

Patient and Provider Perspectives on Mammographic Breast Density Notification Legislation

Elissa V. Klinger, SM, Celia P. Kaplan, DrPH, MA, Stella St. Hubert, BA,
Robyn L. Birdwell, MD, Jennifer S. Haas, MD, MSc

Background: Patient advocacy has fostered the implementation of mammographic breast density (MBD) notification legislation in many states. Little is known about the perspectives of women, primary care physicians (PCPs), and breast radiologists in response to this legislation. The objective of this research was to elicit qualitative information from these multiple stakeholders to understand varied perspectives on the subject of MBD notification and inform best practices around implementation. **Methods:** Content analysis of narrative data from focus groups with women (2 groups, total of 16 participants) and in-depth interviews with PCPs (n = 7) and

breast radiologists (n = 7). **Results:** Three major themes emerged from the data: 1) knowledge and general attitudes about legislation, 2) concerns about consequences, and 3) actions patients and clinicians should consider based on MBD information. For each of these themes, the views of women, PCPs, and radiologists often demonstrated different perspectives. **Conclusion:** This work supports the need for clear and concise tools for patients and providers to understand MBD in the context of a woman's overall breast cancer risk with guidance on next steps. **Key words:** mammography; breast density; legislation. (*MDM Policy & Practice* 2016;1:1-8)

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Address correspondence to Jennifer S. Haas, Division of General Medicine and Primary Care, Brigham and Women's Hospital, 1620 Tremont Street, Boston, MA 02120, USA; telephone (617) 525-6652; e-mail: jhaas@partners.org.

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Mammography remains the cornerstone of breast cancer screening,¹ despite continuing controversy about the age at which screening should start and at what interval.²⁻⁴ In this contested space of preventive screening for breast cancer, mammographic breast density (MBD) has increasingly become an area of inquiry and advocacy. MBD is independently associated with breast cancer risk^{5,6} and may also decrease the sensitivity of a mammogram.⁷⁻⁹ In response to these data, patient advocacy groups have worked to pass state and national legislation to better inform women about the meaning of MBD and the known limitations of mammography.^{10,11} The legislation promotes education of women with dense breast tissue to consider the harms and benefits of additional imaging studies such as breast ultrasound or magnetic resonance imaging (MRI) in an effort to “maximize” the chance that a cancer is not missed.

Despite increasing recognition that MBD may be important to breast cancer screening and risk, most women do not know their MBD or understand its significance and are unaware of their overall risk of breast cancer.¹² Furthermore, recent efforts focused on MBD notification are controversial among



clinicians; some believe the evidence informing screening recommendations for levels of MBD is incomplete and are concerned that the legislation may divert attention from the larger questions about risk and informed decision making regarding appropriate screening; others feel women should be informed about their MBD as a component of informed decision making.¹³

The Commonwealth of Massachusetts passed a breast density inform bill (Chapter 150) in July 2014¹⁴; to date 25 states, including Massachusetts, have passed similar legislation.¹⁵ The Massachusetts law went into effect on 1 January 2015, requiring health facilities that perform mammography to at a minimum notify patients in writing that 1) their mammogram shows dense breast tissue and the degree of density; 2) dense tissue is common and not abnormal but may confer increased risk of breast cancer; 3) dense tissue may reduce the ability of a mammogram to detect abnormalities and that additional imaging may be advisable; 4) the patient has the right to discuss the results with the interpreting radiologist and referring physician and should discuss additional screening in the context of their results; 5) the results have been sent to the referring physician and will become part of the medical record; and 6) where the patient can find additional information about breast density.¹⁴

Despite legislation to inform women of their MBD, questions remain about the impact that providing this information will have on women and their clinicians. To fill this research gap, we performed a qualitative study that included the perspectives of women, primary care physicians (PCPs), and breast radiologists. By eliciting information from multiple stakeholders, we hope to inform best practices and understand varied perspectives on the subject of MBD notification.

