

## Short communication

## Evaluation of existing patient educational materials and development of a brochure for women with dense breasts



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## ABSTRACT

**Objectives:** In this pilot study, we developed and assessed acceptability of a brochure for women with dense breasts.

**Material and methods:** We measured Flesch-Kincaid Readability of 22 existing breast density educational materials. We then developed a brochure and tested it in two populations of women: 44 safety net hospital patients and 13 Breast Cancer Surveillance Consortium stakeholders.

**Results:** Average grade score of existing materials was 10.0 (range: 5.5–12.7). Our brochure had a grade score of 5.9, and patients reported it was easy to understand.

**Conclusion:** Our plain language brochure could improve patient understanding following mandatory dense breast notification.

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## 1. Introduction

As of January 2020, 38 US states and the District of Columbia require that women receive written notification when dense tissue is found on a mammogram [1]. In March 2019, the Food And Drug Administration proposed a new federal rule requiring all mammography facilities in the United States to notify women about dense breast tissue [2]. Notification is meant to inform women that dense breast tissue is common (40–50% prevalence) [3], associated with breast cancer risk, reduces mammography sensitivity by obscuring tumor tissue, and other screening modalities such as ultrasound or MRI may be warranted [4,5]. However, notification letters are written above an 8th grade reading level [6,7], leaving many women anxious and confused about next steps [8].

One of the underlying assumptions of breast density notification laws is that if women know their density they will be better able to make informed decisions about utilizing other screening

modalities. However, while notification may increase awareness of breast density, it does not necessarily increase knowledge [9–11]. Further, the benefits of supplemental screening among women with dense breasts remain unclear [4,12]; and there are no guidelines to direct their clinical management [13]. To help navigate this uncertainty and weigh their personal risks and benefits, patients need accessible educational materials and there is some evidence to suggest existing materials are not sufficient [14]. Women do want to be informed if they have dense breasts [15], but need information beyond their notification letters to translate awareness into knowledge [8]. Our goal is to develop education tools that enhance patient understanding of breast density and clarify next steps. In this pilot study, we used qualitative and quantitative data to develop and assess acceptability of a brochure for women with dense breasts.

## 2. Material and methods

## 2.1. Overview

We evaluated the readability of existing breast density educational materials. Discussions with breast cancer patient advocates were used to identify information needs and preferences. Results of the first two activities and a literature review were used to develop

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a prototype brochure, which we presented in qualitative focus groups to assess acceptability. Data collection occurred between June and August 2019.

### 2.2. Educational material development

We conducted an educational inventory of existing materials that were identified beginning with an investigator generated list of known United States-based breast cancer (e.g. Susan G. Komen) or breast density advocacy (e.g. DenseBreast-info) organizations, or related professional organizations (e.g. American College of Radiology). We searched each organization’s website for available materials with additional sources identified via a Google search. To be eligible for readability assessment, materials had to be written in English and intended for patients or a lay audience—not clinicians. We also only included sources that reported a date last updated to ensure educational material was current. We assessed readability using Flesch-Kincaid Grade Level [16]. Text from each educational material was copied into a Microsoft Word document with headers and extraneous text (e.g. organization, address, etc.) removed. Flesch-Kincaid Grade Level which was obtained from the calculated readability statistics of each material’s text. Study data were collected and managed using REDCap (Research Electronic Data Capture) tools hosted at Boston University (CTSI UL1TR001430) [17].

We facilitated a discussion with 10 breast cancer patient advocates about their experiences with dense breast notification, their opinions and comprehension of two selected existing breast density educational materials, their top three priorities for breast density education, and their preferences for the form and formatting of newly developed educational material(s). We used those findings and the Health Literacy Universal Precautions Toolkit [18]

to develop a printed brochure for women undergoing breast cancer screening.

