive Services Task Force evidence review (24) reported results by age (Table 2) (3). This systematic review also found a reduced risk of advanced breast cancer (stage IIB or greater) with screening mammography in women 50 years and older (RR, 0.62; 95% CI, 0.46–0.83) (24). Although the ACS and U.S. Preventive Services Task Force systematic reviews did not present evidence that screening mammography prevents the need for advanced cancer treatment, it is reasonable to assume that if screening reduces the risk

Table 2. Mammographic Screening and Breast Cancer Specific Mortality Reduction by Age Group ↵

Age Range (years)	Relative Risk (95 % Confidence Interval)
39–49	0.92 (0.75–1.02)
50–59	0.86 (0.68–0.97)
60–69	0.67 (0.54–0.83)
70–74	0.80 (0.51–1.28)

Data from Siu AL. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. U.S. Preventive Services Task Force [published erratum appears in *Ann Intern Med* 2016;164:448]. *Ann Intern Med* 2016;164:279–96.

of advanced breast cancer, it may reduce the need for advanced cancer treatment.

The ACS systematic review also examined the effect of screening mammography on life expectancy. Although the review concluded that there was high-quality evidence that mammographic screening increases life expectancy by decreasing breast cancer mortality, the authors were not able to estimate the size of the increase (23).

Adverse Consequences of Screening Mammography

False-Positive Test Results

False-positive test results from mammography include callbacks for additional images and follow-up biopsies that are found to be benign. The U.S. Preventive Services Task Force conducted a systematic review specifically looking at harms associated with breast cancer screening in average-risk women (25). The review reported results from the Breast Cancer Surveillance Consortium that noted a 10-year, cumulative false-positive rate of 61% with annual screening and a rate of 42% with biennial screening, with a need for biopsy in 7% of women screened annually and 5% of women screened biennially (26). The ACS systematic review (2) included a different analysis of the same data (27). In this analysis, certain patient factors such as combination hormone therapy use and dense breasts were associated with an increased likelihood of false-positive test results among women aged 40–49 years. The systematic review also showed that callbacks were more likely with a woman's first mammogram (detection of prevalent findings) and were minimized with the availability of prior images (2).

Anxiety and Distress

The U.S. Preventive Services Task Force systematic review on the harms of breast cancer screening found

that women who received clear communication of negative test results reported minimal anxiety, whereas those called back for further testing reported increased anxiety, breast cancer-specific worry, and distress (25). In some women, anxiety and distress persisted despite negative test results on the follow-up testing. Two studies reported that women with false-positive test results were less likely to return for their next screening mammography. False-positive test results also have financial costs, which often need to be paid all or in part by the patient.

Discomfort During Procedures

The U.S. Preventive Services Task Force systematic review noted that many women reported pain during mammography; however, few considered it a deterrent to future screening (25). Although not included in the Task Force's systematic review, diagnostic procedures for false-positive mammography results can cause additional pain and discomfort.

Overdiagnosis and Overtreatment

Overdiagnosis occurs when screening detects cancer that would not have progressed to symptomatic cancer if left undetected (23). Thus, overdiagnosis is the identification of cancer that remains indolent. *Overtreatment* is defined as the initiation of treatment for an overdiagnosed cancer. It is difficult to determine the true rate of overdiagnosis because it is not ethically permissible to conduct natural history studies of untreated disease, so a variety of indirect methodologies have been used to estimate its frequency (28–30). There is significant uncertainty as to how often breast cancer overdiagnosis occurs. Reported rates of overdiagnosis and overtreatment are, in part, related to the management of ductal carcinoma in situ. This lesion has a significantly lower risk than breast cancer, although many studies group it with breast cancer and its diagnosis typically leads to treatment. The ACS evidence summary reported wide variation in overdiagnosis rates of breast cancer (crude estimates ranging from 0% to 54% and adjusted estimates ranging from 1% to 10%) depending on modeling assumptions and whether ductal carcinoma in situ was included (2). The U.S. Preventive Services Task Force evidence review reported similar results based on observational trial data, but arrived at higher estimates (ranging from 10.7% to 22.7%) based on data from randomized controlled trials (25). Using modeling estimates from the Cancer Intervention and Surveillance Modeling Network, the U.S. Preventive Services Task Force reported that “1 in 8 women diagnosed with breast cancer with biennial screening from ages 50 to 75