METHODS

We conducted focus groups with patients and semistructured interviews with PCPs and radiologists. Interview guides were developed by the investigators based on the literature pertaining to MBD and breast cancer risk communication. Informed consent was obtained from all participants; all received a \$50 gift card for time and effort. Focus group and interview content was audiotaped and transcribed. The research protocol was approved by the Partners HealthCare Institutional Review Board.

Focus Groups With Women

Women age 40 to 75 years who had undergone breast imaging within the previous 6 months at a Brigham and Women's Hospital (BWH)-affiliated screening facility and who received their primary care within the same health system were contacted with a recruitment letter. We excluded women who had a prior history of ductal carcinoma in situ or invasive breast cancer, or a known breast cancer susceptibility gene mutation. No additional information was collected about risk factors for breast cancer, other than patient self-reported risk perception for breast cancer. Two focus groups with women were divided into three sections (Online Appendix 1). Focus groups were facilitated by a qualitative researcher with experience in cancer screening decisions (CPK). The initial section assessed women's basic understanding of and experience with MBD notification and communication. Topics included how women received information about mammograms, how satisfied they were with the way the information was delivered, and understanding of MBD and its relationship to breast cancer screening and risk. The second component included a 15-minute presentation (Online Appendix 2), as we expected most women to be unfamiliar with MBD. This presentation was structured into four main components: 1) description of the four BI-RADS MBD classifications including mammographic images of different density categories; 2) implications of having dense and nondense breasts on effectiveness of screening mammography; 3) association of MBD with breast cancer risk; and 4) emerging information regarding screening that could be considered and advantages and disadvantages of each. A third component addressed delivery of MBD results in which we asked how women would feel about receiving personalized MBD information and how they would prefer to receive it.

Interviews With PCPs and Breast Radiologists

Parallel interview guides were developed for PCPs and breast radiologists. These consisted of prompts assessing understanding of MBD, legislation, and implications and preferred methods for delivering MBD information to women. A convenience sample of PCPs and breast radiologists was recruited from BWH-affiliated practices. Clinicians were invited by email to participate in 30-minute interviews at their convenience, in person or by phone.

Data Coding and Analysis

Focus groups and interviews were audio-recorded and professionally transcribed. Transcripts were independently coded by two reviewers. All authors met, reviewed, and discussed the coding results until consensus was reached. We used both deductive and inductive coding schemes in which transcripts were coded and analyzed for salient themes that were then compared across stakeholder groups. As codes and themes emerged, they were categorized into themes. Each of the three stakeholder groups was asked parallel questions in order to triangulate findings and compare similarities and differences across groups.

RESULTS

Patient Characteristics

We conducted two focus groups in February of 2015, within 2 months after MBD notification went into effect in Massachusetts. A total of 16 women participated in two 90-minute focus groups. The mean age was 57 years (range = 47–70 years). The sample was racially/ethnically diverse, with five women reporting black or mixed race. Ten women had completed some graduate education. Eleven women did not know their own MBD at the time of the focus group, 10 thought they were at average risk for developing breast cancer, and 3 thought they were at high risk.

Characteristics of PCPs and Radiologists

Interviews were conducted with seven PCPs and seven breast radiologists between 30 May and July 2015, approximately 7 months after legislation went into effect in Massachusetts. Of these physicians, 12 were women. PCPs practiced on average 23 years and radiologists 19 years.

Salient Themes

Three major themes emerged from the data: 1) knowledge and general attitudes about legislation, 2) concerns about consequences, and 3) actions patients and clinicians should consider based on MBD information (Table 1).

Knowledge and General Attitudes About MBD Legislation

Women in the focus groups reported little knowledge about the legislation. After explaining the law

in the focus groups women largely expressed positive attitudes about it overall, stressing that they had a right to the density information. Women noted that greater knowledge about MBD would enable them to be informed, especially for future decision making around breast health. Although women wanted to know the information, they also expressed some ambiguity about what they would do with the knowledge once they had it. One woman was concerned that information about density might give women “hope” that they could access additional imaging (i.e., MRI), when in reality insurance might not cover the testing. Another remarked, “What would I do with that information?”

