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Women's Response to State Mandated Language in Dense Breast Notification

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Abstract

Many states require radiologists to notify women of dense breast status. Our aim was to elicit women's response to state mandated dense breast notification language. Of respondents, 82% report that current notification does not inform them of additional screening studies available, and 41% report notification does not inform them of next steps. Open-ended responses indicate three main areas of patient concern: decisional needs, decision quality, and decision support. We modified an existing decision support framework to capture additional themes specific to dense breast decisions. The developed framework can be used to revise and improve current breast density reporting methods.

Keywords

Mammography; Breast Density; Dense Breast Notification; Legislation; Shared Decision Making

Introduction:

Approximately 40–50% of women in the United States have dense breast tissue¹. Dense breast tissue decreases mammographic sensitivity and specificity for breast cancer detection and serves as an independent risk factor for developing breast cancer^{2–4}. Recently, state-level legislation has mandated that women are informed of their breast density. In 2015, at the time of this study, 24 states mandated Dense Breast Notification (DBN), 19 of which required use of specific state-mandated language⁵. Our aim was to elicit women's feedback to the Tennessee state mandated DBN language including their understanding of next steps.

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Materials and Methods:

The Vanderbilt University Medical Center institutional review board (IRB) approved (IRB# 151230) this study. Participants provided informed consent and were offered the opportunity to enter a drawing to win an iPad mini. Using the Vanderbilt University research recruitment tool, MyResearch, we identified patients with interest in research participation. We then used the Research Derivative, a database of clinical and administrative data derived from our medical center's clinical systems and restructured for research to select eligible patients. Inclusion criteria included encounter for screening mammography (ICD 9-CM V76.11 and V76.12) between January 1, 2014 and November 30, 2015, female sex, and alive at the time of the search.

Between December 1, 2015 and January 18, 2016, we emailed eligible women an invitation containing study information including risks and benefits. Women were assured of anonymity and confidentiality. The email invitation included a unique code to access and complete the web-based survey through the Research Electronic Data Capture (REDCap™) program⁶. An interdisciplinary team developed the survey items, and reviewed them for appropriateness of content, item comprehension, and readability (Flesch-Kincaid Grade Level 6.7). We elicited demographic information and provided participants with the state-mandated DBN language then queried their understanding of the state DBN language and asked an open-ended question that allowed for free text response.

Descriptive statistics including means, medians, and cross-tabulations were conducted to analyze patient demographics and quantitative item responses. For qualitative analysis, we created an a priori list of codes and organized the free-text responses to the open-ended question. Responses were imported into the computer software program Excel Statistical Package for the Social Sciences (SPSS). The constant comparison method was used to capture additional themes emerging in the data. Two members of the research team (KB, DS) reviewed the data independently, identified codes based on themes presented in the data, and reconciled until consensus was reached. The research team used the coded data to sort and summarize the quotes.

We compared our qualitative data to existing conceptual frameworks. Our results aligned well with the Ottawa Decision Support Framework (ODSF). The ODSF is an evidence based guide aimed to improve the development of interventions to prepare patients and physicians for shared decision making⁷. The ODSF is organized into 3 main constructs according to determinants of decision: Decisional Needs; Decision Quality; and Decision Support. We nested coded responses within the ODSF main constructs and sub-themes. Responses containing information pertinent to more than one sub-theme were nested within all applicable constructs and sub-themes. We modified the ODSF sub-themes to meet dense breast decision making needs.

Results:

Of the 18,656 patients in the MyResearch database, 1,924 met study eligibility criteria and were sent an email invitation. Thirty-three emails could not be delivered. Of the 1,891

receiving email invitations, 920 responded (48.6%); and 864 were complete for analysis. There were 199 free text responses to the open-ended question for the qualitative analysis. Demographic characteristics of respondents who answered the free text question were similar to those who did not and are seen in Table 1.

Quantitative survey results are shown in Table 2. Of 864 respondents, 792 (92%) reported that the state mandated DBN language was not confusing. However, only 501/864 (58%) of women reported that they knew next steps to take if they have dense breast tissue. Additionally, only 150/864 (17%) reported that they knew what additional screening options are available for patients with dense breast tissue. If insurance did not cover additional screening tests, 523/864 (61%) reported that they would pursue additional screening if recommended.

We extracted 440 individual codes from the 199 open-ended responses. We retained sub-themes in the ODSF for our coded participant responses. Retained sub-themes in the Decisional Needs construct included Knowledge & Expectations and Support & Resources. A single sub-theme, Actions, was retained within the Decision Quality construct. Retained sub-themes within the Decision Support construct included Guide in Deliberation & Communication and Counseling. As many of our patient responses indicated an emotional response to DBN, we further modified the Decisional Needs construct to contain a sub-theme for Emotional Responses. Our dense breast decision making framework, modified from the ODSF, can be seen in Figure 1.

The main constructs and subthemes are reported in Table 3.

