GUIDELINE SYNTHESIS

Screening for Breast Cancer in Women at Average Risk

Guidelines Being Compared:

1 American Cancer Society (ACS)

Breast cancer screening for women at average risk: 2015 guideline update from the American Cancer Society.

2015 Oct 20

View Summary >

2 U.S. Preventive Services Task Force (USPSTF)

Screening for breast cancer: U.S. Preventive Services Task Force recommendation statement.

2016 Feb 16

View Summary >

Areas of Agreement and Difference

A direct comparison of the recommendations presented in the above guidelines for screening for breast cancer in asymptomatic women at average risk is provided below.

Recommendations for screening women at increased risk of breast cancer due to a personal history of breast cancer, a suspected or confirmed genetic mutation known to increase risk of

Areas of Agreement

Clinical Breast Examination (CBE) and Breast Self-Examination (BSE)

Neither guideline developer recommends routine use of either CBE or BSE. Citing the lack of benefit concurrent with the increase in false-positive rates, ACS does not recommend CBE for breast cancer screening among average-risk, asymptomatic women at any age. Recognizing the time constraints in a typical clinic visit, ACS adds, clinicians should use this time instead for ascertaining family history and counseling women regarding the importance of being alert to breast changes and the potential benefits, limitations, and harms of screening mammography. The USPSTF did not update its 2009 recommendation statement on CBE, which concluded that the evidence was insufficient to assess the additional benefits and harms of CBE beyond screening mammography in women 40 years or older.

The USPSTF also did not update its 2009 recommendation against teaching BSE, but states that it supports all patients being aware of changes in their bodies and discussing these changes with clinicians. ACS states that even though a substantial proportion of breast cancers are self-detected, the relative contributions of a systematic self-examination versus incidental discovery are unknown. According to ACS, given the absence of evidence of improved outcomes associated with self-examination, the previous (2003) ACS guideline did not include a recommendation for routine performance of or instruction in breast self-examination, and no new studies have been reported in recent years that warranted reconsideration of that conclusion.

Digital Breast Tomosynthesis (DBT)

Neither developer recommends routine use of DBT. The USPSTF concluded that the current evidence is insufficient to assess the benefits and harms of DBT as a primary screening method for breast cancer. ACS does not make a recommendation, stating that although DBT units are steadily being introduced in mammography facilities, at the time the protocol for the evidence review was developed there were too few data on DBT to include comparisons of 2D versus 3D mammography.

Areas of Difference

about screening mammography for women in their 40s, although the specifics vary slightly. The USPSTF recommends that women ages 40 to 49 years who place a higher value on the potential benefit than the potential harms may choose to begin biennial screening; the ACS states that women ages 40 to 44 years should have the opportunity to begin annual screening. The developers' recommendations vary slightly on when regular screening mammography should begin: the USPSTF at age 50, and ACS at age 45. Recommendations regarding the frequency with which mammography should be performed differ as well. The USPSTF recommends biennial screening until age 74. ACS, in contrast, recommends that women aged 45 to 54 be screened annually, and that women 55 years and older should transition to biennial screening or have the opportunity to continue annual mammography.

Cessation of Screening

ACS does not recommend cessation of screening mammography at a particular age, but rather that women continue as long as their overall health is good and they have a life expectancy of 10 years or longer. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening in women aged 75 years or older.

Women with Dense Breasts

The USPSTF guideline addresses a population not considered by ACS—women with dense breasts. Dense breasts place some women at a higher risk of developing breast cancer and/or a higher risk of having their breast cancer not detected by mammography. The USPSTF found insufficient evidence to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, MRI, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram.

ACS did not review evidence on the effectiveness of supplemental breast imaging for women with mammographically dense breasts. The developer states that it will consider the evidence for screening effectiveness in women in higher risk groups in a subsequent guideline.

Screening for Breast Cancer in Women at Average Risk

ACS (2015)	<u>Recommendations</u>
	
	1. Women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years. (***Strong Recommendation***)
	   a. Women aged 45 to 54 years should be screened annually. (***Qualified Recommendation***)
	   b. Women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually. (***Qualified Recommendation***)
	   c. Women should have the opportunity to begin annual screening between the ages of 40 and 44 years. (***Qualified Recommendation***)
	2. Women should continue screening mammography as long as their overall health is good and they have a life expectancy of 10 years or longer. (***Qualified Recommendation***)
	3. The ACS does not recommend CBE for breast cancer screening among average-risk women at any age. (***Qualified Recommendation***)

USPSTF (2016)	<u>Summary of Recommendations and Evidence</u> The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. (**B recommendation**) The decision to start screening mammography in women prior to age 50 years should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin biennial screening between the ages of 40 and 49 years. (**C recommendation**)

all of the age groups, women aged 60 to 69 years are most likely to avoid breast cancer death through mammography screening. While screening mammography in women aged 40 to 49 years may reduce the risk for breast cancer death, the number of deaths averted is smaller than that in older women and the number of false-positive results and unnecessary biopsies is larger. The balance of benefits and harms is likely to improve as women move from their early to late 40s.

