ORIGINAL RESEARCH

Dense Breast Notification Laws, Education, and Women's Awareness and Knowledge of Breast Density: a Nationally Representative Survey

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BACKGROUND: To date, 38 states have enacted dense breast notification (DBN) laws mandating that mammogram reports include language informing women of risks related to dense breast tissue.

OBJECTIVE: Nationally representative survey to assess the association between residing in a state with a DBN law and women's awareness and knowledge about breast density, and breast cancer anxiety.

DESIGN: Internet survey conducted in 2018 with participants in KnowledgePanel®, an online research panel.

PARTICIPANTS: English-speaking US women ages 40–59 years without a personal history of breast cancer who had received at least one screening mammogram ($N=1928$; survey completion rate 68.2%).

MAIN MEASURES: (1) Reported history of increased breast density, (2) knowledge of the increased risk of breast cancer with dense breasts, (3) knowledge of the masking effect of dense breasts on mammography, and (4) breast cancer anxiety.

KEY RESULTS: Women residing in DBN states were more likely to report increased breast density (43.6%) compared with women residing in non-DBN states (32.7%, $p<0.01$, adjusted odds ratio, 1.70, 95% CI, 1.34–2.17). Interaction effect between DBN states and education status showed that the impact of DBN on women's reporting of dense breasts was significant for women with greater than high school education, but not among women with a high school education or less (p value = 0.01 for interaction). Only 23.0% of women overall knew that increased breast density was associated with a higher risk of breast cancer, and 68.0% of women understood that dense breasts decreased the sensitivity of mammography. There were no significant differences between women in DBN states and non-DBN states for these outcomes, or for breast cancer-related anxiety.

CONCLUSIONS: State DBN laws were not associated with increased understanding of the clinical implications of breast density. DBN laws were associated with a higher likelihood of women reporting increased breast density, though not among women with lower education.

KEY WORDS: breast cancer screening; legislation; education; awareness.

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INTRODUCTION

In the USA, 43% of women ages 40 to 74 have dense breasts, or an increased amount of non-fatty breast tissue compared with fatty tissue on a mammogram [1]. While increased breast density is normal and common, especially among younger women, it is associated with a 1.6 to 2.0 fold increased risk of breast cancer and also has a masking effect impairing the sensitivity of mammography to detect breast cancer [2, 3].

In response to a largely grass-roots effort, 38 states to date have enacted laws mandating language in mammogram reports to inform women of risks related to dense breast tissue [4]. While content of the required language varies across states, these laws generally inform women of the masking effect of dense breast tissue and increased risk of breast cancer, and encourage women to discuss their breast density with their provider. While a subset of states provide notification language to all women, the majority only notify those with increased breast density.

Dense breast notification laws have been controversial. While stakeholders agree increased knowledge and awareness around breast density is an important goal, some have expressed concern these laws do not take into consideration other risk factors for breast cancer, and may result in increased downstream testing and anxiety despite unclear benefits on breast cancer mortality [5–7]. There are also concerns about the understandability of the notification language; prior work has shown that most notifications are written above the recommended 7th to 8th grade reading level [8, 9]. Hence, providing breast density information in mammography reports may not ensure that patients with low literacy or education

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understand the clinical implications of the notifications. This is especially concerning given that women at lower educational levels are at increased risk of breast cancer mortality [10, 11].

In March 2019, the FDA announced a proposed rule that extends dense breast notification requirements to all mammogram facilities [12]. Given the scope of this rule and the potential for important clinical consequences, it is critical to understand possible benefits of the notifications, including greater awareness and knowledge about breast density, and risks, such as anxiety. Although several studies have examined state legislation mandating breast density reporting, they have limitations in their scope and methods [9, 13–17]. Early studies were of only one state or not representative [13, 14], but did find women in DBN states were more likely to be aware of their breast density status. For instance, a 2012 survey compared one state with a breast density law (Connecticut) to residents of states without a law, and found that women living in Connecticut were more likely to have heard of breast density and be aware of its masking effect, but were not more likely to know of its increased risk of breast cancer [13]. None of these studies examined differential effects of DBN laws by education.