Both PCPs and radiologists were knowledgeable about the law, but had mixed attitudes about its utility for patients and providers. Although PCPs had relatively positive attitudes about how legislation might affect patient engagement, PCPs also noted lack of evidence informing next steps for screening patients with dense breasts. Radiologists were concerned about the lack of evidence around increased imaging and how it could adversely affect patient outcomes and create additional work and worry for patients and providers. One radiologist noted the grassroots origin of the law; most expressed a neutral or negative view of the legislation, citing inadequate input from radiologists and other health care providers. The most extreme perspectives came from radiologists, with one implying that the legislation was “a hoax . . . perpetrated on the public for the wrong reason.”

Concerns About Consequences of the Legislation

Several concerns about MBD legislation were identified in the patient focus groups and clinician interviews, including potential for increasing patient anxiety, lack of evidence to support the legislation, concerns about cost and insurance, possibility of overtreatment, and provider malpractice liability.

Increase in patient anxiety. Importantly, while no patient explicitly recognized increased anxiety as a consequence of the law, patients conveyed uncertainty about actions to take after learning about density. One patient noted that MBD information without contextual information would “just flip me out.” Both PCPs and radiologists identified stress and anxiety much more frequently as possible negative consequences of informing patients.

Lack of evidence to support the legislation. Patients, PCPs, and radiologists were concerned about the lack of evidence informing decision

Table 1 Summary of Themes by Stakeholder

Patients	Primary Care Providers	Breast Radiologists
<p>1. <i>Knowledge and general attitudes about MBD legislation</i></p> <p>“It’s about time that women get paid attention to, and a law for our safety is put into place.”</p> <p>“The more you know, the better informed you are if things should change.”</p>	<p>“I think anything that helps patients understand their health condition is a good thing.”</p> <p>“... why did we mandate this and not other things?”</p> <p>“It’s difficult to have a law ... where the science hasn’t caught up. ... I’m kind of sorry that it had to be legislated.”</p>	<p>“I think it’s something that patients, sort of grassroots, sort of organized to have happen.”</p> <p>“It becomes a cumbersome thing ... that’s probably creating a lot more work and worry, and maybe over-utilization of imaging.”</p> <p>“... there is far too much government involvement in dictating how medicine should be practiced. I think that this legislation was put through without adequate input from radiologists, and other healthcare providers who deal with breast cancer.”</p>
<p>2. <i>Concerns about consequences of the legislation</i></p> <p>a. <i>Increase in patient anxiety</i></p>	<p>“My concerns are that it is going to cause harm by causing increased anxiety.”</p>	<p>“Another step—to create anxiety in women who are already anxious about the potential for developing breast cancer in their lifetime.”</p>
<p>b. <i>Lack of evidence to support the legislation</i></p> <p>“I don’t know what to do with that, you know. What do I do with that information?”</p>	<p>“I feel like it’s a bad thing to tell people—to tell women that they have a problem, when you do not have a good solution to offer them.”</p>	<p>“I feel like it’s tricky because it’s hard to tell people what to—we don’t really know what to do, so now people are kind of burdened with this knowledge and not really knowing what to do with it. So I’m not sure that it’s all that helpful.”</p>
<p>c. <i>Concerns about cost and insurance</i></p> <p>“I would think this would be useful as long as the person has access to all of these things. What I mean by that is, maybe insurance will not pay for an MRI—I would not want to give a person the hope and to have them see something like this and say, well, I want an MRI because, obviously, an MRI gives me the best, you know, results.”</p> <p>d. <i>Liability</i></p> <p>“... they’ve got to be extra careful, because we live in such a litigious society.”</p>	<p>“Patients [may be] requesting additional studies that may or may not be covered by their health insurance, and then that becomes a huge battle.”</p>	<p>“We’re seeing a lot of discussion with the tomosynthesis. They all tell us, you know, ‘No, my insurance company won’t cover it, so I’m not going to get it.’ If their insurance company covers it, we bill it, but if their insurance company doesn’t cover it, we’re not going to bill them.”</p>
<p>“... they’ve got to be extra careful, because we live in such a litigious society.”</p>	<p>“I think my patients don’t sue very much. I think at the end of the day, there’s a lot of trust.”</p> <p>“I would hate to see them [radiologists] hide behind this density as a way of reducing their malpractice risk, by</p>	<p>“I don’t think it has changed it in any way because I was already concerned.”</p> <p>“... it’s hard for me to be consistent in always saying something has scattered fibroglandular densities or it’s</p>

