

The Density Conundrum: Does Legislation Help or Hurt?

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Breast density and breast density legislation are controversial and potentially emotional issues in breast screening. Informing individual patients of their breast density status is an extremely important and highly personal conversation that must focus on patients' specific situations. The unanswered questions about converting population risk make it difficult to provide an individual woman with an explanation of what breast density means to her individual risk for developing breast cancer now or in the future. There are no standards or guidelines for what doctors should tell patients about their risk with dense breasts, and legislating the conversation may not improve it or a woman's response to the information. It is necessary to learn more about breast density, understand its meaning, and communicate clearly and compassionately with patients about what we know and what we do not know about breast cancer risk. Precipitous legislation can, in fact, undermine both the patient-physician relationship and the need for more evidence that would expand our understanding of the risk associated with breast density.

Key Words: Dense breasts, mammography, screening, legislation, patient-physician communication

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INTRODUCTION

Breast density has become a controversial issue in breast cancer screening, partly because we do not really understand what to do with this information. As an advocate and two-time breast cancer survivor, it is my role to bring the broad patient perspective to the research community and the research process and, where possible, outcomes to the patient community in a meaningful way. Having a cancer diagnosis introduced me to the language of cancer, the fear and uncertainty that accompany a life-threatening disease or condition, and the desire to help others similarly touched by the disease. As a breast cancer survivor, I am aware that I have a personal story to tell to increase the resonance of and "put a face" on the disease. However, I also recognize that I am an "n of 1," and this can limit my ability to fully represent the range of patient preferences and opinions, particularly those that do not coincide with my own. Therefore, my discussion focuses on the usefulness and meaning of information to a broad range of patients, especially as it relates to dense breast legislation.

BREAST DENSITY AS A RISK FACTOR

Breast density is a conundrum. A recent meta-analysis of more than 40 studies conducted by McCormack and dos Santos Silva [1] reported that women with dense

breasts have a 2-fold to 6-fold increased risk for developing breast cancer. However, the authors also stated that the increased risk associated with breast density is confounded by age and body mass index. Young women are more likely to have dense breasts and therefore are considered at greater risk for developing breast cancer. However, breast density decreases with age, while breast cancer risk increases with age.

Mammographic density cannot be found by palpation. It is an imaging finding, not a clinical finding. Dense tissue and tumors both look white on a mammogram, making mammograms with higher density harder to read and interpret than mammograms of less dense breasts. The dense tissue may mask the presence of a breast cancer tumor. Whether reducing breast density also reduces the risk for breast cancer remains an unanswered question.

Although increased breast density may increase the risk for developing breast cancer, it does not reduce survival. In a recent study of more than 9,000 women with confirmed diagnoses of breast cancer, high mammographic density was not associated with the risk for death from breast cancer or death from all causes combined [2]. Instead, there was a paradoxical increased risk for breast cancer death associated with low breast density, particularly in obese women.

Breast density is measured using a number of different classification systems. Measurement is qualitative and not standardized by age, body mass index, race, ethnicity, or breast size, even though these factors can affect mammographic density [1,3-5]. The system most

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frequently used and referenced in the current mandatory notification legislation is the ACR's BI-RADS[®]. BI-RADS is a qualitative rather than a quantitative approach, relying on radiologist readers to evaluate what they see. As a result, BI-RADS classifications are subject to interreader variability.

Variability in readers' subjective classifications of breast density can result in one woman having her mammographic density classified as category 2 and another woman, with the same amount of density, having her mammographic density classified as category 3. The woman with category 2 breast density would not be told that she has dense breasts and may be left with a false sense of security. The woman with category 3 breast density would be told that she has dense breasts and might undergo subsequent screening and experience anxiety and added cost that might be unfounded. Radiologists who read mammograms regularly are more reliable than those who do so less often [3]. Therefore, some experts believe that measurement of breast density outside an academic medical center with radiologists who specialize in reading mammograms is problematic.