To address these important knowledge gaps, we conducted a nationally representative survey to determine the association between state dense breast notification laws on women's awareness of increased breast density, knowledge of its association with breast cancer and the sensitivity of mammography, and anxiety around breast cancer screening. We hypothesized that women in dense breast notification states would be more likely to report a history of increased breast density, have more knowledge about the clinical implications of mammography screening for women with dense breasts, and would be more likely to report anxiety about breast cancer screening. We also assessed whether the association between residence in a DBN state and women's awareness of breast density differed by educational level, hypothesizing that lower educational status would mitigate the potential relationship between DBN laws and awareness.

METHODS

Data were obtained from an Internet-based survey on women's breast cancer screening practices conducted between March and April 2018 on a nationally representative sample of English-speaking US women aged 40 to 59 years. Relevant survey questions are available as a [Supplemental Appendix](#). We constructed and tested the survey instrument through 12 cognitive interviews [18] and pretesting, and then administered via Ipsos (formerly GfK) KnowledgePanel. The online research panel consists of approximately 55,000 US households selected using high-quality address-based sampling methods similar to those used by US government surveys [19, 20]. Panelists that do not have Internet access are provided with tablets or computers and dial-up Internet access for survey participation, and only sampled individuals are able

to participate in the panel. The probability-based sampling used to construct the panel and its representativeness of the US population have been validated [21]. Panelists are incentivized to complete weekly surveys through access to Internet and hardware if needed and raffles for cash and other prizes.

We sent a series of screener questions to women ages 40–59 to identify women without a personal history of breast cancer who had ever had a mammogram. A history of increased breast density was assessed with the question, “Have you ever been informed by a health care provider and/or mammogram letter that you have dense breasts?” We considered a woman to have heard of dense breasts if either she reported having increased breast density, or answered “Yes” to the question, “Before this survey, have you heard about breast density?” Knowledge of the clinical impact of breast density was assessed with the questions, “If a woman has dense breasts, how does this affect the chance of her getting breast cancer at some point in her life?” and, “If a woman has dense breasts, how does this affect the ability of a mammogram to find breast cancer?” We also asked women if they thought of dense breasts as “normal,” “a disease,” or, “an abnormal finding on a mammogram.” We adapted the anxiety subscale of the validated Consequences of Screening in Breast Cancer (COS-BC) questionnaire to assess anxiety about breast cancer [22]. Scores were dichotomized with women reporting scores > 0 considered to have breast cancer anxiety. Demographic information collected on all panel members was provided by KnowledgePanel.

All reported analyses were weighted to match the sample to the US population based on Current Population Survey data on age, race/ethnicity, education, Census region, household income, and to adjust for panel recruitment, attrition, oversampling, and survey nonresponse. We used frequencies and χ^2 tests to describe the sample based on participant characteristics. We then tested whether dense breast awareness and knowledge differed among women residing in DBN states compared with non-DBN states. We used multivariable logistic regression models with robust estimation of standard errors (to account for clustering of patients within states) to examine if residence in a DBN state was associated with awareness and knowledge of breast density, while controlling for age, race/ethnicity, education, marital status, health insurance, and facility type for most recent mammogram. Region was excluded from the models due to association between a state's region and having a DBN law (i.e., states in the Northeast were also more likely to have DBN laws) and household income was excluded as it was correlated with other socioeconomic variables in the model and it did not significantly improve performance of the model.

To test our hypothesis that DBN effects might differ by education, we examined an interaction effect between the DBN state indicator and the four-level education variable, in addition to the main effects of DBN state and education level. Based on coefficient estimates on these main effects and interaction terms, we then produced predicted probabilities

for reporting a history of increased breast density for each education level and DBN state status, while evaluating all other respondent characteristics at the sample mean value [23]. We compared the predicted probabilities of reporting dense breasts for women in DBN states versus non-DBN states within each level of education. We used the Bonferroni correction to account for multiple comparisons.