years will be overdiagnosed. Even with the conservative estimate of 1 in 8 breast cancer cases being overdiagnosed, for every woman who avoids a death from breast cancer through screening, 2 to 3 women will be treated unnecessarily” (3). Modeling data also indicate that the risk of overdiagnosis appears to be lower with older age and with less frequent screening (31). Although the ACS acknowledged that there is a high likelihood that breast cancer overdiagnosis occurs at some level, its authors concluded that “Regardless of the study design, practically all estimates [of overdiagnosis] require unverifiable assumptions or use methods that are biased by inadequate follow-up or failure to properly adjust for trends in incidence and lead time, leading to inflated estimates” (23). Research to develop better prognostic indicators of progressive versus nonprogressive ductal carcinoma in situ and other lesions may allow more customized treatment in the future, thereby reducing overtreatment (3).

Radiation Exposure

The U.S. Preventive Services Task Force systematic review found no direct studies of radiation exposure from mammography but included a modeling study that estimated that the number of deaths caused by mammography radiation-induced cancer was 2 per 100,000 among women aged 50–59 years screened biennially, and 11 per 100,000 among women aged 40–49 years screened annually (25). A more recent modeling study estimated that the potential mortality benefit of early breast cancer detection through annual screening starting at age 40 years far outweighed (by 60-fold) the risk of dying from mammography radiation-induced cancer (32). In this model, radiation from annual screening of 100,000 women aged 40–74 years was estimated to induce 125 cases of breast cancer and 16 cases of breast cancer deaths, compared with 968 cases of cancer deaths prevented by early detection through screening.

Shared Decision Making

Shared decision making is a process in which patients and physicians share information, express treatment preferences, and agree on a treatment plan (see Committee Opinion No. 587, *Effective Patient–Physician Communication*) (33). It combines the expertise of the physician, who provides the details of the clinical information, including the benefits (eg, decreased risk of dying of breast cancer) and harms (eg, callbacks, benign breast biopsies, overdiagnosis), and the values of the patient, who shares her experiences, concerns, and priorities. The clinical information can be provided in ways that are efficient for patients and physicians (eg, online videos or reliable web pages, infor-

mational handouts, or face-to-face conversations). Shared decision making is particularly important for decisions regarding breast cancer screening because many choices involve personal preferences related to potential benefits and adverse consequences. For more information, see ACOG’s online [Breast Cancer Screening and Treatment Resource Overview](#).

Clinical Considerations and Recommendations

► How should individual breast cancer risk be assessed?

Health care providers periodically should assess breast cancer risk by reviewing the patient’s history. Breast cancer risk assessment is based on a combination of the various factors that can affect risk (Box 1) (6, 10–13). Initial assessment should elicit information about reproductive risk factors, results of prior biopsies, ionizing radiation exposure, and family history of cancer. Health care providers should identify cases of breast, ovarian, colon, prostate, pancreatic, and other types of germline mutation-associated cancer in first-degree, second-degree, and possibly third-degree relatives as well as the age of diagnosis. Women with a potentially increased risk of breast cancer based on initial history should have further risk assessment. Assessments can be conducted with one of the validated assessment tools available online, such as the Gail, BRCAPRO, Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm, International Breast Cancer Intervention Studies (IBIS, also known as Tyrer–Cuzick), or the Claus model (34).

Risk assessment is important to determine if a woman is at average or increased risk of breast cancer to guide counseling regarding breast cancer surveillance, risk reduction, and genetic testing. Risk assessment should not be used to consider a woman ineligible for screening appropriate for her age. Rather, risk assessment should be used to identify women who may benefit from genetic counseling, enhanced screening such as magnetic resonance imaging screening, more frequent clinical breast examinations, or risk-reduction strategies. Information regarding screening and risk reduction for women at high risk is discussed elsewhere (4, 5, 35, 36).