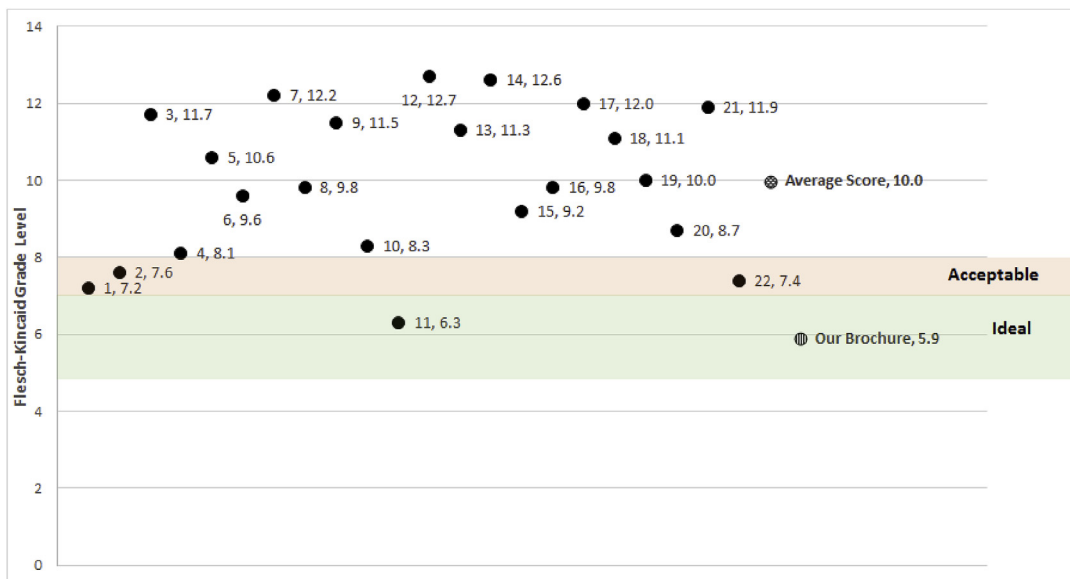
### 2.3. Focus group data collection

Data on brochure acceptability and satisfaction were collected from 44 English-speaking women ages 40–75 recruited from a safety-net hospital in Boston, MA. Participants evaluated the brochure as part of a 60-90-min focus group in which they also provided feedback on a computer-animated agent that provided breast density education [19]. Seven groups with 2–6 women each were held at either Boston Medical Center or a community site. Women were queried about what they liked about the brochure, how it could be improved, and where and when they would like to receive a brochure like ours. A survey administered at the end of the discussion assessed satisfaction using seven questions rated on a five point Likert scale from “strongly disagree” to “strongly agree”. Women received a \$40 debit card to compensate them for their time. This study was approved by the Boston Medical Center Institutional Review Board.

Subsequently, 13 Breast Cancer Surveillance Consortium (BCSC) patients and researcher stakeholders provided feedback in an on-line closed discussion about our brochure as well as a flyer developed by BCSC. This discussion was conducted as part of ongoing stakeholder engagement [20]. They were asked what they liked about the brochure and what they would want to change.

## 3. Results

We identified 22 publicly-available breast density educational materials with an average Flesch-Kincaid grade score of 10.0 (range 6.3–12.7; Fig. 1). Only one met readability standards for below 8th



Note: Labels represent the item number followed by the Flesch-Kincaid Grade Level. Shading represents the range of grade level scores considered acceptable (7–8) and ideal (5–7). Item numbers correspond to the following sources: 1=American Cancer Society/Cancer.org; 2=American College of Radiology; 3=Are You Dense; 4=Blue Cross Blue Shield; 5=Breast 360; 6=Breastcancer.org; 7=CDI; 8=Dense Breast Info; 9=Dr. Susan Love Research Foundation; 10=GE Healthcare; 11=Healthwise; 12=iCAD medical; 13=ICER – CEPAC; 14=Massachusetts Radiological Society; 15=Mayo Clinic; 16=Medical News Today; 17=Michigan Breast Density Notification; 18=National Cancer Institute; 19=Seattle Cancer Care Alliance; 20=Susan G, Komen; 21=Wake Radiology; 22=Web MD

**Fig. 1.** Flesch-Kincaid Grade Level of 22 Existing Breast Density Education Materials and our Prototype Brochure. Note: Labels represent the item number followed by the Flesch-Kincaid Grade Level. Shading represents the range of grade level scores considered acceptable (7–8) and ideal (5–7). Item numbers correspond to the following sources: 1 = American Cancer Society/Cancer.org; 2 = American College of Radiology; 3 = Are You Dense; 4 = Blue Cross Blue Shield; 5 = Breast 360; 6 = Breastcancer.org; 7 = CDI; 8 = Dense Breast Info; 9 = Dr. Susan Love Research Foundation; 10 = GE Healthcare; 11 = Healthwise; 12 = iCAD medical; 13 = ICER – CEPAC; 14 = Massachusetts Radiological Society; 15 = Mayo Clinic; 16 = Medical News Today; 17 = Michigan Breast Density Notification; 18 = National Cancer Institute; 19 = Seattle Cancer Care Alliance; 20 = Susan G, Komen; 21 = Wake Radiology; 22 = Web MD. (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

grade level. Patient advocates reported the two existing materials they reviewed did not convey a clear definition of breast density and used too much medical jargon, consistent with their Flesh-Kincaid scores of grades 8.7 and 9.8. Advocates' highest priorities included knowing what they could do about dense breasts, being able to ask questions, and getting information quickly. Advocates expressed interest in written materials and preferred a trifold brochure format to other options.

We designed a brochure that addressed their priorities using plain language, as reflected by a Flesh-Kincaid grade score of 5.9 (Fig. 1). The brochure was divided into sections with frequently asked questions including: 'What does it mean to have dense breasts?'; 'How do I know if I have dense breasts?'; 'Why is breast density important?'; 'Can my dense breasts be treated?'; 'What do I do if I have dense breasts?'; 'Topics to discuss with your doctor'; 'What are the levels of breast density?'; and 'Why was I informed about my breast density?'