(continued)

Table 1. (continued)

Patients	Primary Care Providers	Breast Radiologists
<p>saying, ‘Well, that mammogram was uninterpretable . . . it should’ve been the PCP’s responsibility to really tell that patient.’ I feel, a lot of times, as a PCP, that risky situations are a hot potato, and the specialists are always trying to find a way to pass that hot potato to us instead of holding onto it themselves.”</p>	<p>heterogeneously dense. I think sometimes, I could go either way.”</p>	
<p>3. <i>Actions patients and clinicians should consider based on MBD information</i></p> <p>a. <i>Who should provide information?</i></p> <p>“I think I would just ask somebody that I trust—a doctor that I trust. It may not necessarily be my primary care doctor or my gyno—it would just be someone that I have a relationship with that I feel would make the best recommendation for me.”</p> <p>“My tendency is to listen to the person that’s an expert and then ask somebody that I trust.”</p> <p>“ . . . if you come and you get a test, and the person who is the breast doctor should be the one to be able to tell you what to recommend.”</p>	<p>3. <i>Actions patients and clinicians should consider based on MBD information</i></p> <p>a. <i>Who should provide information?</i></p> <p>“My preference, you know, [PCP speaking as a patient], would be to have that conversation with the person ordering the test, which would be the PCP or the GYN . . . as opposed to hearing it from the radiologist, whom I don’t know and has never felt my breasts and doesn’t know the context in which I’m having the test done.”</p> <p>“I would say that the information should be delivered first by the radiology folks, and then with us, as primary care doctors, there for backup [for] further questions, discussion of alternatives.”</p>	<p>“One, if there’s a miscommunication about what their density is, if you tell them it’s not dense and other people say it’s dense, you’ve already got a discrepancy . . . it definitely opens up issues of liability.”</p> <p>“Well, it can’t really be us, because we don’t have the entire information about the patient, about the risk factors.”</p>
<p>b. <i>How to present the information and broader discussion of risk</i></p> <p>“If I saw something that said, ‘this is what dense is, and this is where you fall,’ that is good information for me, and then something from my doctor saying, ‘looking at this, based on</p>	<p>and then with us, as primary care doctors, there for backup [for] further questions, discussion of alternatives.”</p> <p>“ . . . if you come and you get a test, and the person who is the breast doctor should be the one to be able to tell you what to recommend.”</p>	<p>“I think both. I mean, I think we’re obligated to do it in the law, and we’re doing it, but then it probably leads to a lot of questions afterwards. I think we can answer the questions well, but we don’t know the patients as well as the clinicians might know the patients.”</p> <p>“If we are reading 50 patients in a half day—I cannot begin to imagine talking with 50 women a day about their breast density . . . you’re going to need somebody who’s paid on a different scale.”</p> <p>“I think the good thing about the breast density legislation is, it’s brought up the idea of risk, and it’s put it a little bit higher in the visibility ladder, and women are more—should be, and probably in general will be—a little bit more aware of where they lie in the spectrum of whether they’re just at normal risk or whether they’re medium or high-risk.”</p>

(continued)

Table 1. (continued)