We conducted a sensitivity analysis examining results for women who received a mammogram in the last 18 months (vs. ever in a lifetime as in the primary analysis). All analyses used SPSS version 24.0 (Armonk, NY: IBM Corp). The Yale University Institutional Review Board approved this study.

RESULTS

The final sample included 1928 women ages 40–59 without a personal history of breast cancer and who had at least one mammogram. Of the 10,112 women receiving the survey invitation, 6898 responded, yielding a study completion rate of 68.2%. Qualifying respondents ($n = 2539$) completed the 10-min survey. We excluded women with potential data quality concerns ($> 20\%$ missing data or spent < 4 min (5th percentile) completing the survey); these excluded women ($n = 70$) were more likely to be Hispanic and have less education and income. Women who never had a screening mammogram or resided in a state where the impact of the law could not be assessed (e.g., notification suggested but not required, law implemented within 18 months, law expired, supplemental screening covered but no notification law) were also excluded from the final sample (Supplemental Figure). Women residing in DBN states were more likely to be Hispanic and have private insurance (Table 1).

Awareness

In weighted analyses, 41.3% of women reported a history of increased breast density. A significantly greater proportion of women residing in states with DBN laws reported having increased breast density as compared with women residing in states with no law (43.6% vs. 32.7%, $p < 0.01$) (Table 1). In multivariable regression, women residing in a DBN state were more likely to report increased breast density (OR 1.70, 95% CI 1.34–2.17), as were older women, those with a high school or higher education, and with private or public insurance (versus no insurance). Black and Hispanic women were less likely than white women to report having increased breast density (Table 2). A sensitivity analysis examining results for women who received a mammogram in the last 18 months (vs. ever in a lifetime as data is currently reported) showed similar results.

The association between residence in a DBN state and reporting a history of DB differed by women's educational level (p value = 0.01 for interaction between education and residence in a DBN state). Predicted probabilities of reporting DB among women in DBN states were higher than those in

Table 1 Relationship Between Residence in State with Dense Breast Notification Law and Demographic Characteristics, Awareness of Breast Density, and Breast Density Knowledge Among All Women

	Non-DBN state <i>N</i> = 488	DBN state <i>N</i> = 1440	<i>p</i>
Demographics			
Age			0.08
40 to 49	38.7%	43.3%	
50 to 59	61.3%	56.7%	
Race/ethnicity			0.01
White	67.9%	61.1%	
Black	13.4%	12.7%	
Other	4.2%	7.8%	
2+ races	1.5%	2.4%	
Hispanic	13.0%	16.0%	
Education			0.79
< High school	7.3%	8.6%	
High school	25.3%	24.8%	
Some college	33.0%	31.6%	
≥ Bachelor's degree	34.5%	35.0%	
Household income			0.11
< \$25,000	13.2%	11.6%	
\$25,000 to \$49,999	18.7%	15.7%	
\$50,000 to \$74,000	17.1%	16.8%	
\$75,000 to \$99,999	16.0%	14.3%	
≥ \$100,000	34.7%	41.5%	
Marital status			0.28
Never married	10.1%	10.2%	
Married	64.8%	68.2%	
Other*	25.1%	21.6%	
Health insurance			< 0.01
No insurance	8.6%	4.2%	
Private/employer	73.2%	79.4%	
Public	18.0%	15.8%	
Recent mammogram facility type			0.29
Hospital	35.2%	37.0%	
Radiology center	53.4%	49.2%	
Other^	11.2%	13.0%	
Awareness of breast density			
History of dense breasts			< 0.01
No	67.3%	56.4%	
Yes	32.7%	43.6%	
Heard of breast density			0.03
No	27.9%	23.1%	
Yes	72.1%	76.9%	
Knowledge of clinical implications			
Impact of DB on breast cancer risk			0.43
Increase risk	22.4%	23.2%	
No impact	21.5%	25.1%	
Decrease risk	1.3%	1.1%	
Do not know	52.7%	49.6%	
Impact of DB on mammography detecting cancer			0.56
Make it more difficult	65.5%	68.7%	
No impact	2.2%	2.6%	
Make it easier	1.5%	1.9%	
Do not know	29.5%	26.6%	
Perception of dense breasts			0.27
Normal	69.0%	73.1%	
Abnormal mammogram finding	26.8%	24.2%	
A disease	0.7%	1.2%	

