



Facing Hereditary Cancer EMPOWERED

June 4, 2023

Dear Chair and esteemed members of the USPSTF:

We appreciate the opportunity to comment on the Screening for Breast Cancer Draft Recommendation Statement. FORCE (Facing Our Risk of Cancer Empowered) is a national nonprofit organization representing people facing hereditary cancers. Many of our constituents carry an inherited genetic mutation that increases their risk of cancer, including breast, ovarian, prostate, pancreatic, and colorectal. Our organization is committed to providing information, education, and advocacy to empower members of this community to make informed decisions about their health, including decisions about cancer screening.

We disagree with the conclusions presented in the Draft Recommendation Statement. The proposed guidelines will worsen existing disparities, lead to confusion, and cost the lives of women in the community that FORCE serves.

We encourage the USPSTF to consider the evidence in support of:

- Annual mammography, beginning at age 40.
- Defining “high risk” beginning at age 25 using validated risk tools that consider inherited cancer risk and other factors.
- Adding additional screening recommendations including breast ultrasound and/or MRI for those at high risk due to an inherited genetic mutation, family history, those with dense breasts and other risk factors.

The proposed recommendation to begin screening mammography at age 40 is an important acknowledgment that the incidence of breast cancer in young women is increasing and, when diagnosed, is often invasive.

Cronin, KA, Scott, S, Firth, AU, et al. Annual report to the nation on the status of cancer, part 1: National cancer statistics. *Cancer*. 2022; 128 (24): 4251- 4284.
doi:10.1002/cncr.34479

Currently, mammography remains the only validated screening tool to reduce breast cancer mortality. We and numerous other professional societies such as the American College of Radiology and Society of Breast Imaging recommend **annual** mammography screening for all average-risk women ages 40 and older. **Annual** screening mammography is well-documented to save lives. This documentation includes USPSTF’s new modeling report which finds that annual screening saves more lives than screening every two years.

Monticciolo DL, Malak SF, Friedewald SM, Eby PR, Newell MS, Moy L, Destounis S, Leung JWT, Hendrick RE, Smetherman D. Breast Cancer Screening Recommendations Inclusive of All Women at Average Risk: Update from the ACR and Society of Breast Imaging. *J Am Coll Radiol*. 2021 Sep;18(9):1280-1288. doi: 10.1016/j.jacr.2021.04.021. Epub 2021 Jun 19. PMID: 34154984.

Henderson JT, Webber, EM, Weyrich M, Miller M, Melnikow J. Screening for Breast Cancer: A Comparative Effectiveness Review for the U.S. Preventive Services Task Force. Evidence Synthesis No. 231. Rockville, MD: Agency for Healthcare Research and Quality; 2023. AHRQ Publication No. 23-05303-EF-1.

While we are encouraged by the USPSTF's acknowledgment that Black, Latina women, and women who were treated with radiation therapy for cancer as children or young adults are also at high risk, we would like to point out that, unfortunately, the USPSTF based its cancer screening recommendations on research that consisted of mostly non-Hispanic white women.

We urge the USPSTF to consider that cancer screening methods for young, average-risk women of Color need to be individualized. Black, Hispanic, and Asian women are more likely to be diagnosed with breast cancer before the age of 50 and it is well known that many of these are highly aggressive triple-negative breast cancers. This observation is supported by several key epidemiologic studies showing that in comparison with White women, Black women were more likely to be diagnosed with breast cancer before the age of 50 years.

Thus, we believe that the newly proposed breast cancer screening recommendations will adversely affect Women of Color. Mammographic screening beginning at age 40 will not detect all early breast cancers that affect women of Color. One size does not fit all.

Gao B; Zhang H; Zhang SD; Cheng XY; Zheng SM; Sun YH; Zhang DW; Jiang Y; Tian JW Mammographic and clinicopathological features of triple-negative breast cancer. *Br J Radiol* 2014, 87, 20130496, doi: 10.1259/bjr.20130496

Stapleton SM; Oseni TO; Bababekov YJ; Hung YC; Chang DC Race/Ethnicity and Age Distribution of Breast Cancer Diagnosis in the United States. *JAMA Surg* 2018, 153, 594–595, doi: 10.1001/jamasurg.2018.0035.

The draft excludes recommendations for additional screening in women at high risk for breast cancer due to an inherited mutation. There is good evidence that increased screening beginning at an earlier age using breast MRI can improve outcomes and lead to down-staged cancers in this population.

Warner E, Zhu S, Plewes DB, Hill K, Ramsay EA, Causer PA, Seely J, Jong RA, Lenkov P, Elser C, Crystal P, Yaffe MJ, Giannakeas V, Sun P, Narod SA. Breast Cancer Mortality among Women with a BRCA1 or BRCA2 Mutation in a Magnetic Resonance Imaging Plus Mammography Screening Program. *Cancers (Basel)*. 2020 Nov 23;12(11):3479. doi: 10.3390/cancers12113479. PMID: 33238387; PMCID: PMC7700272.