In-person focus group participants had a mean age of 59 years (range 44–75), were predominantly Black (73%, n = 32), and 48% (n = 21) had ≤12 years of education (Table 1). BCSC stakeholders volunteered from a pool of 48 women who were predominantly White (70%), 49% had at least a bachelor's degree, with a mean age of 58 years (range 40–80) [20]. Patients reported that our brochure was easy to read (n = 41, 93.2%), understand (n = 42, 95.4%), and made them 'feel less worried about dense breasts' (n = 34, 77.3%) (Table 2). Qualitative responses centered around the brochure's ease of use and accessibility. One participant noted, "... I think that is the most important thing - that it is easy to read. It's not hard to understand. There's not a whole lot of medical mumbo jumbo in here and it is pretty much broken down into plain English." Another stated that it was "very concise and to the point, not overwhelming, not

negative and not scary." Several participants also identified areas for improvement including putting a mammogram image on the cover, changing the title from "Breast Density: What you should know about dense breasts" to a question like "What does it mean to have dense breasts?", and adding information about risk factors associated with dense breasts. They suggested that the brochure be placed in hospital or doctor's office waiting rooms, distributed by community organizations, and could be mailed with dense breast notification letters.

Online BCSC stakeholders reviewed the brochure favorably, with many reporting satisfaction with the design and interpretability of the content. For example, one participant reported, "I think this pamphlet is excellent! You can easily see the differences in the images, and the definition next to each is concise and easy to understand." Another participant reported that the "explanation of breast density is very easy to understand." A few disagreed, noting "I found the description of breast composition and density to be downright confusing." Others provided some suggestions for improvements including: "I thought this looked great. The one thought that came to my mind was that it might be good to try to emphasize further that dense breasts are 'normal'. In both groups, discussants appreciated the information on suggested topics to discuss with a health care provider.

#### 4. Discussion

This study assessed the readability of 22 existing breast density materials and tested the acceptability of a plain language breast density brochure among a diverse population of women. We found that existing publicly available breast density educational materials are likely too complex for the average reader and are not aligned with patient priorities. Participants were satisfied with the brochure and felt that it addressed an unmet need for dense breast educational materials. One concern sometimes raised about plain language materials is that they may oversimplify information and may not meet the needs of individuals with high levels of educational attainment [21]. However, previous work has shown that confusion about dense breasts exists across the education spectrum [10,15], and our results show that a plain language brochure appeals to women regardless of their background.

While our brochure received generally positive feedback, there were some suggestions for improvement including changing the title and cover art to make it more eye-catching, clarifying the intended audience, providing clarity in the language since for some the description of dense breasts was still confusing, and emphasizing how common and 'normal' dense breasts are. Additionally, while women generally liked the brochure and would recommend it to others, it had less impact on worry about dense breasts. We plan to revise the brochure to address these findings and suggestions and potentially test the impact of the updated brochure on patient outcomes including knowledge, worry, and unmet information needs in a larger population. The final brochure could then be disseminated in partnership with healthcare and community organizations and made available online.

#### 5. Conclusions

Our results demonstrate that a community engaged approach, combining readability metrics with qualitative and quantitative feedback, can support the development of an educational tool. Though sample size was small, multiple stakeholder groups were engaged and group discussions were diverse in socioeconomic status. This study is an important first step in providing effective patient education on breast density, a topic with which many women have limited knowledge [22,23]. Our brochure could be

**Table 1**  
Characteristics of in-person (N = 44) focus group participants.

Variable	In-Person
	<b>Mean (SD)</b>
Age	59.0 (8)
	<b>Frequency (%)</b>
Race/Ethnicity	
Asian	0 (0)
Black or African-American	32 (73)
Hispanic White	2 (5)
Non-Hispanic White	6 (14)
Other	1(2)
Declined	3(7)
Education	
< High School	6 (14)
High School/GED	15 (34)
Some college or 2-year degree	16 (36)
Bachelor's degree	3 (7)
More than bachelor's degree	4 (9)

Note: Percentages do not add to 100 because participants could select multiple responses.

**Table 2**  
In-Person Patient (N = 44) Evaluation of Brochure, % endorsement.

Statement	Endorsement <sup>a</sup> N(%)
The brochure was easy to understand	42(95.4)
I liked the look of the brochure	35(79.5)
The layout of the brochure was easy to follow	42(95.4)
I would recommend the brochure to a friend	40(90.9)
I liked the images in the brochure	38(86.4)
The brochure was easy to read	41(93.2)
The brochure made me feel less worried about dense breasts	34(77.3)

<sup>a</sup> N's and percentages reflect those that selected strongly agree or agree.

used in combination with other tools to support women receiving mandatory dense breast notification and improve patient understanding. Future work should focus on development of similar materials in other languages [24,25], and assess their impact on patient psychosocial and behavioral outcomes.

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## Ethical approval

This study was approved by the Boston Medical Center Institutional Review Board.

## Declaration of competing interest

The authors have no conflicts of interest to report.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.breast.2020.02.001>.

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