A number of validated breast cancer risk assessment tools are readily available online and can be completed quickly in an office setting. Some tools are better for certain risk factors and populations than others. The Gail model (www.cancer.gov/bcrisktool) has been validated and is widely used. It is of limited use in some women, including those younger than 35 years, those with a family history of breast cancer in paternal

family members or in second-degree or more distantly related family members, those with family histories of nonbreast cancer (eg, ovarian and prostate) known to be associated with genetic mutations, and high-risk lesions on biopsy other than atypical hyperplasia (eg, lobular carcinoma in situ). Women who cannot be assessed appropriately with the Gail model can be assessed with other validated tools that incorporate these other elements into risk assessment, including the BRCAPRO, Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm, IBIS, or Claus model (34). One study showed that the IBIS model was more accurate for assessing breast cancer risk based on family history than the Claus or Gail model (37). If a patient's level of risk is unclear after initial assessment, referral for a more in-depth hereditary cancer risk assessment is appropriate. A hereditary cancer risk assessment is conducted by a genetic counselor or other health care provider with expertise in cancer genetics and includes gathering family history information, risk assessment, education, and counseling (38). This assessment may include genetic testing, if desired, after appropriate counseling and informed consent is obtained.

► ***Is screening breast self-examination recommended in women at average risk of breast cancer, and what should women do if they notice a change in one of their breasts?***

Breast self-examination is not recommended in average-risk women because there is a risk of harm from false-positive test results and a lack of evidence of benefit. Average-risk women should be counseled about breast self-awareness and encouraged to notify their health care provider if they experience a change. *Breast self-awareness* is defined as a woman's awareness of the normal appearance and feel of her breasts. Breast self-examination is the inspection of a woman's breasts on a regular, repetitive basis for the purpose of detecting breast cancer. Unlike breast self-examination, breast self-awareness does not include a recommendation for women to examine their breasts in a systematic way or on a routine basis. Rather, it means that a woman should be attuned to noticing a change or potential problem with her breasts. Women should be educated about the signs and symptoms of breast cancer and advised to notify their health care provider if they notice a change such as pain, a mass, new onset of nipple discharge, or redness in their breasts.

In its 2009 breast cancer screening guidelines, the U.S. Preventive Services Task Force recommended against teaching breast self-examination (grade D recommendation) based on the lack of evidence regarding

benefits and because of potential harms from false-positive findings (39). The U.S. Preventive Services Task Force did not change this recommendation in the 2016 update of its breast cancer screening guidelines (3). The ACS also no longer recommends breast self-examination for women at average risk of breast cancer because of the lack of evidence regarding improved outcomes (23).

Although breast self-examination is no longer recommended, evidence on the frequency of self-detection of breast cancer provides a strong rationale for breast self-awareness in the detection of breast cancer. Approximately 50% of cases of breast cancer in women 50 years and older and 71% of cases of breast cancer in women younger than 50 years are detected by women themselves (40, 41). For example, 43% of the 361 breast cancer survivors who participated in the 2003 National Health Interview Survey reported detecting their cancer themselves (42). Additional evidence of the important role of breast cancer self-detection comes from a study of low-income women who received breast cancer care through California's Breast and Cervical Cancer Treatment Program. Of the 921 women in the cohort, 64% self-detected their breast cancer (43).

Although there are no studies in the United States that have directly examined the effectiveness of breast self-awareness, based on the frequent incidence of self-detected breast cancer, patients should be counseled about breast self-awareness. The U.S. Preventive Services Task Force "supports all patients being aware of changes in their bodies and discussing these changes with clinicians" (3). The ACS states clinicians should counsel women "regarding the importance of being alert to breast changes" (23).

► ***Should practitioners perform routine screening clinical breast examinations in average-risk women?***

Screening clinical breast examination may be offered to asymptomatic, average-risk women in the context of an informed, shared decision-making approach that recognizes the uncertainty of additional benefits and the possibility of adverse consequences of clinical breast examination beyond screening mammography. If performed for screening, intervals of every 1–3 years for women aged 25–39 years and annually for women 40 years and older are reasonable. The clinical breast examination continues to be a recommended part of evaluation of high-risk women and women with symptoms.