Lowry KP, Geuzinge HA, Stout NK, Alagoz O, Hampton J, Kerlikowske K, de Koning HJ, Miglioretti DL, van Ravesteyn NT, Schechter C, Sprague BL, Tosteson ANA, Trentham-Dietz A, Weaver D, Yaffe MJ, Yeh JM, Couch FJ, Hu C, Kraft P, Polley EC, Mandelblatt JS, Kurian AW, Robson ME; Breast Working Group of the Cancer Intervention and Surveillance Modeling Network (CISNET), in collaboration with the Breast Cancer Surveillance Consortium (BCSC), and the Cancer Risk Estimates Related to Susceptibility (CARRIERS) Consortium. Breast Cancer Screening Strategies for Women With ATM, CHEK2, and PALB2 Pathogenic Variants: A Comparative Modeling Analysis. *JAMA Oncol.* 2022 Apr 1;8(4):587-596. doi: 10.1001/jamaoncol.2021.6204. PMID: 35175286; PMCID: PMC8855312.

Heemskerk-Gerritsen BAM, Jager A, Koppert LB, Obdeijn AI, Collée M, Meijers-Heijboer HEJ, Jenner DJ, Oldenburg HSA, van Engelen K, de Vries J, van Asperen CJ, Devilee P, Blok MJ, Kets CM, Ausems MGEM, Seynaeve C, Rookus MA, Hooning MJ. Survival after bilateral risk-reducing mastectomy in healthy BRCA1 and BRCA2 mutation carriers. *Breast Cancer Res Treat.* 2019 Oct;177(3):723-733. doi: 10.1007/s10549-019-05345-2. Epub 2019 Jul 13. PMID: 31302855; PMCID: PMC6745043.

The specific exclusion of high-risk women from this guideline, and a lack of separate USPSTF guidelines for this population leads to a dangerous information gap regarding breast screening in high-risk women. The exclusion of these high-risk individuals from any USPSTF guidelines on preventive breast health contributes to disparities for this segment of the U.S. population.

Further, the draft excludes recommendations that women with dense breast tissue be referred for supplemental imaging, such as ultrasound or MRI, despite mounting evidence supporting the need for additional exams in that population.

Wendie A Berg, MD, PhD and others, Opinion: USPSTF Guideline Fails to Address Dense Breasts, *Journal of Breast Imaging*, 2023; wbad043, <https://doi.org/10.1093/jbi/wbad043>

Many women are not aware of their breast cancer risk. To help identify high-risk individuals, we propose the USPSTF advise that lifetime breast cancer risk is calculated for all women at age 25 using a risk assessment tool that includes family history and the likelihood of inherited breast cancer risk and other factors. We further encourage the USPSTF to recommend that those with a calculated lifetime risk of 20% or more, undergo high-risk breast screening beginning at age 25-30 with annual breast MRI in addition to mammography, and to consider other risk reduction strategies.

Because USPSTF recommendations are utilized by health insurers to determine coverage, the Task Force should note the data suggesting that many women are subject to a high financial burden when receiving breast cancer screening MRIs; those enrolled in high-deductible plans and who reside in the South are also especially financially vulnerable.

Pan IW, Oeffinger KC, Shih YT. Cost-Sharing and Out-of-Pocket Cost for Women Who Received MRI for Breast Cancer Screening. J Natl Cancer Inst. 2022 Feb 7;114(2):254-262. doi: 10.1093/jnci/djab150. PMID: 34320199; PMCID: PMC8826560.

In summary, the Task Force's 2023 evidence review and recommendation demonstrate only modest benefits, especially for younger high-risk women. All women have a substantial risk for breast cancer but breast cancers that occur in premenopausal persons tend to be more aggressive, diagnosed at a later stage, and result in early mortality. **Annual** mammography beginning at 40 years old maximizes benefits and improves outcomes for those determined to be at average risk of breast cancer.

For women at higher risk (dense breasts, lifetime risk over 20%, women of Color), **annual** screening as well as supplemental screening (breast ultrasound and/or MRI), at younger ages is indicated. The need for earlier, annual and supplemental screening and, importantly—the need for coverage with no patient cost-sharing to reduce barriers to care—suggest that the USPSTF should reconsider these critically important issues and its draft recommendation.

How to make this draft Recommendation Statement clearer:

Emphasize the importance of assessing breast cancer risk at age 25 to inform appropriate screening.

Needed information not included in this draft Recommendation Statement:

Screening recommendations for transgender individuals are needed. For example, the American College of Radiology recommends annual breast screening starting at age 40 for male-to-female transgender individuals.

Resources or tools that would make this Recommendation Statement more useful:

Information on hereditary cancer syndromes and risk calculation tools, and their value in identifying individuals at increased risk of breast cancer due to family history, genetic predisposition, ethnicity, and other factors.

Thank you for your consideration.



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