THE AMERICAN SOCIETY OF Breast Surgeons

Position/Policy Report

Position Statement on Screening Mammography

ASBrS Breast Cancer Screening Guidelines Recommendations

1. Women age >25 should undergo formal risk assessment for breast cancer
2. Women with an average risk of breast cancer should initiate yearly screening mammography at age 40
3. Women with a higher-than-average risk of breast cancer should undergo yearly screening mammography and be offered yearly supplemental imaging; this screening should be initiated at a risk-based age
4. Screening mammography should cease when life expectancy is <10 years

Table 1 – Summary of ASBrS Recommendations for Breast Cancer Screening*

Women with average risk	• Women with non-dense breasts (A and B density)^	Annual mammography (3D preferred modality) starting at age 40, no need for supplemental imaging
	• Women with increased breast density (C and D density)^	Annual mammography (3D preferred modality), starting at age 40, and consider supplemental imaging
Women with higher-than-average risk	• Hereditary susceptibility from pathogenic mutation carrier status • Prior chest wall radiation age 10-30	Annual MRI starting at age 25 Annual mammography (3D preferred modality) starting at age 30
	• Predicted lifetime risk >20% by any model • Strong family history	Annual mammography (3D preferred modality) and access to supplemental imaging (MRI preferred modality) starting at age 35 when recommended by their physician
Women with prior history of breast cancer age ≥50 with non-dense breasts#		Annual mammography (3D preferred modality)
Women with prior history of breast cancer at age <50, or with dense breasts#		Annual mammography (3D preferred modality) and access to annual supplemental imaging (MRI preferred modality) when recommended by their physician

*All women to undergo risk assessment at age 25-30 and updated at appropriate intervals

^Class A or 1 density = fatty; Class B or 2 density = scattered fibroglandular density; Class C or 3 density = heterogeneously dense; Class D or 4 density = extremely dense

#Women with prior breast cancer who did not undergo bilateral mastectomy

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Introduction and Review of Guidelines

Controversy surrounding screening mammography guidelines has resulted in conflicting recommendations from physicians and uncertainty for women. The underlying evidence supporting the use of screening mammography is largely derived from nine randomized trials initiated between 1963-1991. These nine trials were undertaken in the United States (US), Sweden, the United Kingdom, and Canada, and recruited more than 660,000 women with average risk for breast cancer. Several advances and paradigms have evolved in the field of breast oncology over the past several decades since these trials were completed, leading to questions regarding their 21st century relevance. For example, the technology of mammographic imaging has progressed substantially, and we have a deeper understanding of heterogeneity in breast tumor biology; both of these issues generate concerns regarding the balance between "over-diagnosis" versus the outcome benefits of early detection. Furthermore, we have refined documentation of disparities in breast cancer burden related to associations between racial/ethnic identity, age, and breast tumor subtype. These issues, as well as shifting population demographics and increasing diversity in the US, elevate the screening mammography debate in discussions of strategies to achieve health equity. Changes in our understanding of breast cancer epidemiology justify re-evaluation of these trials in the context of contemporary recommendations for mammographic screening, despite the paucity of data these trials provide regarding screen-detected tumor biology and diverse patient populations.

The most recent United States Preventive Services Task Force (USPSTF) report (1) recommended that women with average risk begin screening mammography at age 50, to be performed in a biennial fashion, through age 74. They recommended that women between ages 40 and 50 should have an individualized approach weighing benefits and false-positive risks. The American Cancer Society (ACS) also updated their screening mammography guidelines for women with average risk (2), and they recommended that women with an average risk of breast cancer begin screening mammography starting at age 45 and continue yearly between ages 45 and 54. Women age 55 and older were recommended to undergo biennial screening, with an opportunity for yearly screening mammography. Further, they recommended that women continue screening as long as their life expectancy was 10 years or longer. Despite differences regarding the preferred age for initiating mammographic screening, all guidelines advocate in favor of access to screening mammography beginning at age 40 for women who are asymptomatic and have average risk in the US. The "shared decision-making" approach recommended for women in their 40s has left many women and their health care providers without clarity regarding integration of screening mammography into health maintenance routines. It is also worth noting that the demographic of American women in the 40-49-year-old age category has grown by approximately 10 million since the era that launched the screening mammography trials, yielding an expanded population struggling with these decisions.

