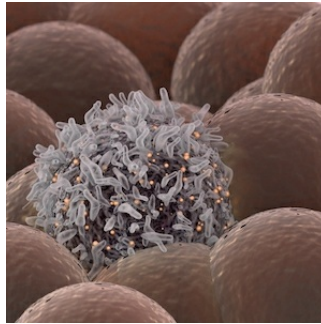


U.S. dense breast notification laws: awareness & early cancer detection after mammo



Breast density is recognised as a risk factor for breast cancer, and dense breast tissue can decrease **mammographic** sensitivity, leading to **diagnostic delay**. This is of particular concern to women in their **40s** and **50s**, for whom the prevalence of dense breasts ranges from **38% to 57%**. Concerns about the low sensitivity of screening mammography among women with dense breast tissue have led to an increased interest in **informing women of the limits of mammography and incorporating additional modalities such as ultrasound and magnetic resonance imaging (MRI) into the screening algorithm**. In a study published in the [American Journal of Public Health](#), researchers set out to evaluate the association of state dense breast notification (DBN) laws with use of supplemental tests and cancer diagnosis after screening mammography.

Although the use of **breast ultrasound** or MRI after **screening mammography** improves **cancer detection** among average-risk women with **dense breasts**, it results in higher **false-positive** screenings and has not been demonstrated to improve survival. Adding to these concerns, prior cost-effectiveness evaluations have indicated that supplemental ultrasound screening is not cost-effective under a wide range of assumptions and screening strategies.

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Data Source and Study Population

Researchers used administrative claims data obtained through a secure portal from the [Blue Cross Blue Shield](#) (BCBS) Alliance for Health Research, with members in all 50 US states, to identify women aged 40 to 59 years who underwent screening mammography from **January 1, 2014, through December 31, 2015**. Screening ultrasound and MRI were covered benefits during the period studied but were still subject to copayments, coinsurance and deductibles.

Women were required to have continuous enrolment with primary medical coverage in a BCBS plan in the 9 months before screening mammography, the full calendar year of screening, and in the 9 months after screening. Screening mammography was identified from claims data by adapting a validated algorithm. Specifically, the study omitted women who received a diagnostic mammogram or breast-related diagnosis or procedure in the 9 months before the index mammogram. Detailed inclusion criteria are available as a supplement to the [online version](#) of this article.

In this study assessing the impact of state DBN laws, researchers found significant increases in the use of supplemental breast ultrasound and the cancer detection rate after screening mammography within 6 to 18 months of states' implementation of DBN+SS laws. Although statistically significant, the 10.5 per 1000 mammograms increase in the use of supplemental ultrasound in states with DBN+SS laws suggests a relatively small incremental uptake rate among women with dense breasts. Prior work has reported that approximately 38% to 57% of women aged 40 to 59 years have heterogeneously dense or extremely dense breasts, suggesting that for every 1000 women receiving a screening mammogram, at least 380 were required to be notified about the increased risks of dense breasts and the potential benefits of supplemental screening. Notably, this low uptake is for an insured population with plans that cover breast ultrasounds and is among women already receiving a screening mammogram, suggesting that these women perceive some benefits to breast cancer screening.

Despite the relatively low uptake in supplemental ultrasound, researchers observed a significant increase in cancer detection (0.37 per 1000 mammograms) in states with DBN+SS laws. This finding suggests that the type of information delivered in the notification has an impact on utilisation and potentially on clinical outcomes. Women in states with DBN+SS laws may be more likely to approach their provider regarding supplemental testing or may perceive more benefits of supplemental testing. In addition, providers in these states may be more likely than other providers to recommend additional testing. Overall, the study findings suggest that if one of the goals of DBN laws is to suggest that women discuss supplemental imaging with their provider and thereby increase utilisation among women at the highest risk, the **specific information delivered is important**.

Overall, the study found increases in ultrasound rates similar to those identified by Horný et al. It is reassuring that although the studies are not directly comparable because of the differences in population age, states studied, follow-up time, and methodological approach, they also found relatively small increases in ultrasound use. This study further examined changes in biopsy and breast cancer detection rates and differences in receipt of supplemental testing and other outcomes by age.