p values in italics < 0.05

N represent unweighted survey participants, percentages are weighted

*Includes widowed, divorced, or separated

^Includes specialty center and mobile van

non-DBN states for women with a greater than high school education (some college 33.8% vs. 20.7%, $p = 0.02$; Bachelor's or higher 43.0% vs. 28.9%, $p = 0.03$). However, among women with a high school education or less, there was no

Table 2 Characteristics Associated with Reporting a History of Increased Breast Density

	Adjusted OR	95% CI	
Residence in state with DBN law			
No	Ref		
Yes	1.70	1.34	2.17
Age categories			
40 to 49	Ref		
50 to 59	1.36	1.12	1.65
Race/ethnicity			
White	Ref		
Black	0.62	0.45	0.85
Other	0.80	0.56	1.15
2+ races	0.99	0.53	1.84
Hispanic	0.73	0.55	0.96
Education			
< High school	Ref		
≥ High school	3.20	2.05	5.00
Marital status			
Never married	Ref		
Married	0.98	0.69	1.39
Other*	0.72	0.49	1.05
Health insurance			
No insurance	Ref		
Private/employer	2.48	1.52	4.06
Public	2.29	1.34	3.91
Recent mammogram facility type			
Hospital	Ref		
Radiology center	1.16	0.94	1.42
Other^	1.32	0.97	1.81

Model uses robust estimation. All variables reported in this table were simultaneously included in the regression model

Values in italics indicate $p < 0.05$

*Includes widowed, divorced, or separated

^Includes specialty center and mobile van

significant difference in predicted probabilities of reporting dense breasts between DBN and non-DBN states (high school 30.9% vs. 20.3%, $p = 0.28$; less than high school 11.0% vs. 20.5%, $p = 0.99$) (Fig. 1).

Knowledge

Approximately 23.0% of all women and 25.6% of women with increased breast density knew of the association between breast density and increased risk of breast cancer, with no

significant difference between women residing in DBN states and those with no laws. As for the masking effect of dense breasts on mammography, 68.0% of all women and 84.3% of women with increased breast density correctly answered that dense breasts make it more difficult for mammography to detect cancer, again with no significant difference seen by residence in a DBN state (Table 1 for all women, [Supplemental Table](#) for women with increased breast density). In adjusted analysis, there was no relation between residence in a DBN state and either of these outcomes (data not shown). There was also no difference by residence in a DBN state in women's perception of increased breast density as normal, an abnormal finding on a mammogram, or a disease. Overall, 72.2% of women viewed dense breasts as a normal finding (Table 1).

Anxiety

Among all women, the proportion of women reporting breast cancer anxiety in DBN states versus states with no law was not different (44.6% vs. 44.2%; $p = 0.87$) (Table 3). A greater proportion of women with increased breast density reported breast cancer anxiety as compared with women without dense breasts (55.7% vs. 36.6%; $p < 0.01$) (Table 3). However, there was no significant difference in anxiety by residence in a DBN state versus non-DBN state among women with increased breast density (54.6% vs. 61.1%; $p = 0.12$) ([Supplemental Table](#)).

DISCUSSION

In a large nationally representative survey, we found that women living in states with dense breast notification laws were more likely to report having increased breast density. However, this increase in awareness of breast density status was not accompanied by an increase in knowledge of its clinical implications; women living in DBN states were no more likely to know that dense breasts were associated with an

Figure 1 Predicted probability of reporting a history of increased breast density by education level and residence in a state with a dense breast notification law, based on the marginal effects at the mean. p values compare the predicted probabilities of reporting increased breast density for women in DBN states to non-DBN states within each educational level.

