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1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

February 17, 2021

Dr. Alex H. Krist, MD, MPH
Chairperson
United States Preventive Services Task Force
540 Gaither Road
Rockville, MD 20850

Re: Screening for Breast Cancer: Draft Research Plan

Dear Dr. Krist:

The Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the United States Preventive Services Task Force (USPSTF or the Task Force) draft research plan on breast cancer screening. As the leading trade association representing medical imaging device manufacturers, MITA has in-depth knowledge of the significant benefits that early detection and accurate diagnosis through medical imaging provides.

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Breast cancer is the second most common cancer among women in the United States.[1] Screening for breast cancer is essential to reduce breast cancer mortality and improve outcomes for patients.[2] Medical imaging technologies play a key role in breast cancer screening, and diagnosis, that leads to early and more effective treatment. We encourage USPSTF to adopt a research and analysis plan that ensures appropriate access to breast cancer screening technologies.

As USPSTF reviews the current evidentiary landscape, we urge review of the guidelines of other expert groups—and the underlying evidence those groups relied upon to publish their guidelines. The current inconsistency between USPSTF guidance and those of relevant clinical professional societies hinders the consistent practice of evidence-based care and shared decision-making between women and their clinicians.

[1] American Cancer Society. How Common Is Breast Cancer? Jan. 2020. Available at: https://www.cancer.org/cancer/breast-cancer/about/how-common-is-breast-cancer.html

[2] Dibden A, Offman J, Duffy SW, Gabe R. Worldwide Review and Meta-Analysis of Cohort Studies Measuring the Effect of Mammography Screening Programmes on Incidence-Based Breast Cancer Mortality. *Cancers (Basel)*. 2020;12(4):976. Published 2020 Apr 15. doi:10.3390/cancers12040976

Examples of breast cancer screening guidelines from professional societies and public health organizations include:

- **The American College of Obstetricians and Gynecologists** (ACOG) recommends that women at average risk of breast cancer "should be offered screening mammography starting at age 40 years" and "should have screening mammography every 1 or 2 years based on an informed, shared decision-making process…"[3]
- **The American Cancer Society** (ACS) recommends that "women with an average risk of breast cancer should undergo regular screening mammography starting at age 45 years (strong recommendation). Women aged 45 to 54 years should be screened annually (qualified recommendation). Women 55 years and older should transition to biennial screening or have the opportunity to continue screening annually (qualified recommendation). Women should have the opportunity to begin annual screening between the ages of 40 and 44 years (qualified recommendation). 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)."[4]
- **The American College of Radiology** (ACR) "recommends annual mammographic screening beginning at age 40 for women of average risk. Higher-risk women should start mammographic screening earlier and may benefit from supplemental screening modalities."[5]
- **The National Comprehensive Care Network** (NCCN) recommends "annual mammographic screening for average-risk women beginning at age 40 years."[6]

We support assessing any mammography screening modality plus supplemental screening for a defined population (e.g., negative mammography, dense breasts, age group). Depending on the particular circumstances, including risk profile, of a patient, different screening technologies, used individually or in combination, may refine diagnosis and deliver better outcomes. A robust assessment of the latest research will enable women and their providers to make informed decisions about the best course of care.

With respect to breast density, we encourage examination of the use of BI-RADS[7] to determine breast density. This needs to be considered in the context of mandated reporting of density in mammography results. Currently, information to support shared decision-making on additional testing is insufficient as it occurs in the absence of consensus and guidelines.

To give context to its analysis, USPSTF intends to assess how social factors contribute to disparities in accessing breast cancer screening. MITA supports this research. Gaining a better understanding of the barriers to screening, as well as barriers to access of follow-up screening or diagnostic imaging, will enable progress toward ensuring women can access the care they need, when they need it.

It is our position that USPSTF should adopt open and transparent research methodologies for its assessment of breast cancer screening, as well as for other preventive services in the future. The modeling used by USPSTF should be much clearer to interested parties, including a full explication of the models being used, the data being inputted into the models, and how the data are being manipulated. Further, the Task Force should also be open to other types or levels of evidence in its assessment, including well designed observational studies and real-world evidence. This will ensure that a holistic assessment of available data is being conducted.

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[3] https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/07/breast-cancer-risk-assessment-and-screening-in-average-risk-women

[4] https://jamanetwork.com/journals/jama/fullarticle/2463262

[5] https://www.jacr.org/article/S1546-1440(17)31524-7/fulltext

[6] https://pubmed.ncbi.nlm.nih.gov/30442736/

Finally, we suggest that USPSTF be more flexible in its review cycles for preventive services, including for breast cancer screening. The clinical evidence is rapidly evolving and differing recommendations are being issued by the public health community (some from organizations with shorter review cycles) and USPSTF must keep pace.

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MITA welcomes this opportunity to comment on the breast cancer screening draft research plan. Please contact Peter Weems, Senior Director, Policy & Strategic Operations, at pweems@medicalimaging.org or (703) 841-3238 if MITA can be of any assistance.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.