The recommendations become further complicated when considering women at higher risk for breast cancer, as addressed in the most recent guideline issued jointly by the American College of Radiology (ACR) and the Society for Breast Imaging (SBI) (3). The ACR/ SBI recommends annual mammographic screening beginning at age 40 for women of average

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risk, and they suggest that women with higher risk should start mammographic screening earlier and that they may benefit from supplemental screening modalities. For women with genetics-based increased risk (and their untested first-degree relatives), those with a calculated lifetime risk of 20% or more, or those with a history of chest or mantle radiation therapy at a young age, the ACR/SBI recommends supplemental screening with contrast-enhanced breast magnetic resonance imaging (MRI). Breast MRI is also recommended for women with a personal history of breast cancer who have dense tissue, and those with a history of breast cancer diagnosed before age 50. The ACR/SBI further supports considering additional surveillance with MRI for women with biopsy-proven atypia, especially if other risk factors are present. The ACR/SBI also reported that screening whole-breast ultrasound could be considered for those who qualify for, but cannot undergo, MRI. Finally, the ACR/SBI supported that all women, especially black women and those of Ashkenazi Jewish descent, should be evaluated for breast cancer risk no later than age 30, so that those at higher risk can be identified and can benefit from supplemental screening (3).

The goals of the current ASBrS position statement are to summarize the data and to make clear recommendations regarding breast cancer screening for both women with average and higher risk, as well as to make surveillance imaging recommendations for women with a prior history of breast cancer. In addition, the role of the various screening modalities will be delineated for these risk groups.

Risk Assessment

To determine the appropriate screening approach, the first step is risk assessment. We recommend that individual women undergo formal risk assessment as follows, with ages chosen where the results of the risk assessment will change management:

Age 25 or when first seen by a breast physician or other appropriate health care provider (age 25-30):

- Assess family history of malignancies
    - Discuss genetic testing of the unaffected woman if she meets the National Comprehensive Cancer Network (NCCN) guidelines for genetic testing, https://www2.tri-kobe.org/nccn/guideline/gynecological/english/genetic_familial.pdf
- Determine if the woman has a prior history of atypical hyperplasia or lobular carcinoma in situ (LCIS)
- Determine if the woman has a prior history of chest or mantle radiation therapy between the ages of 10 and 30

If the risk assessment described above reveals a significant finding (hereditary susceptibility related to a pathogenic mutation, prior atypia and/or LCIS, or history of mantle radiation between ages 10-30), then the woman is considered to be at higher risk of breast cancer development and should follow higher-risk screening.

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Age 30 or above or when first seen by a breast physician or other appropriate health care provider (at age over 30):

- Assess risk factors as above
- Estimate breast cancer risk using the current Tyrer-Cuzick model or a comparable validated model including similar factors (family and personal history, including breast density and any biopsy results). Note all models have limitations in minority populations. Tyrer-Cuzick is available on the ASBrS Mastery website: https://www.breastsurgeons.org/programs/mastery/ or can be downloaded at: http://www.ems-trials.org/riskevaluator/
- Update risk at regular intervals

Breast Cancer Risk

Absolute risk is used to describe an individual's likelihood of developing breast cancer. It is based on the number of people who will develop breast cancer within a certain time period. Absolute risk also can be stated as a percentage. Currently, 1 in 8 women in the US, or 12%, will develop breast cancer over the course of a lifetime. The absolute risk of developing breast cancer during a particular decade of life is lower than 1 in 8. The younger you are, the lower the risk. For example, a woman at age 30 who has no other breast cancer risk factors has a 1 in 228 risk of breast cancer, or 0.44%, in the next 10 years. On the other hand, a woman at age 60 who has no other breast cancer risk factors has a 1 in 29 risk of breast cancer, or 3.49%, in the next 10 years.

In contrast, **relative risk** is a number or percentage that compares one group's risk of developing breast cancer to another's. For the purposes of the current recommendations, women with average risk women are considered to have an absolute risk comparable to the general population at any given age.

Special note: The ACS (and later, other groups generating guidelines) chose the 20% remaining lifetime risk threshold to approximate the various thresholds that had been used in the international MRI screening trials where the focus had been on women who are younger and have higher risk. However, using remaining lifetime risk is inherently problematic for women as they age wherein short-term incidence is increasing while remaining lifetime risk is decreasing. As a result, women who qualify when younger for screening MRI can potentially fall below the 20% threshold while still at peak short-term disease incidence. Although not included in MRI screening guidelines by any organization in the US, short-term risk calculations (5- or 10-year risks) should be included in future studies, ideally in combination with breast density, as was done in the ACRIN 6666 trial (4).

ASBrS Recommendations – Women with Average Risk

We recommend that women with average risk undergo yearly screening mammography beginning at age 40. Such screening should continue as long as the woman remains in good health with an average life expectancy of 10 years or longer. Tomosynthesis, or three-

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dimensional (3D) mammography, became available in the US in 2011 and improves the sensitivity and specificity of mammography, particularly for women with nonfatty breasts and in the assessment of noncalcified lesions. Where available, 3D mammography is the preferred sole modality for women with an average risk for breast cancer. It is also important to note that most current 3D mammography units result in no greater radiation exposure than traditional 2D units.