Patients	Primary Care Providers	Breast Radiologists
<p>where you are, this is what we recommend as a follow-up.” “I think you should be talking about breast cancer in general, versus dense breasts.”</p>	<p>and we really want you to understand the experience and what’s happening.” “I think if it opens up a discussion between primary care physicians and patients about breast cancer risk, and what are the other risk factors that influence your breast cancer risk that are more modifiable—such as alcohol intake—then it could have a positive effect on patients being more fully informed about what—how to impact their breast cancer risk.”</p>	<p>“Well I think what would be helpful is knowing comparative risks for patients. Because I think that patients now hear ‘density, density,’ and they don’t really understand what level of risk that is compared to other levels of risk . . .”</p>
<p>“ . . . exercise, things that you can control on your own self. . . . You can’t control your genetics, but you can control your behaviors.”</p>		

Note: MBD = mammographic breast density; PCP = primary care physician; MRI = magnetic resonance imaging.

making for next steps. Women’s sentiments included, “What do I do with that information?” PCPs and radiologists were concerned about providing the information without a clear course of action. Radiologists saw the additional information as a burden rather than a help for patients.

Concerns about cost and insurance. When presented with alternatives to mammography such as tomosynthesis or MRI, women worried that insurance might not pay. PCPs and radiologists also recognized the complexity and tradeoffs resulting from limitations of healthcare coverage.

Liability. Patients and providers noted liability as a concern although they were divided on how important it was in response to MBD notification laws. Patients saw providers protecting themselves from liability. PCPs were less concerned about legal implications for their own practice, citing the trust they had built with their patients. One PCP suggested that the legislation provided a way for radiologists to reduce their malpractice risk, and highlighted tensions between generalists and specialists who were “always trying to find a way to pass that hot potato to us instead of holding onto it themselves.” Radiologists as a whole were more worried about litigation, implying that extra images were ordered defensively, but clarifying that this behavior had not changed because of the law but rather had always been part of their practice. A new law also meant potential for noncompliance, meaning risk of litigation might go up as a result. An important domain that emerged among radiologists in particular was that their practice of reading images had changed in response to the law, that is, changing the way they would code a density result. Here the implications for practice were mixed. Two noted “coding up” to a higher density category when they were on the fence while one “coded down.” One was more likely to go back and compare the film to the previous year’s exam, highlighting the subjectivity inherent to making the call consistently, especially when women had scattered or heterogeneous MBD.

Actions Patients and Clinicians Should Consider Based on MBD Information

Women and their providers noted several ways to promote benefits of MBD reporting and our understanding of how best to deliver this information.

Who should provide this information? For patients, “trust” emerged as a major theme when receiving MBD information and considering next steps. A minority of women wanted the MBD

information from the radiologists directly, as they were the “breast doctors” with the specialized expertise and knowledge to read the images and make appropriate recommendations. The most important dimension for most patients was that they trust the clinician delivering the news, especially if follow-up was necessary, and that they understand the reasons for the recommendations. Some patients also felt that they should discuss the information with someone they trusted, whether that person was a medical provider, family member, or friend.

While some PCPs thought women wanted to hear about MBD from the PCP, most thought the information should be reported first by the radiologist, preferably in a face-to-face meeting, with the PCP available to answer additional questions and contextualize the results. PCPs felt that the radiologists read the exams and “owned the interpretation” and therefore had the responsibility to disseminate the results. Radiologists had mixed views. Some thought PCPs were better positioned, as they had access to the “entire information” about the patient and her risk factors. Other radiologists felt that the domain belonged to both the radiologist and the PCP. Still others said that the information and resulting conversation might best be delivered and mediated by a non-clinician, presumably a health educator.