There are conflicting guidelines from the National Comprehensive Cancer Network, ACS, and the U.S. Preventive Services Task Force on whether to perform

screening clinical breast examination in women at average risk of breast cancer (Table 1) (3, 4, 23). The recent ACS systematic review found no studies directly estimating the association between clinical breast examination and mortality (2). However, three studies in the systematic review looked at false-positive test results in combination with mammography, and two noted there are approximately 55 false-positive test results for every one case of cancer detected. A supplemental systematic review on clinical breast examination performance characteristics conducted for the ACS recommendation report estimated that clinical breast examination will detect approximately 2–6% more cases of invasive cancer than mammography alone; however, there was no evidence that patient outcomes were improved by detection of these additional cases of cancer (23). Given the lack of evidence for benefit combined with the increase in false-positive test results, the ACS no longer recommends clinical breast examination. In its 2009 breast cancer screening guidelines, the U.S. Preventive Services Task Force similarly stated that there was insufficient evidence to assess the benefits and harms of the clinical breast examination (category I recommendation) (39); and, it did not change this recommendation in the 2016 update of the guidelines (3). The National Comprehensive Cancer Network continues to recommend clinical breast examination at intervals of 1–3 years for asymptomatic, average-risk women aged 25–39 years and annually for asymptomatic, average-risk women aged 40 years and older.

► ***When should screening mammography begin in average-risk women?***

Women at average risk of breast cancer should be offered screening mammography starting at age 40 years. Women at average risk of breast cancer should initiate screening mammography no earlier than age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years. The decision about the age to begin mammography screening should be made through a shared decision-making process. This discussion should include information about the potential benefits and harms. The use of information sheets or decision aids can assist health care providers and patients with this discussion. For more information, see ACOG’s online [Breast Cancer Screening and Treatment Resource Overview](#).

The decision about when to recommend initiating screening is driven by a number of factors that vary with age, including risk of breast cancer, risk of death from breast cancer, likelihood of screening mammography to diagnose cancer, risk of false-positive test results

and other harms, and the balance between benefits and harms. One measure of the efficiency of breast cancer screening is the number needed to screen, which is a measure of overall risk reduction useful for comparing effectiveness of screening between populations. The number needed to screen depends largely on the mortality benefit from screening and the incidence of the disease in the population screened. The U.S. Preventive Services Task Force and the ACS reviewed these issues at length in preparation for their guideline revisions (2, 24, 25).

The distribution of breast cancer cases and deaths by age at diagnosis increase with age starting in the 40s and continue through the 50s. The incidence of breast cancer also increases as women age (23). Mammography appears to provide better mortality reduction as women get older (Table 2) (2, 3, 24). Harms appear to decrease, with approximately the same number of biopsies performed across age groups, and a higher proportion leading to cancer diagnoses in older women (3). Because breast cancer is less common in women younger than 40 years, the frequency of harms associated with screening mammography is higher relative to the benefits (lives saved) in this age group. Thus, the risk–benefit balance improves with age. In its systematic review, the ACS extracted relative risks and calculated the number needed to screen by age group; the results showed effectiveness of screening for all age groups, but efficiency of screening improved with age and assumed mortality reduction with screening (2).

The recommended age of initiation of mammography in average-risk women differs among the consensus guidelines groups in the United States (Table 1) (3, 4, 23). The ACS and the U.S. Preventive Services Task Force recognize that although mammography starting at age 40 years is less effective and more frequently associated with harms than in older women, it does save lives. Benefits and adverse consequences vary over a continuum, and selection of a specific age for initiation of screening is largely a subjective decision that balances benefits and harms according to an individual woman’s values and preferences.

