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## Towards More Equitable Breast Cancer Outcomes

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36 In their revised recommendation statement, the U.S. Preventive Services Task Force (Task Force) now  
37 recommends that all women undergo routine breast cancer screening every other year beginning at age  
38 40. This is an adjustment from the previous recommended start age of 50 and part of an overarching aim to  
39 increase earlier detection of breast cancer and address inequalities in breast cancer mortality, especially  
40 among Black women.<sup>1</sup> Additionally, the Task Force, in acknowledgement of evolving technology, updated  
41 the recommended primary screening modalities to include digital breast tomosynthesis (3D  
42 mammography). They noted that digital breast tomosynthesis improves the benefit-to-risk ratio compared to  
43 digital mammography, primarily by decreasing false-positive results, a well-known screening-related harm.<sup>2</sup>  
44

45 The revised recommendations from the Task Force shed light on two major issues that demand greater  
46 attention: addressing health inequities related to breast cancer outcomes and ensuring benefits for all  
47 women amidst rapid screening technological advancements. The major impetus for lowering the  
48 recommended start age to 40 stems from the observed increase in breast cancer incidence noted among  
49 women in their 40s and the need to tackle disparities affecting specific subpopulations. Notably, Black  
50 women continue to face disproportionately high mortality rates, 40% higher compared to White women in  
51 the U.S.<sup>3</sup> Black women also experience more aggressive cancer subtypes, such as triple negative cancers,  
52 and tend to have cancers diagnosed at later stages, compared to White women.  
53

54 Some may question the recommendation changes given the absence of new randomized controlled trials  
55 (RCTs). Such trials are expensive, require many years to complete, and randomization of women to no  
56 mammography screening would be unethical given its known mortality benefit. Moreover, both screening  
57 technologies and treatments are rapidly evolving, potentially making screening RCTs less informative by  
58 the time data are collected and results published. Instead, the Task Force relied on statistical simulation  
59 modeling from the Cancer Intervention and Simulation Modeling Network (CISNET) using the older trial  
60 data complemented with newer observational evidence. The modeling incorporates parameters and  
61 variables with uncertain, and even unknowable, values. However, by considering multiple different  
62 simulation modelling approaches, CISNET provides overall estimates of the expected magnitude of  
63 benefits and harms of different screening strategies at the U.S. population level.  
64

65 By lowering the starting age to 40, the hope is that more women will have their cancers detected earlier  
66 with the potential for earlier intervention with curative intent. Across all women, CISNET modeling found  
67 that starting biennial digital breast tomosynthesis screening at age 40 instead of age 50 until age 74 could  
68 avert 8.2 breast cancer deaths per 1000 women versus no screening (a 30% mortality reduction).  
69 However, among the more than 16000 mammography exams that these 1000 women will have during their  
70 screening years, this benefit comes at the expense of 1376 false-positive recalls and 14 overdiagnosed  
71 cases per 1000 women.<sup>4</sup> For Black women, expanding biennial digital breast tomosynthesis screening to  
72 women 40-49 (i.e., starting a decade earlier), averted a median of 1.8-2.8 additional breast cancer deaths  
73 per 1000 women.<sup>4</sup>  
74

75 While the CISNET simulation models are robust, they hinge on additional assumptions. Encouraging earlier  
76 screening at age 40 represents just one facet of the breast care continuum. These assumptions include  
77 women accessing screening facilities with up-to-date technology, receiving prompt diagnostic evaluations,  
78 and accessing high quality definitive treatment – a reality that doesn't always hold, particularly for  
79 individuals belonging to groups and communities that are traditionally underserved and under-resourced.  
80 Studies in the U.S. highlight disparities in access to breast cancer care. A cohort study involving 2 million  
81 U.S. screening mammograms revealed that Black and Hispanic women, women with lower income, and  
82 women with less education, were less likely to utilize facilities offering digital breast tomosynthesis and

83 were less likely to obtain this technology if it was an option on-site compared to their White, higher income,  
84 and more educated counterparts.<sup>5</sup> In another study of >45,000 U.S. women with abnormal mammography  
85 screening results, Black women faced a 20% higher likelihood of experiencing delays exceeding 90 days in  
86 obtaining a breast biopsy compared to their White counterparts.<sup>6</sup> Inequities in screening technology access  
87 and timely diagnosis and treatment diminish the benefits of early cancer detection.

88  
89 There is an urgent need for better evidence on the topic of supplemental screening with ultrasound or  
90 magnetic resonance imaging (MRI) for women with dense breasts. The topic is of critical concern since  
91 starting September 2024, the FDA will mandate that all U.S. screening facilities inform women about their  
92 breast density with their mammography results. Some states additionally require a statement  
93 recommending women discuss the option of supplemental screening ultrasound or MRI due to dense  
94 breasts with their primary care providers. It is important to recognize that nearly half of all women in the  
95 U.S. have dense breasts, a normal variation associated with a small increase in breast cancer risk similar  
96 to having an aunt with breast cancer.<sup>7</sup> As the Task Force states, there is currently inadequate evidence to  
97 recommend for or against additional screening with breast ultrasound or MRI due to dense breasts.

98  
99 Although the Task Force emphasizes the need for further research in many areas, it overlooks the pressing  
100 issue of emerging use of artificial intelligence (AI) support tools. Mammography-based AI tools are already  
101 FDA-cleared and are being used in community settings. Historically, millions of U.S. women underwent  
102 screening mammograms with older, pre-AI computer-aided detection tools for nearly two decades before  
103 population-level studies revealed decreased accuracy when these tools were used.<sup>8,9</sup> This historical error  
104 provides a clear warning that larger studies are required before wide adoption of newer AI tools for  
105 mammography. We are concerned that a similarly swift adoption of new AI support tools may occur before  
106 we have adequate scientific data to justify use at a population screening level. While AI algorithms show  
107 promise for enhancing cancer detection, their impact on patient outcomes and the balance between benefit  
108 and harms remain uncertain. How radiologists will incorporate AI tools into their decision-making may differ  
109 from the findings of small retrospective reader studies used to obtain FDA clearance.<sup>10</sup> Moreover, these AI  
110 tools have been primarily trained and tested on older White women, potentially exacerbating existing  
111 disparities unless they are validated on diverse populations to ensure that benefits are equitably  
112 experienced across all races and ethnicities.<sup>10</sup>

113  
114 Overall, the updated Task Force recommendations highlight a rapidly evolving intersection of technology  
115 and equity within an already complex healthcare ecosystem where disparities remain a persistent problem.  
116 It remains imperative that physicians continue to practice medicine's art to ensure that women make  
117 informed decisions aligned with their preferences. Moving ahead, population-level data collection  
118 throughout the entire breast care continuum is imperative to pinpoint interventions at individual,  
119 neighborhood, and healthcare facility levels that can help address existing disparities gaps across the  
120 entire screening and diagnostic episode of care. With the advent of emerging technologies like AI, it is  
121 crucial to gather real-time, real-world data to assess clinical effectiveness and performance across diverse  
122 populations. Until that is fully realized, we must continue to do our best with the current resources,  
123 knowledge, and recommendations to ensure that enhancements in cancer outcomes benefit all individuals  
124 equitably.

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