Of the 440 codes, 194 (44%) corresponded to Decisional Needs, 52 (12%) corresponded to Decision Quality, and 194 (44%) corresponded to Decision Support. Three sample responses are below:

“In my case I wasn’t informed of the high risk of breast cancer for patients with dense breasts, otherwise I would have insisted on further screening.” Participant 192
(Decisional Needs)

“Not much use to know if nothing will be done about it; seems like a ploy to avoid liability.” Participant 133
(Decisional Quality)

“Cancer and in particular breast cancer can cause panic in a patient. This type of information should be discussed in person so that the patient can ask questions and fully understand the situation rather than a random letter to scare them.” Participant 3
(Decisional Support)

Discussion:

Our study demonstrates that despite a high proportion of women reporting that they understood the DBN language, fewer than half knew the next steps or options for screening among those who had dense breasts. Many women remain unaware of their breast density and its relationship to cancer detection and cancer risk^{8–10}. A high percentage of women have expressed interest in knowing their density and in understanding follow up options⁹.

Study limitations include the analysis of a small number of predominantly white, well-educated women receiving care at a single institution, the qualitative nature of the research, and the potential for non-response bias. These may contribute to limited generalizability of the study results.

Allowing for these limitations, this study is an important preliminary step in documenting patient perspectives on DBN language and patient needs for dense breast decision support. Future work should elicit information from a larger more geographically, racially, and socially diverse sample of women. Our dense breast decision support framework can be used as a guide to revise and improve current breast density reporting methods to better meet patient needs.

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Figure 1.
Dense Breast Decision Support Framework

Table 1.**Demographics**

	Participants not completing open-ended response (N=665)	Participants completing open-ended response (N=199)
Variable	n (%)	n (%)
Age		
<40	9 (1)	1 (0.5)
40–49	129 (19)	33 (17)
50–59	194 (29)	51 (26)
60–69	164 (25)	60 (30)
70	42 (6)	25 (13)
Missing Data	127 (19)	29 (15)
Race/Ethnicity		
White	610 (92)	185 (92)
Black/African American	33 (5)	9 (4)
Asian	8 (1)	4 (2)
Pacific Islander	1 (0.2)	0 (0)
American Indian	5 (0.8)	1 (0.5)
Hispanic/Latino	9 (1)	2 (1)
Education		
High School/GED or less	42 (6)	7 (4)
Some College	159 (24)	50 (25)
Bachelors degree	222 (33)	49 (25)
Graduate or professional	236 (35)	92 (46)
Missing Data	6 (0.9)	1 (0.5)
Income		
Less than \$24,999	24 (4)	9 (4)
\$25,000 to \$49,000	98 (15)	32 (16)
\$50,000 to \$74,999	128 (19)	36 (18)
\$75,000 to \$99,999	132 (20)	40 (20)
\$100,000 to \$199,000	175 (26)	61 (31)
\$200,000 or more	89 (13)	12 (6)
Missing Data	19 (3)	9 (4)
Employment		
Employed for wages	426 (64)	110 (55)
Self-employed	39 (6)	12 (6)
Out of work	11 (2)	5 (3)
A Homemaker	45 (7)	7 (4)
A Student	1 (0.2)	0 (0)
Retired	127 (19)	58 (29)

	Participants not completing open-ended response (N=665)	Participants completing open-ended response (N=199)
Variable	n (%)	n (%)
Unable to work	12 (2)	5 (3)
Missing Data	4 (0.6)	2 (1)

Table 2.

Quantitative Survey Data

QUESTION	“YES” n (% total [*])	“NO” n(% total [*])	Missing n(% total [*])
Is this statement regarding breast density confusing?	68(8)	792 (92)	4(0)
Do you think this statement adequately informs patients:			
that they have dense breast tissue?	822 (95)	38(5)	4(0)
that dense breast tissue can affect the interpretation of a mammogram?	825 (96)	35(4)	4(0)
that breast density affects their risk of developing breast cancer?	707 (82)	151(17)	6(1)
what they should do if they have dense breast tissue?	501 (58)	354(41)	9(1)
what additional screening options are available for patients with dense breast tissue?	150(17)	708 (82)	6(1)
If recommended, would you pursue additional screening tests if insurance did not pay for them?	523 (61)	329 (38)	12(1)

* total study participants = 864

Table 3.**Coding Counts**

Main Construct - n (% total codes)* Sub-theme - n (% of main construct)	Individual Code	n (% of sub-theme)
Decisional Needs - 194 (44)		
Knowledge & Expectations - 137 (70)		
	Definition of breast density	10(7)
	Cancer risk	25 (18)
	Severity of breast density	7(5)
	Next steps	29 (21)
	Causation of breast density	1 (0.7)
	Relationship to mammogram	65 (47)
Emotional Response - 21 (11)		
	Fear/Anxiety	17(81)
	Stress	0(0)
	Coping with emotions	1(5)
	Other emotions	3(14)
Support & Resources - 36 (19)		
	Insurance status	16 (44)
	Cost	13 (36)
	Scheduling additional tests	7(19)
Decision Quality - 52 (12)		
Actions - 52 (100)		
	Seek information	29 (56)
	Pursue additional testing	16(31)
	Uncertainty	7(19)
Decision Support - 194 (44)		
Guide in Deliberation & Communication – 149 (77)		
	Postal letter	29 (19)
	Electronic	13(9)
	Telephone	9(6)
	Reading level	10(7)
	Delivery style	57 (38)
	Adequate information	31(21)
Counseling – 45 (23)		

*
total codes = 440