The U.S. Preventive Services Task Force chose their starting age of 50 years based on an analysis of benefits (measured by fewer breast cancer deaths and more life years gained) and various measures of harm across the lifetimes of women screened biennially starting at age 40 years compared with those screened biennially starting at age 50 years (Table 3) (3). The Task Force noted that for women in their 40s, mammography results in only a small decrease in breast cancer deaths compared with a proportionately larger increase in callbacks and benign biopsies. Of note, the estimated years of life

Table 3. Lifetime Benefits and Harms of Biennial Screening Mammography Starting at Age 40 Years Versus Age 50 Years Per 1,000 Women Screened†** ←

Variable	Age 40–74 years	Age 50–74 years
Fewer breast cancer deaths, n	8 (5–10)	7 (4–9)
Life-years gained	152 (99–195)	122 (75–154)
False-positive test results, n	1,529 (1,100–1,976)	953 (830–1,325)
Unnecessary breast biopsies, n	213 (153–276)	146 (121–205)
Overdiagnosed breast tumors, n	21 (12–38)	19 (11–34)

*Model results compared with no screening

†Values reported are medians (ranges).

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gained was substantially greater in women beginning screening at a younger age, which would be expected because this age group has the largest potential years of life lost from cancer. The Task Force summarized as follows (3):

For women in their 40s, the number who benefit from starting regular screening mammography is smaller and the number experiencing harm is larger compared with older women. For women in their 40s, the benefit still outweighs the harms, but to a smaller degree; this balance may therefore be more subject to individual values and preferences than it is in older women. Women in their 40s must weigh a very important but infrequent benefit (reduction in breast cancer deaths) against a group of meaningful and more common harms (overdiagnosis and overtreatment, unnecessary and sometimes invasive follow-up testing and psychological harms associated with false-positive test results, and false reassurance from false-negative test results). Women who value the possible benefit of screening mammography more than they value avoiding its harms can make an informed decision to begin screening.

The ACS made a qualified recommendation that women should have the opportunity to begin screening at age 40 years and a strong recommendation that women should undergo regular screening mammography starting at age 45 years based on an analysis of burden of disease by 5-year intervals (23). The analysis noted that the 5-year risk in women aged 45–49 years (0.9%) was similar to women aged 50–54 years (1.1%) as was the proportion of incident breast cancer cases (10% and 12%, respectively). However, the 5-year risk and the proportion of incident breast cancer cases were

lower in 40–44-year-olds (5-year risk, 0.6%; proportion of incident breast cancer cases, 7%). The ACS provides a qualified recommendation that women between the ages of 40 years and 44 years should have the opportunity of initiating screening (23).

The National Comprehensive Cancer Network recommends annual screening mammograms starting at age 40 years for all average-risk women (4). The American College of Obstetricians and Gynecologists' recommendation to offer mammography to average-risk women beginning at age 40 years and to initiate screening by no later than age 50 years is consistent with all three major consensus guidelines (Table 1) (3, 4, 23). Given the reduction in mortality and years of life extended by screening women starting at age 40 years, it is appropriate to begin offering screening starting at age 40 years using shared decision making involving a discussion of the anticipated benefits and adverse consequences. Given that the benefit-to-harm ratio improves with age, women who have not chosen to initiate mammography in their 40s should begin screening by no later than age 50 years.

► **How frequently should screening mammography be performed in average-risk women?**

Women at average risk of breast cancer should have screening mammography every 1 or 2 years based on an informed, shared decision-making process that includes a discussion of the benefits and harms of annual and biennial screening and incorporates patient values and preferences. Biennial screening mammography, particularly after age 55 years, is a reasonable option to reduce the frequency of harms, as long as patient counseling includes a discussion that with decreased screening comes some reduction in benefits.