COMMUNICATING WITH AND INFORMING PATIENTS

Informing individual patients of their breast density status is an extremely important and highly personal conversation that must focus on patients' specific situations. However, studies showing that breast density increases risk for developing breast cancer are population based and do not tell an individual woman about her personal risk. There are many unanswered questions about the meaning of breast density for individual women. How does high mammographic density affect a specific woman's risk? When in her lifetime is a woman's breast density most predictive of risk? It may be that looking at breast density over time rather than as a onetime finding is more predictive. According to Boyd [5], it is the cumulative breast density that is most predictive. There remains disagreement about whether current or past breast density serves as the better predictor of risk or whether reducing breast density also reduces cancer risk [6].

These unanswered questions make it difficult to provide an individual woman with an explanation of what breast density means to her individual risk for developing breast cancer now or in the future. Instead of using density alone, the patient and her physician can use a number of risk assessment tools to determine her risk for developing breast cancer. These risk models can incorporate menopausal status, age, breast density, family history of breast cancer, prior breast procedures, and other factors [7]. The National Cancer Institute has a risk calculator available on its website [8]. Some models incorporate breast density, whereas others do not. All have their relative strengths and weaknesses. However, breast density is not a dominant component

of breast cancer risk prediction in any of these models. Patients would benefit from understanding that the risk for breast cancer from having dense breasts alone is very small, compared with other, potentially greater risks factors for breast cancer, such as family history or age. This would allow patients to make more informed decisions about choosing additional screening tests, such as ultrasound or breast MRI.

Given that there are no standards or guidelines for what doctors should tell patients about their risk with dense breasts, are the majority of internists and gynecologists ready and willing to have these discussions? The language in the legislation regarding who is responsible for communication varies from state to state. This variation makes it even more important that a woman hears the same information regardless of who tells her or how many times she has been told about the risks of dense breasts. Although the radiologist who establishes a woman's breast density best understands its meaning, it is currently more likely that the woman's personal physician will be the provider discussing the imaging findings with her. However, because measuring breast density over time may be a better predictor of her risk, it may be important for the patient to have continuity in reading and in discussing risk assessment with a radiologist. This is not a routine conversation radiologists are comfortable having; will it be enough to meet the letter of law and send a written report? This discussion is a complex one that will take considerable time, at least initially. Legislating the conversation does not necessarily improve its quality or a woman's response to the information.

Currently, all women with dense breasts are treated as a homogeneous group. As radiologists clearly understand, these women are not a homogeneous group. Women with extremely dense breasts constitute only about 10% of the population; however, they tend to have the greatest increase in relative risk for developing breast cancer. These women, especially those aged 40 to 49 years, may choose digital over film mammography to optimize cancer detection [9]. The current legislation groups women with category 3 and 4 breast density together, giving them both the same information about their risk for developing breast cancer. Moreover, our current screening guidelines for all women recommend one screening method and one time interval. The screening tool and the time interval should be made specific to a woman's individual calculated risk. Schousboe et al [10] suggested that "recommendations about the frequency of mammography should be personalized on the basis of a woman's age, breast density, history of breast biopsy, and family history of breast cancer, as well as the effect of mammography on her quality of life."

In communicating with an individual woman about her specific risk, including her breast density category, her physician should put the known research findings in context, given the evidence and how it relates to her

specific situation and her individual preferences for both information and fear of breast cancer diagnosis and treatment. How risk averse is the patient? What is her history of breast findings, eg, previous biopsy? What is her family history of breast and other cancers? Is she an information gatherer, or does information overwhelm her, making treatment decisions more difficult?

LEGISLATION

Some advocates see mammography as an imperfect screening method for women with dense breasts and want these women to be able to access additional screening tests. These advocates have chosen legislation as a way of increasing awareness among both women and their physicians and providing options for women found to have mammographically dense breasts. California's state legislation requires the following notification [11]:

Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician.

The ACR's 2012 position statement on reporting breast density in mammography states that the assessment of breast density is not reliably reproducible. It cautions that high-risk women may be complacent and forgo recommended screening because their summaries state that they have fatty breasts. The position statement includes a statement that the significance of breast density as a risk for breast cancer is highly controversial and that there are no randomized trial data showing that adding either ultrasound or MRI to mammography screening saves lives [12].