There are known disadvantages of screening mammography for women age 40-49. There are multiple factors accounting for this, including a shorter lead time of mammography to breast cancer diagnosis, a lower sensitivity and specificity for mammography in women 40-49 versus those 50 and older with associated higher rates of recall and biopsy, and a longer period of follow-up that is necessary to demonstrate benefit for the cancers detected in women 40-49, which were skewed towards good to intermediate prognosis disease in the screening trials (5). All medical interventions carry potential for benefit as well as harm, and mammography screening is no exception. Women who undergo screening mammography should be informed of the potential downsides of screening as well as the benefits. These potential risks include false-negatives (resulting in false reassurance), false-positive (abnormal findings on imaging resulting in additional medical interventions and anxiety), exposure to radiation, and over-diagnosis (i.e., the concept that some extremely indolent cancers might be detected that pose no threat to life and that would never have been detected in the absence of screening). Despite these potential disadvantages, the ASBrS supports the use of annual screening mammography beginning at age 40 for women with average risk. Although the meta-analysis performed by the USPSTF revealed a 15% mortality reduction for screening women age 40-49, the Task Force placed an increasing emphasis on the harms of screening beginning in 2009 and continuing through the most recent update in 2016 (6). This position was a reversal of their earlier pro-screening position that had been based on the identical 15% mortality reduction (7).

Indeed, when the USPSTF reversed their opinion regarding screening mammography beginning at age 40, they acknowledged that their updated guideline was based on choosing between two different statistical models related to outcome benefits, and both models were generated by the Cancer Intervention and Surveillance Modelling Network (CISNET). The "efficiency"-based model revealed advantages with delayed mammography screening until age 50 (6, 7). In contrast, the "life-years-gained"-based model demonstrated survival benefits associated with screening beginning at age 40 (6, 7). The USPSTF opted to base their screening guideline on the efficiency model. Updated analyses of CISNET models have continued to reaffirm estimates of greatest mortality reduction achieved with annual screening beginning at age 40 (8). The ASBrS opposes the USPSTF approach that ranks efficiency over life-years gained. We have chosen to prioritize the mortality reduction benefits associated with annual screening mammography beginning at age 40.

The screening mammography debate regarding women in their 40s has heightened relevance in discussions of breast cancer disparities related to racial-ethnic identity. While a comprehensive review of the multifactorial etiology of this important issue and its impact on the full spectrum of our diverse American population is beyond the scope of this ASBrS guideline, a few well-documented differences in the breast cancer burden of African

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American compared to White American women warrant comment. The age distribution of breast cancer is younger, and the stage distribution is more advanced in African American women. Population-based breast cancer mortality rates are higher among African American women, and population-based incidence rates of triple-negative (estrogen receptor-negative, progesterone receptor-negative, Her2neu non-amplified) breast cancer are two-fold higher among African American women (9, 10). Although the extent to which screening mammography can reverse outcome disparities is unclear, the benefits of early detection through screening for all breast tumor phenotypes (e.g., improved survival, reduced need for adjuvant chemotherapy) are compelling arguments in favor of mammography screening as a valuable weapon in achieving health equity (11).

ASBrS Recommendations – Women with Higher-than-average Risk

According to the NCCN guidelines (12-15), women with higher-than-average risk for breast cancer include: 1) women with a BRCA gene mutation or other germline mutation known to predispose to a high risk of breast cancer (or women with a very strong family history who have not undergone complete testing); 2) women with a history of chest irradiation between the ages of 10 and 30; and 3) women with a greater than 20% estimated lifetime risk of breast cancer based on risk assessment models such as Claus, BRCAPro, and Tyrer-Cuzick (which includes almost all women with atypical hyperplasia or LCIS).

These women with higher-than-average risk should have annual 3D screening mammography and should have access to supplemental imaging with an additional modality (MRI preferred) as suggested by ACR/SBI when recommended by their physician (3).

ASBrS Recommendations - Women with Prior History of Breast Cancer

In women with prior breast cancer and intact breasts, there is a higher risk for an in-breast tumor recurrence (IBTR) or new primary breast cancer. For women who have undergone unilateral mastectomy, the contralateral breast should be followed with yearly screening mammography. For women who have undergone breast-conserving therapy, annual mammography for the cancerous breast should be performed per local institutional protocol. In addition, the ASBrS supports access to supplemental imaging for women with a personal history of breast cancer who have either dense breast tissue or were under age 50 at diagnosis when recommended by their physician.