How to present the information and broader discussion of risk. Women were interested in a visual aid to understand where their personal density fell on the spectrum, but felt that a qualitative assessment would also be useful. Other women discussed having a checklist of follow-up options. Patients expressed the desire to receive specific, individualized recommendations about screening and actionable suggestions from “trusted” sources based on their MBD and other risk factors. Both patients and PCPs noted that a video might be a good way to present this information. PCPs thought that the presentation should be integrated with information about overall risk. Radiologists noted the importance of providing comparative information for each woman in terms of where she falls on the risk spectrum.

Chief among limitations of the legislation identified by both patients and providers was failure to contextualize MBD into a broader conversation about risk factors for breast cancer. Women noted that MBD information without context would “just flip me out.” Women and PCPs were particularly interested in discussion of modifiable risk factors like exercise and alcohol intake.

DISCUSSION

We talked to patients and providers in the months following the implementation of MBD legislation in Massachusetts and found differences in how women and providers perceived the legislation. Patients were not very knowledgeable about the new law; however, they were largely positive about its goals after learning about MBD and its implications. Women tended to frame their perspectives around their right as patients to understand information about their own bodies and to be ready and informed in the future if things should change.

PCPs and radiologists were more neutral or negative about the legislation and its impact on patients and their own practices. The concerns of the PCPs reflect physicians’ views expressed in the literature.¹³ While PCPs noted that the legislation theoretically invites patients and providers to engage in a dialogue about broader breast cancer risk and shared decision making regarding screening, they were concerned about the lack of evidence necessary to make sound recommendations about additional screening and the possibility of overutilization of screening and subsequent overtreatment. Furthermore, they worried that an emphasis on density might divert attention away from more important risk factors for developing breast cancer such as family history and genetic risk. Radiologists were most negative overall, noting not only lack of evidence but also increases in workflow, changes in subjective coding practices, and potential for increased anxiety on the part of patients.

Deficiencies in the legislation noted by stakeholders underscore a lack of evidence supporting legislation and implications for practice including harm to patients and providers. Legislating MBD notification may invite a broader conversation about breast cancer risk; however, given the relatively little knowledge patients have about MBD, lack of evidence supporting additional screening, and limited bandwidth on the part of providers, such mandated efforts may alarm patients with dense breasts and falsely reassure patients without dense breasts that they are at average risk for developing breast cancer. Women with dense breasts may also desire a greater level of testing and scrutiny, which may ultimately open them up to harm through increased exposure to radiation from additional scans and unnecessary invasive procedures like biopsies, with little improvement in cancer detection. Whereas advocacy movements to educate

the public about MBD continue to gain momentum, we are unaware of data that demonstrate that these efforts improve patient education about breast cancer risk or have a measurable effect on patient diagnosis and treatment outcomes.

Our work has several limitations. Women and providers were recruited from a single large integrated health care delivery system. Providers who practice in the same institution may have views that are more similar to each other. This may limit the generalizability of these findings. While our sample of patients was racially and ethnically diverse, the majority of the women were well educated, and those who volunteered to participate may have been more engaged in their health. This work was completed during the first year of the implementation of MBD legislation. Patient and provider perspectives may evolve over time as more information about MBD is presented in both lay and professional media.

MBD legislation mandates that women know their density but stops short of educating women about breast density in the context of their overall risk for breast cancer. The momentum created by MBD legislation provides an opportunity to improve communication of breast cancer risk more broadly. Health systems and providers should work with women to develop clear and concise tools that educate patients about MBD and situate it in the context of other risk factors that collectively make up a woman's breast cancer risk. Educational materials provided to women at the time that they receive their mammogram result may help deliver a clear message about screening intervals and possible next steps. Platforms for such materials might include web links to videos disseminated through patient portals or available on health system websites in addition to written materials. Integrating patient breast cancer risk factor data (i.e., family history) with information on density can help identify women at higher than average risk for breast cancer and facilitate connecting these women with appropriate and evidence-based screening. Future research in this area should include additional qualitative research with women to develop appropriate educational materials and pragmatic trials to test the efficacy of educational interventions. Any strategy employed should provide clear guidance on next steps for individual women and indicate a clear process for addressing questions and concerns.

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