In addition to the unclear language of many notification laws, there are several reasons why mandated DBN may lead to relatively low uptake of services. Clinical uncertainty surrounds the utility of supplemental ultrasound and MRI screening; therefore, clinicians may be less likely to recommend them to women. Moreover, DBN laws may be more difficult to enforce than other policies. For example, since 1986 federal law has

required the distribution of Centers for Disease Control and Prevention vaccine information sheets noting the risks and benefits to vaccine recipients (or their parents). Yet, 1 study indicated that in 1998 only about 69% of paediatricians self-reported that they distributed these sheets. Others have commented on whether and how communication mandates interfere with patient-provider relations. For example, there has been significant controversy related to state laws that limit specific communication between providers and patients related to gun ownership and other laws that require certain information be provided during counselling to women before abortion.

Although the researchers found limited clinical impact except in situations in which the DBN law specifically mentions the benefit of supplemental screening, these laws may empower women to make more informed decisions about whether to pursue supplemental testing. The study mentions they were not able to directly determine whether DBN led to more women inquiring about the increased risk of breast cancer among women with dense breasts, but in a survey of screening-age women, residents of a state with DBN were more likely to have discussed their breast density with a health care provider than were residents of other states (67% vs 43%). However, about 50% of primary care physicians in California were not aware of the California law 10 months after implementation, and only 5% felt "completely comfortable" answering questions about breast density.

In some cases, perhaps because of past mammogram findings, providers may order an ultrasound and mammogram for the same day; if this practice is affected by DBN laws, it will be included in the study's future estimates. Considering only the last 6 months of data for their sample, the proportion of ultrasounds occurring on the same day as screening mammograms was 15.4%, 14.3%, and 13.8% in no DBN, generic DBN, and DBN+SS states, respectively. This result suggests that although this occurrence is not rare, **the majority of supplemental screening ultrasounds are not conducted on the same day as mammography.**

In part, DBN laws were passed in response to observational cohort studies that indicated that supplemental screening led to improved cancer detection among high-risk women, albeit alongside high recall and false-positive rates. A recent US Preventive Services Task Force review summarised extant studies, noting that in the best-rated studies, supplemental ultrasound resulted in additional cancer detection of 4.4 per 1000, with a recall rate of 14%.

In the context of the low incremental uptake of supplemental ultrasound found in this study, the 0.37 increase in cancer detection per 1000 mammograms found is relatively large, although the 95% confidence interval of 0.05, 0.69 includes relatively small increases. In a hypothetical population of 1 million women aged 40 to 59 years, the researchers state they would expect an additional 370 cancers detected in the 6 to 18 months after implementation of DBN+SS legislation, although the lower bound of the confidence interval suggests this could be as low as 50 cancers per 1 million women. The point estimate indicating a high rate of cancer identification found relative to ultrasound uptake may be due to providers recommending ultrasounds only for the highest risk women. For example, when counselling patients, providers may consider available information on breast cancer risk, including patient age, family history of breast cancer, and the woman's reproductive history. Finally, it is important to note that even though some DBN laws were associated with the diagnosis of additional breast cancer, the authors state this study **does not examine whether this leads to a decrease in cancer morbidity and mortality.**

In addition to possible benefits, consideration of potential adverse consequences of DBN is warranted. Health system costs may be substantial, although these results indicate that these may be less than originally hypothesised because the increase in ultrasound and biopsy was less than anticipated. However, **women who receive DBN may experience increased anxiety, regardless of whether they ultimately receive supplemental imaging.** In 1 convenience sample of women with dense breasts, **43% reported that knowledge of their breast density increased their anxiety about getting breast cancer.**

This study is not without limitations, state the researchers. The BCBS administrative claims data do not contain clinical information on individual breast density or cancer staging or enough information to distinguish screening from diagnostic tests. Because of the relatively short follow-up period (maximum 18 months after implementation), they could not evaluate breast cancer morbidity or mortality or determine whether the effect of DBN laws increased over time. The study limited the analyses to individuals who remained continuously enrolled in an insurance plan for 2 years or more. To the extent that the effect of DBN laws differs among individuals who switch plans, this study will not capture these effects. They used claims-based algorithms that were originally validated in older women aged 65 years or older to identify receipt of screening mammography as well as to identify invasive screening-detected cancer in a population of women aged 40 to 59 years. Moreover, the study period resulted in analysis of only 9 states with mandatory DBN laws.

This study provides useful information to state policymakers considering DBN legislation with the goal of increasing awareness and early breast cancer detection. Researchers found that laws that specifically mention the potential benefit of supplemental imaging are associated with small increases in use of breast ultrasound after screening mammography as well as increases in breast cancer detection. Some states may consider amending existing laws to include this language.

Source: [American Journal of Public Health](#).

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