Supplemental Screening Modalities

Contrast-enhanced Breast Magnetic Resonance Imaging (MRI). Contrast-enhanced breast MRI is more sensitive than either mammography or ultrasound in high-risk populations (16, 17). For BRCA and other germline mutation carriers, MRI is recommended as a supplemental screening modality starting at age 25 (with mammography beginning at age 30). For women with a history of chest or mantle radiation therapy under age 30, the incremental cancer detection rate with the addition of MRI is approximately 4% (17). Breast cancer risk increases substantially approximately eight years after the completion of

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radiation therapy. Thus, MRI surveillance should begin at that time but not before age 25 (18). If MRI is contraindicated or the woman declines it, other enhanced screening modalities are available to consider.

Ultrasound. Multiple studies confirm the incremental cancer detection capabilities of whole-breast ultrasound in women with higher risk. ACRIN 6666 was a large prospective multicenter study evaluating women with higher risk and demonstrated a supplemental cancer detection rate of 4.3 per 1,000 (4). However, this supplemental detection is counter-balanced by an increase in false-positive findings and lower positive predictive value compared to mammography and MRI (19). As supplemental ultrasound screening evolves, and automated technology improves, some of these drawbacks may diminish. In the Japan Strategic Anti-cancer Randomized Trial (J-START), women were randomized to screening mammography alone versus screening mammography and supplemental screening ultrasound (20). Women undergoing supplemental screening ultrasound had more cancers detected than those undergoing mammography alone [184 (0.50%) versus 117 (0.32%), p=0.0003], and those cancers were more frequently Stage 0 and Stage I (20).

Molecular Breast Imaging (MBI). There are currently no large trials to validate the efficacy of MBI for screening. However, several studies have demonstrated significant incremental cancer detection rates when used as a supplement to mammography (21). An advantage of MBI is that breast density is not a confounder for sensitivity and specificity. However, one must also consider the whole-body radiation exposure when compared to breast-only radiation with mammography. At this time, further advances in detector technology to allow lower dosing are underway, and prospective trials are needed to recommend MBI as a screening tool for women with a high risk of breast cancer.

Contrast-enhanced Mammography (CEM). CEM is an emerging breast imaging technique that uses contrast-enhanced recombined images for evaluation of neovascularity similar to MRI (22). This modality has not gained wide adoption to date. The use of additional ionizing radiation is less favorable than other available modalities. Further, there are currently no commercially available systems to biopsy regions of suspicious enhancement under CEM guidance. However, as technology with this modality improves, implementation of CEM as a supplemental imaging modality may increase as well.

ASBrS Recommendations - Populations in which Screening may be De-escalated/Unnecessary

Older Women. Prior randomized prospective trials of screening mammography exclude women older than 74. This led the USPSTF to conclude that there are no definitive data to recommend for or against screening mammography in this age group (1). On the other hand, the American Cancer Society recommends continued screening as long as women have a life expectancy of at least 10 years (2). We recommend that women with a life expectancy of at least 10 years continue yearly screening mammography. In this population, prior studies have demonstrated a survival benefit in women who do not have severe co-morbidities (23, 24). In addition, mammographic screening in an older population would be expected to have a lower rate of false-positives and unnecessary biopsies compared to a younger population.

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Routine screening mammography, 2D or 3D, without supplemental imaging should be sufficient for this group, even if they met higher-risk criteria at a younger age.

Younger Women with Average Risk. There are currently no data to support routine screening in women under age 40 who have average risk.

Conclusions

The ASBrS recommends that women age 25 and older undergo formal risk assessment for breast cancer including evaluation of indications for genetic testing and personal history of radiation, adding calculated lifetime risk using a validated model such a Tyrer-Cuzick at age 30 and beyond. The ASBrS recommends that women who have an average risk undergo yearly screening mammography beginning at age 40, and stop screening mammography when the woman has a life expectancy of less than 10 years. The ASBrS recommends that women with a higher risk for breast cancer undergo yearly screening mammography and yearly supplemental imaging. At this time, MRI is the favored supplemental imaging modality.

Furthermore, the ASBrS acknowledges the presence of breast cancer outcome disparities in the US. African American women, for example, face a disproportionately high risk of breast cancer mortality, which is at least partly explained by differences in stage distribution as well as tumor biology. These screening recommendations for the overall diverse population of adult women represent an opportunity to minimize breast cancer disparities through earlier detection of disease in all women.

This statement was developed by the panel members listed below, and on April 10, 2019, was approved by the Board of Directors. Similar Guidelines have been previously put forth from this body in 2011 and 2015.

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Relevant Author Disclosures

Alan Hollingsworth, MD - Scientific Advisory Board, Aurora Healthcare US Corp (breast-dedicated MRI)

Kevin Hughes - Honoraria from Focal Therapeutics (Surgical implant for radiation planning with breast conservation), 23andMe, and is a founder of and has a financial interest in CRA Health (Formerly Hughes RiskApps). Dr. Hughes's interests were reviewed and are managed by Massachusetts General Hospital and Partners Health Care in accordance with their conflict of interest policies.

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