Neither the ACS nor the U.S. Preventive Services Task Force systematic review identified any randomized

trials directly comparing annual to biennial screening. However, both groups reviewed indirect evidence from meta-analyses and observational studies. [Table 4](#) contains a summary of data from the ACS review, which was supplemented with additional work commissioned for the final recommendations document (2, 23, 26, 32, [44](#), [45](#)). These data suggest that shorter screening intervals are associated with improved outcomes (most clearly for women younger than 50 years) and an increase in callbacks and biopsies. However, the nature of the retrospective data makes it difficult to estimate the extent of benefits and the trade-off with harms. The the U.S. Preventive Services Task Force and the ACS used modeling studies from the Cancer Intervention and Surveillance Modeling Network to make their recommendations. The U.S. Preventive Services Task Force commissioned updated modeling studies from the Cancer Intervention and Surveillance Modeling Network that were not available at the time of the ACS review ([Table 5](#)) (3, 31). The updated model predicted that annual screening will result in two additional lives saved balanced against 82 additional biopsies and six overdiagnosed breast tumors for every 1,000 women screened between the ages of 50 years and 74 years (3, 31).

Annual screening intervals appear to result in the least number of breast cancer deaths, particularly in younger women, but at the cost of additional callbacks and biopsies. In light of this, the National Comprehensive Cancer Network continues to recommend annual screening (4). The ACS recommends that women should be offered the opportunity to begin annual screening at age 40 years and that women aged 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. The rationale for managing the age groups differently is that “screening annually appears to provide additional benefit over biennial screening particularly in younger women” (23). The U.S. Preventive Services Task Force continues to recommend biennial screening at all ages based on the rationale that the mortality benefit is extended to approximately 80% of the population with biennial screening and that there are considerably fewer harms (eg, callbacks and benign breast biopsies) (3).

Clinicians should initiate a discussion about the frequency of screening once a woman has decided to initiate screening. Clinicians and patients should engage in shared decision making that includes a discussion of the trade-offs between benefits and harms and supports the woman’s decision to choose the screening frequency that achieves the trade-off consistent with her values and concerns. A woman who chooses annual screening may place greater value on the potential for averting breast cancer death and less value on the possible harms. A

woman who chooses biennial screening may be more concerned about experiencing the potential harms of screening than she is about the incremental chance of a breast cancer death that could have been averted. Given that the benefit of more frequent screening decreases in older women, a hybrid approach to screening in which a woman initially chooses annual screening and then decreases to biennial after age 55 years also is a reasonable option.

► *When should screening mammography cease?*

Women at average risk of breast cancer should continue screening mammography until at least age 75 years. Age alone should not be the basis to continue or discontinue screening. Beyond age 75 years, the decision to discontinue screening mammography should be based on a shared decision-making process informed by the woman’s health status and longevity.

More than one quarter of cases of breast cancer are diagnosed in women 75 years and older (23), but there are limited data on screening mammography in this population. The systematic reviews conducted for the ACS and the U.S. Preventive Services Task Force did not identify any randomized clinical trials of screening mammography conducted in women 75 years and older. Furthermore, neither review specifically cited any observational data from studies of women older than 74 years. Even for women aged 70–74 years, both reviews presented only limited data on screening mammography (2, 24). The ACS guidelines paper (23) cites the results of two observational trials ([46](#), [47](#)) that showed a reduction in breast cancer mortality associated with mammographic detection of breast cancer in women 75 years and older. To address the lack of clinical evidence on screening mammography in older women, both the ACS and the U.S. Preventive Services Task Force used data from modeling studies to help inform their guidelines. The most recent simulation study, which did not include women older than 74 years, suggested that women aged 70–74 years can have a reduction in mortality with screening mammography if they remain in good health, but not if they have significant comorbidities ([48](#)). The prior Cancer Intervention and Surveillance Modeling Network modeling study included women up to age 84 years, and showed benefit ([49](#)).

The U.S. Preventive Services Task Force concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women 75 years and older (3). The ACS provided a qualified recommendation that women should continue screening mammography as long as their overall health

Table 4. Studies on Screening Interval Included in the American Cancer Society Systematic Review and Guideline Update ↵

