Ensuring Clarity and Understandability of the FDA’s Breast Density Notifications

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Journalist Katie Couric recently revealed that she had been diagnosed and treated for breast cancer. She urged women who have dense breasts, like herself, to consider obtaining supplemental screening (eg, ultrasound, magnetic resonance imaging), given that dense breast tissue, defined as having proportionally more fibroglandular than fatty tissue, can mask cancers on mammography and slightly increase the risk of developing breast cancer. Indeed, for over a decade, advocates whose own late-stage breast cancers were missed on mammography have been calling for notifications about personal breast density to accompany mammographic results, with the desired outcomes of informing and educating women about the risks of breast density and encouraging them to consult their doctors about personal risk and the potential benefits (and harms) of undergoing supplemental screening.

Since 2019, the US Food and Drug Administration (FDA) has been preparing a nationwide breast density notification after legislation requiring breast density notification had been enacted in 38 US states and the District of Columbia. However, the value of supplemental screening is still being debated; advocates argue that it can save lives due to early detection, while the US Preventive Services Task Force declared that the evidence to support its use is insufficient. Further, research detailed below has shown that women’s understanding about breast density from states’ notifications varies considerably based on race, ethnicity, education, and literacy levels. Therefore, utmost care must be taken when developing future notices to ensure equity and not further worsen disparities in breast cancer outcomes.

FDA Commissioner Robert Califf recently wrote that one of the agency’s top priorities is reducing health inequities by “including improved efforts to deliver reliable information to diverse audiences.” He indicated that the FDA aims to benefit from “high-quality evidence in a transparent environment while working together with the US biomedical ecosystem.” Evidence suggests that without careful preparation and testing, breast density notifications may not be clear or understandable to all women and that they may not lead to the desired outcomes.

Based on a substantial body of evidence describing thousands of women’s responses and reactions to states’ breast density notifications, it is known that women understand and react to state notifications in a variety of ways. Indeed, some women misunderstand the meaning of breast density and its effect on cancer detection. Many in the medical, research, and advocacy communities provided comments on the proposed FDA language in 2019, identifying several opportunities to improve the quality of communication. However, the extent to which feedback has been used to inform the final notification has not been made public.

Based on our own research, the FDA’s proposed notifications are not likely to be understandable to all women in the general population, as most proposed notifications from states and the FDA exceed the general literacy level of women in the population and the recommended eighth-grade reading level (FDA’s own best practice requirement). It is not clear that the FDA has tested its language to ensure understandability, verified that the language will lead to desired outcomes, or prepared notifications in languages other than English. Our research also showed that knowledge about breast density is unevenly distributed, being greatest among White, more educated women with higher incomes. After being informed of breast density, Black women and women with less literacy or lower incomes were more likely to report anxiety and confusion. Qualitative research has suggested that the novelty and complexity of breast density information delivered in a letter format actually led to confusion for some women. For example, Spanish-speaking women expressed uncertainty about the impact of breast density on their health, with a minority of respondents interpreting the notifications as telling them that they had breast cancer or a precursor to breast cancer. We also found that less than half of the women studied realized that breast density also increases their risk of breast cancer. In addition, despite the notifications’ goal of encouraging women to discuss personal risk and the need for supplemental screening with their physicians, few women report having such conversations. Finally, our research confirmed that the primary care system is ill-equipped for such conversations, as few health care clinicians reported having sufficient knowledge about breast density to confidently advise their patients about supplemental screening.
So, what should the FDA do? First, the FDA must learn from the published literature detailing women’s experience with states’ density notification laws, which has revealed a wide range of responses. Careful crafting of the notification language is key to ensuring desired outcomes and minimizing any unintended outcomes. Second, the FDA should test the notification language to ensure readability and understandability by patients of all backgrounds and cultures. The FDA did rigorously evaluate the language used to notify the public about the harms of cigarette smoking, in campaigns to reduce youth tobacco use, and to promote the use of generic drugs. Similarly, the FDA must invest resources to ensure that women’s reactions to the breast density notification language will lead to the intended outcomes of increased awareness and knowledge regarding breast density and informative conversations with health care clinicians about personal risk and the appropriateness of supplemental screening.

The enactment of this federal breast density legislation is no small undertaking, but efforts to improve the notifications’ clarity and understandability must reach women from all backgrounds and cultures, and especially those with limited literacy or limited English proficiency. Only with such efforts will the implementation maximize equitable outcomes for women from all races and ethnicities, cultures, literacy levels, educational levels, and socioeconomic backgrounds.