

Viewpoint: FDA needs to ensure that information on dense breast notifications are clear and understandable to all

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You are among the women who dutifully gets an annual mammogram. Year after year, the results are "normal." But after one mammogram you

are shocked to feel a breast lump, which turns out to be cancer. The tumor was hidden behind dense breast tissue so the radiologist couldn't see it and you wish you had known you were among the nearly 50 percent of women with dense breasts to whom this might happen.

It was this experience that motivated activists to lobby for the breast density notifications that now accompany mammogram results and inform women about the risks of breast density in the 38 U.S. states and the District of Columbia where they are required. The U.S. Food and Drug Administration (FDA) is now preparing language for a nationwide density notification with the goal of informing women and encouraging them to consult their doctors about their personal risk and the [potential benefits](#) (and harms) of undergoing supplemental screening.

In a Viewpoint in this week's *JAMA*, a researcher from Boston University Chobanian & Avedisian School of Medicine urges the FDA to communicate that warning in language all women can understand to ensure that outcomes are equitable.

"When the FDA crafts this public health message, it needs to be extremely cautious to ensure that all women, and especially women of color or those with low health literacy, understand the message and that the message leads to desired outcomes of appropriate supplemental screening and not to unintended outcomes such as avoidance of future mammograms or receipt of unnecessary additional screening," says corresponding author Nancy Kressin, Ph.D., professor of medicine.

Kressin's research revealed that some states' and the FDA's proposed notifications exceeded the general literacy level of women as well as the recommended 8th grade reading level (FDA's own best practice requirement). They found that knowledge about breast density is not evenly distributed; it is greater among white, more educated women with higher incomes.

Some women, especially Latinas, do not always understand the message of the notifications. Less than half of the women they studied understand that breast density also increases the risk of breast cancer.

"After being informed of breast density, Black women and women with less literacy or lower incomes are more likely to report anxiety and confusion. Despite the notifications' goal of encouraging women to discuss personal risk and the need for supplemental screening with their doctors, few women report such conversations," says Kressin.

Kressin recommends that the FDA learn from the more than fifty studies detailing women's experience with states' [breast density](#) notifications. Additionally, she wants the FDA to use the numerous available tools to test the language of health notifications.

"New density notification language must be rigorously evaluated, like the FDA did for [their cigarette warnings, campaigns to reduce youth tobacco use, and promotional materials on the value of generic drugs](#), to ensure that the wording is clear and understandable to all women, and reactions are those that were intended," she adds.

Kressin acknowledged this is no small undertaking and that extensive field testing and re-testing will be needed, requiring significant resources. "Yet, evidence indicates that health communications designed to be inclusive of populations with limited literacy or limited English proficiency are preferred by individuals of all literacy levels, so the benefits of doing this work are significant for all women. We believe such efforts can ensure equitable outcomes across strata of race/ethnicity, education and socioeconomic status."

More information: Nancy R. Kressin et al, Ensuring Clarity and Understandability of the FDA's Breast Density Notifications, *JAMA* (2022). [DOI: 10.1001/jama.2022.22753](https://doi.org/10.1001/jama.2022.22753)

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