Study Design	Comparison	Outcome Measure	Result
Meta-analysis of screening trials*	Screening intervals less than 24 months versus 24 or more months	Disease specific mortality	Relative risk (RR) among those younger than 50 years, 0.82 (95% CI, 0.72–0.94) RR among those 50 years and older, 1.04 (95% CI, 0.72–1.5)
Observational study (national screening service)†	Screened versus unscreened women	Clinically apparent cancer detected after first normal mammogram but before next mammogram (interval cancer)	Younger than 50 years: 38% of the breast cancer incidence in screened versus unscreened women 50 years and older: 13% of the breast cancer incidence in the screened versus unscreened women
Reanalysis of Breast Cancer Surveillance Consortium observational data‡	Screening intervals of approximately 12 months versus 24 months	Tumor characteristics	In multivariate analysis, premenopausal women were more likely to have <ul style="list-style-type: none"> • advanced stage tumor (RR, 1.28; 95% CI, 1.01–1.63) • larger tumor size (RR, 1.21; 95% CI, 1.07–1.37) • poor prognosis tumors at diagnosis (RR, 1.11; 95% CI, 1.00–1.22)
Breast Cancer Surveillance Consortium pooled observational studies§	Annual screening versus biennial screening	False-positive recall False-positive biopsy	Estimated 10-year cumulative risk with first screen at age 40 years: <ul style="list-style-type: none"> • 61.3% (95% CI, 59.4–63.1) for annual screening • 41.6% (95% CI, 40.6–42.5) for biennial screening Estimated 10-year cumulative risk with first screen at age 50 years: <ul style="list-style-type: none"> • 61.3% (95% CI, 58.0–64.7) for annual screening • 42.0% (95% CI, 40.4–43.7) for biennial screening Estimated 10-year cumulative risk with first screen at age 40 years: <ul style="list-style-type: none"> • 7.0% (95% CI, 6.1%–7.8%) for annual screening • 4.8% (95% CI, 4.4%–5.2%) for biennial screening. Estimated 10-year cumulative risk with first screen at age 50 years: <ul style="list-style-type: none"> • 9.4% (95% CI, 7.4%–11.5%) for annual screening • 6.4% (95% CI, 5.6%–7.2%) for biennial screening

*Fitzpatrick-Lewis D, Hodgson N, Ciliska D, Peirson L, Gault M, Liu YY. Breast cancer screening. Ottawa (ON): [Canadian Task Force on Preventive Health Care; 2011](#).

†Tabár L, Faberberg G, Day NE, Holmberg L. What is the optimum interval between mammographic screening examinations? An analysis based on the latest results of the Swedish two-county breast cancer screening trial. [Br J Cancer 1987;55:547–51](#).

‡Miglioretti DL, Lange J, van den Broek JJ, Lee CI, van Ravesteyn NT, Ritley D, et al. Radiation-induced breast cancer incidence and mortality from digital mammography screening: a modeling study. [Ann Intern Med 2016;164:205–14](#).

§Hubbard RA, Kerlikowske K, Flowers CI, Yankaskas BC, Zhu W, Miglioretti DL. Cumulative probability of false-positive recall or biopsy recommendation after 10 years of screening mammography: a cohort study [published erratum appears in [Ann Intern Med 2014;160:658](#)]. [Ann Intern Med 2011;155:481–92](#).

Data from Oeffinger KC, Fontham ET, Etzioni R, Herzog A, Michaelson JS, Shih YC, et al. Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society [published erratum appears in [JAMA 2016;315:1406](#)]. [JAMA 2015;314:1599–614](#).

Table 5. Lifetime Benefits and Harms of Annual Versus Biennial Screening Mammography Per 1,000 Women Screened*† ↵

Variable	Annual Screening for Those Aged 50–74 Years	Biennial Screening for Those Aged 50–74 Years
Fewer breast cancer deaths, n	9 (5–10)	7 (4–9)
Life-years gained	145 (104–180)	122 (75–154)
False-positive test results, n	1,798 (1,706–2,445)	953 (830–1,325)
Unnecessary breast biopsies, n	228 (219–317)	146 (121–205)
Overdiagnosed breast tumors, n	25 (12–68)	19 (11–34)

*Model results compared with no screening

†Values reported are medians (ranges).

Modified with permission from Siu AL. Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement. U.S. Preventive Services Task Force [published erratum appears in *Ann Intern Med* 2016;164:448]. *Ann Intern Med* 2016;164:279–96.

is good and they have a life expectancy of 10 years or longer (23). This recommendation is based on the rationale that as women get older, competing causes of death lower the benefit of screening mammography, particularly if women have substantial comorbidities (23, 50).