Table 3 Report of Breast Cancer Anxiety by History of Increased Breast Density and Residence in a State with a Dense Breast Notification Law

	Any anxiety N = 949	No anxiety N = 1183	<i>p</i>
Total	44.5%	55.5%	
History of dense breasts			<i>< 0.01</i>
No	36.6%	63.4%	
Yes	55.7%	44.3%	
Residence in a state with DBN law			0.87
No	44.2%	55.8%	
Yes	44.6%	55.4%	

p values in italics *< 0.05*

N represent unweighted survey participants, percentages are weighted

increased risk of breast cancer or limited the ability of mammography to detect cancer.

We also found that the association between DBN laws and awareness of breast density status did not extend across all educational strata. The effect of DBN laws was seen among women with higher education but not women with a high school education or less. Previous work has shown that text of dense breast notifications are above women's average literacy level and have poor understandability [8], and women receiving notifications struggle to understand the meaning of breast density [9]. Our results, along with these previous studies, raise concern that women of low education may benefit less from DBN laws and policies are needed to ensure that existing breast cancer disparities are not widened.

Stakeholders have expressed concern that breast density notifications may cause harm by increasing women's anxiety around breast cancer [24]. Our study found that women with dense breasts were more likely to report breast cancer anxiety. Additionally, living in a state with a DBN law increased the proportion of women reporting dense breasts. This suggests that DBN laws may indirectly increase anxiety by increasing the proportion of women informed of their increased breast density. However, we found that residence in a DBN state was not associated with higher anxiety. This lack of effect is likely because of the small absolute increase in the number of women with anxiety attributable to increased awareness of dense breasts from living in a DBN state. Larger questions remain on whether the risk of anxiety associated with a dense breast finding is outweighed by benefits given current evidence is insufficient on the use of supplemental screening.

The results of this study should be taken in the context of previous studies examining the impact of dense breast notification laws, though direct comparison is limited due to differences in survey design and methods. Generally, our work is consistent with past studies that have found that DBN laws are associated with an increase in awareness of breast density [13, 14]. Comparison with a prior study also using KnowledgePanel suggests that over time more women have heard of breast density (76% in our 2018 study compared with 58% in a 2012 study) and are more knowledgeable of the masking effect of dense breasts on

mammography (68% in our 2018 study versus 49% in 2012) [13].

This study has several limitations. First, as with all survey research, it is subject to self-report and non-response biases. Several measures were taken to mitigate recall bias. Cognitive interviewing was used to ensure understandability of question wording and eliminated questions that cannot be reliably answered by self-report. We also used explanatory definitions and pictures (such as of a woman obtaining a mammogram) throughout the survey to clarify potentially confusing concepts. To limit the effects of non-response, all our analyses used post-stratification weights that adjusted for panel recruitment and attrition, as well as nonresponse to our survey. Second, because data are cross-sectional, we cannot establish causal effects. Third, women excluded due to data quality concerns (i.e., > 20% missing data or too brief a time spent on completing the survey) were more likely to be Hispanic and have less education and income than those included in analyses which may bias results. However, these characteristics were included in adjusted analyses.

In conclusion, we find that dense breast notification laws were associated with a higher likelihood of women knowing that they have increased breast density, but not with improved understanding of the risks associated with dense breasts. We also find that women with lower education may be less likely to benefit from DBN laws. A broad evidence base supports the use of culturally and educationally appropriate patient educational materials [25]. Improving readability and understandability of notification language, or other forms of educational efforts may help improve understanding of breast density for all women.

Ultimately, the clinical implications of a dense breast finding are complex and personalized and require a conversation between a woman and her provider. Providers can perform a comprehensive breast cancer risk assessment needed to inform use of supplemental screening and importantly help place breast cancer risk and screening within the larger context of a woman's overall health priorities and goals. Future efforts to help women understand their risks of increased breast density may best be directed toward informing this challenging conversation, such as additional research to clarify the benefits and harms of supplemental screening and tools to help providers engage and educate women.

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Compliance with Ethical Standards:

The Yale University Institutional Review Board approved this study.

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