- In addition to false-positive results and unnecessary biopsies, all women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to their health, or even apparent, during their lifetime (known as "overdiagnosis"). Beginning mammography screening at a younger age and screening more frequently may increase the risk for overdiagnosis and subsequent overtreatment.
- Women with a parent, sibling, or child with breast cancer are at higher risk for breast cancer and thus may benefit more than average-risk women from beginning screening in their 40s.

See the Clinical Considerations section in the NGC summary for information on implementation of the C recommendation. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women aged 75 years or older. (**I statement**)

The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of DBT as a primary screening method for breast cancer. (**I statement**)

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasonography, MRI, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. (**I statement**)

ACS (2015)	<u>Overall Quality of the Body of Evidence Using Grading of Recommendations Assessment, Development and Evaluation (GRADE)</u> **High** — The reviewers are very confident that the true effect lies close to that of the estimate of the effect. (Alternative: Further research is very unlikely to change confidence on the estimate of effect.) **Moderate** — The reviewers are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different. (Alternative: Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.) **Low** — Confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. (Alternative: Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.) **Very low** — The reviewers have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect. (Alternative: Evidence on an outcome is absent or too weak, sparse, or inconsistent to estimate an effect.) <u>Strength of the Recommendations</u> ACS assessed recommendations as "strong" or "qualified," in accordance with GRADE guidance. A strong recommendation conveys the consensus that the benefits of adherence to the intervention outweigh the undesirable effects. Qualified recommendations indicate there is clear evidence of benefit but less certainty about either the balance of benefits and harms, or about patients' values and preferences, which could lead to different decisions (Table 1 in the original guideline document).

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.

	recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description

	includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.

		to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Methodology

Click on the links below for details of guideline development methodology	
ACS **(2015)**	**USPSTF** **(2016)**
Both guidelines were developed from systematic reviews of the evidence. The USPSTF guideline is based on evidence reviews prepared by the Pacific Northwest Evidence-based Practice Center (EPC); the Center for Healthcare Policy and Research, University of California Davis, Sacramento and the Kaiser Permanente Research Affiliates EPC. The USPSTF also commissioned a report from the CISNET Breast Cancer Working Group to	

cancer risk, and comorbidity level affect the balance of benefit and harms of screening mammography. A second decision analysis estimated the number of radiation-induced breast cancer cases and deaths associated with different screening mammography strategies over the course of a woman's lifetime. ACS selected the Duke University Evidence Synthesis Group to conduct an independent systematic evidence review after a response to a request for proposals, and commissioned the Breast Cancer Surveillance Consortium (BCSC) to update previously published analyses related to the screening interval and outcomes. The ACS Surveillance and Health Services Research Program provided supplementary data on disease burden using data from the Surveillance, Epidemiology, and End Results (SEER) Program. To collect the evidence, hand-searches of published literature and searches of electronic databases were performed for both guidelines. Relevant details regarding the search including databases searched, keywords used, and date ranges applied are provided. To assess the quality and strength of the evidence, both groups weighted it according to a scheme and provide the scheme. With regard to methods used to analyze the evidence, in addition to performing systematic reviews with evidence tables, both developers reviewed published meta-analyses. The USPSTF also performed a meta-analysis of randomized controlled trials. To formulate the recommendations, both ACS and the USPSTF employed expert consensus; the USPSTF also utilized balance sheets. The guideline developers rate the strength of the recommendations according to a scheme and provide the scheme. To validate the guidelines, the groups sought both internal and external peer review; the USPSTF also compared its guideline with those developed by other groups, including the ACS guideline included in this synthesis, and posted the draft research plan, draft evidence reviews, and draft recommendation statement for public comment on its Web site.