Determining candidates for screening mammography among women older than 75 years requires assessing their general health and estimating their life expectancy. Many women 75 years and older are in good health and can be expected to live considerably longer than 10 years, and more than one half of women older than 80 years are expected to live more than 10 years (51). Women with a life expectancy of less than 10 years are unlikely to have an appreciable mortality reduction from mammographic detection of an early breast cancer and are at a substantial risk of discomfort, anxiety, and decreased quality of life from adverse effects of treatment that is unlikely to extend their life. Despite the general consensus that women with less than 10 years of life expectancy should not routinely receive screening mammography (3, 4, 23, 52), women who are unlikely to benefit because of serious comorbidities still get screening mammograms (53, 54). Even in women younger than 75 years, health assessment is important to determine appropriateness of screening mammography because women of any age with serious comorbidities are unlikely to benefit from screening. In addition, screening mammography should not be performed on women who would not choose further evaluation or treatment based on abnormal screening results. Clinical judgment and predictive models that combine age, comorbidities, and functional status can be used to identify women who may continue to benefit from screening mammography (generally defined as having greater than a 50% probability of surviving 10 years) (55).

There also are simplified online tools that use pictograms and list possible benefits and harms that may help with decision making for older women contemplating screening mammography. For more information, see ACOG's online [Breast Cancer Screening and Treatment Resource Overview](#). Consultation with the patient's other health care providers also may be helpful.

Summary of Recommendations

Recommendations based on good and consistent scientific evidence (Level A)

- ▶ Women at average risk of breast cancer should be offered screening mammography starting at age 40 years. Women at average risk of breast cancer should initiate screening mammography no earlier than age 40 years. If they have not initiated screening in their 40s, they should begin screening mammography by no later than age 50 years. The decision about the age to begin mammography screening should be made through a shared decision-making process. This discussion should include information about the potential benefits and harms.
- ▶ Women at average risk of breast cancer should have screening mammography every 1 or 2 years based on an informed, shared decision-making process that includes a discussion of the benefits and harms of annual and biennial screening and incorporates patient values and preferences. Biennial screening mammography, particularly after age 55 years, is a reasonable option to reduce the frequency of harms,

as long as patient counseling includes a discussion that with decreased screening comes some reduction in benefits.

- ▶ Women at average risk of breast cancer should continue screening mammography until at least age 75 years.

Recommendations based on limited or inconsistent scientific evidence (Level B)

- ▶ Health care providers periodically should assess breast cancer risk by reviewing the patient's history.
- ▶ Women with a potentially increased risk of breast cancer based on initial history should have further risk assessment.
- ▶ Breast self-examination is not recommended in average-risk women because there is a risk of harm from false-positive test results and a lack of evidence of benefit.

Recommendations based primarily on consensus and expert opinion (Level C)

- ▶ Screening clinical breast examination may be offered to asymptomatic, average-risk women in the context of an informed, shared decision-making approach that recognizes the uncertainty of additional benefits and the possibility of adverse consequences of clinical breast examination beyond screening mammography. If performed for screening, intervals of every 1–3 years for women aged 25–39 years and annually for women aged 40 years and older are reasonable. The clinical breast examination continues to be a recommended part of evaluation of high-risk women and women with symptoms.
- ▶ Average-risk women should be counseled about breast self-awareness and encouraged to notify their health care provider if they experience a change. Breast self-awareness is defined as a woman's awareness of the normal appearance and feel of her breasts.
- ▶ Age alone should not be the basis to continue or discontinue screening. Beyond age 75 years, the decision to discontinue screening mammography should be based on a shared decision making process informed by the woman's health status and longevity.

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for ob-gyns, other

health care providers, and patients. You may view these resources at <http://www.acog.org/Womens-Health/Breast-Cancer-Screening>.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's website, or the content of the resource. These resources may change without notice.

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The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and April 2017. 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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