Benefits and Harms

Benefits

ACS (2015)	Mammography screening has been shown to be associated with a reduction in breast cancer mortality across a range of study designs, including randomized

	benefit (see Table 3 in the original guideline document for a table of estimated relative reduction in breast cancer mortality associated with mammography screening, by study design among pooled studies).
USPSTF (2016)	**Benefit of Screening and Early Treatment** The USPSTF found adequate evidence that mammography screening reduces breast cancer mortality in women aged 40 to 74 years. The number of breast cancer deaths averted increases with age; women aged 40 to 49 years benefit the least and women aged 60 to 69 years benefit the most. Age is the most important risk factor for breast cancer, and the increased benefit observed with age is at least partly due to the increase in risk. Women aged 40 to 49 years who have a first degree relative with breast cancer have a risk for breast cancer similar to that of women aged 50 to 59 years without a family history. Direct evidence about the benefits of screening mammography in women aged 75 years or older is lacking. The USPSTF found inadequate evidence on the benefits of DBT as a primary screening method for breast cancer. Similarly, the USPSTF found inadequate evidence on the benefits of adjunctive screening for breast cancer using breast ultrasonography, MRI, DBT, or other methods in women identified to have dense breasts on an otherwise negative screening mammogram. In both cases, while there is some information about the accuracy of these methods, there is no information on the effects of their use on health outcomes, such as breast cancer incidence or mortality rates.

Harms

ACS (2015)	• False-positive findings are common in breast cancer screening. The most common outcome of a false-positive finding is being recalled for additional imaging.

	would result in overtreatment, uncertainty about the magnitude of the risk of overdiagnosis poses a challenge to providing complete and accurate information to women about what to expect from breast cancer screening. • When making decisions on screening intervals, it is important to consider the harm-benefit trade-off. While annual screening yielded a larger reduction in breast cancer mortality than biennial screening, a more frequent screening schedule also resulted in a higher rate of false-positive findings. • Women in poor health or with severe comorbid conditions and limited life expectancy may be more vulnerable to harms of screening, including anxiety and discomfort associated with additional testing and risk of overdiagnosis (due to increased risk of dying from non–breast cancer–related causes) as well as to harms from breast cancer treatment. Thus, health and life expectancy, not simply age, must be considered in screening decisions.
USPSTF (2016)	**Harms of Screening and Early Treatment** The USPSTF found adequate evidence that screening for breast cancer with mammography results in harms for women aged 40 to 74 years. The most important harm is the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to a woman's health, or even apparent, during her lifetime (that is, overdiagnosis and overtreatment). False-positive results are common and lead to unnecessary and sometimes invasive follow-up testing, with the potential for psychological harms (such as anxiety). False-negative results (that is, missed cancer) also occur and may provide false reassurance. Radiation-induced breast cancer and resulting death can also occur, although the number of both of these events is predicted to be low. The USPSTF found inadequate evidence on the harms of DBT as a primary screening method for breast cancer. Similarly, the USPSTF found inadequate evidence on the harms of adjunctive screening for breast cancer using breast ultrasonography, MRI, DBT, or other methods in women identified to have dense

	information on the effects of their use on overdiagnosis rates.

Abbreviations

ACS, American Cancer Society

BSE, breast self-examination

CBE, clinical breast examination

DBT, digital breast tomosynthesis

MRI, magnetic resonance imaging

USPSTF, U.S. Preventive Services Task Force

Status

This synthesis was prepared by ECRI on December 28, 1998. It was reviewed and verified by the guideline developers as of February 19, 1999. This synthesis was subsequently modified by ECRI in 2001, 2002, 2003, 2004, and 2005. The most current version of this synthesis incorporates the 2004 UMHS recommendations. This synthesis was verified by UMHS on November 3, 2005. This synthesis was updated by ECRI on August 8, 2006 and on December 14, 2006 following the withdrawal of the Kaiser Permanente Southern California guideline, and the Brigham and Women's and Canadian Task Force guidelines respectively from the NGC Web site. This synthesis was revised on November 27, 2007 to remove recommendations from the USPSTF. This synthesis was revised on January 28, 2008 to add ACP recommendations. The information was verified by ACP on February 4, 2008. This synthesis was revised on May 2, 2008 to incorporate the 2007 ACS addendum. This synthesis was revised in October 2008 to remove outdated ACOG recommendations and again in December 2009 to add USPSTF recommendations and to remove ACS and UMHS recommendations. The information was verified by the USPSTF on 1/29/10. This synthesis was revised in October 2011 to add ACOG recommendations, and again in February 2012 to

synthesis was revised in May 2015 to add CTFPHC recommendations. The information was verified by CTFPHC on June 23, 2015. This synthesis was revised most recently in February 2016 to remove recommendations from ACOG, CTFPHC and KPCMI, and to add recommendations from ACS and the USPSTF. The information was verified by ACS on April 25, 2016 and the USPSTF on March 31, 2016.