The ACRIN[®] 6666 trial, studying combining ultrasound and mammography for breast cancer screening, found that neither screening modality is perfect. The investigators found that 20% of the participants' cancers were not discovered at the time of initial screening. They also found that the combined screening strategy resulted in nearly 4 times as many false-positives as mammography alone [13].

Legislation does not solve the problem of what breast density means to an individual woman's risk. It may make a woman and her physician more aware of breast density as a risk factor. It may also cause a woman greater anxiety and cost, as well as more painful diagnostic procedures and time lost to subsequent screening. It will encourage more testing, and those tests could result in additional unnecessary biopsies. It could mean a repetitive cycle of testing and biopsies that eventually could result in a woman's choosing prophylactic mastectomy without detection of malignancy. Although this may seem like an extreme scenario to some, for those of us who live with the anxiety and discomfort of repeat

testing, the scars from frequent surgeries, and the lack of clarity around the meaning of the findings, it is a rollercoaster ride that can make a woman ready to consider an intervention she believes will provide her greater peace of mind. Legislation could also result in a false sense of security for those women who will be told that they do not have dense breasts but in fact may still have indolent breast cancer not yet detected on mammography.

Most state laws requiring mandatory reporting of breast density lack a requirement for insurers to pay for additional screening, thus making the additional screening an unfunded mandate and increasing the disparity of access for women who cannot afford to pay for the additional screening examinations. Most legislation also states that information is being given so that patients can have conversations with their doctors, but some doctors may not understand the meaning of breast density for any particular individual woman. Given the current lack of consensus on density measurement tools, interreader variability in density interpretation, and deficits in understanding of the meaning of BI-RADS density at the individual patient level, legislation is not the best use of our collective time and money.

Current legislation on mandatory density notification also does not establish a permanent standard of care, given sunset provisions. Section 123222.3(d) of California's health and safety code, for instance, states, "This section shall remain in effect only until January 1, 2019, and as of that date is repealed." Moreover, because legislation is frozen in time and will not reflect new research findings after the date of enactment, it may become out of date quickly (which is part of the reason for the sunset provision). Some state laws do not have enforcement provisions to ensure that notification is provided in the manner stated in the laws. Furthermore, if legislation is an unfunded mandate and does not require insurers to pay for additional screening tests such as ultrasound, reporting will be inconsistent and variable, adding to general confusion.

CONCLUSIONS

What would be more helpful for women? What would be a better use of society's resources? I would argue that more research is needed to inform evidence-based practice. Increased precision of screening imaging modalities could provide more accurate detection of malignancy. Enhanced understanding of the biology of breast density and its meaning for different ages, races, ethnicities, and body types would provide individual women with more information for informed decision making. Research showing that breast density is a surrogate marker for breast cancer might provide women with interventions that could both reduce breast density and their risk for developing breast cancer.

Raising awareness of breast density does not prevent breast cancer, and it is uncertain whether it aids women

and their physicians in understanding and coping with risk. There are too many unanswered questions about the meaning of breast density for individual women and how much of a factor it should be in discussing a woman's overall breast cancer risk. Legislation may be asking physicians to do too much with this conversation, discussing population-level risk, translating this to an individual woman's risk, conveying uncertainty about the actual risk, and seeking to reassure patients at the same time. Also, because physicians cannot give clear-cut recommendations about alternative screening tests to mammography, especially those that are covered by insurance, legislating the conversation may increase uncertainty for women about what to do next.

In conclusion, it is necessary to learn more about breast density, understand its meaning, and communicate clearly and compassionately with patients about what we know and what we do not know about breast cancer risk. However, the overwhelming majority of breast cancers occur in women with no or average risk factors. Importantly, discussing breast cancer risk and screening for breast cancer are individual decisions on the part of patients and their physicians. It is not a legislative issue. Precipitous legislation can, in fact, undermine both the patient-physician relationship and the need for more evidence that would expand our understanding of the risk associated with breast density.

TAKE-HOME POINTS

- Informing individual patients of their breast density status is highly personal conversation that must focus on patients' specific situations.
- Breast density legislation does not necessarily improve the quality of physician-patient conversations.
- Expanding understanding of the risk associated with dense breasts will enhance individual patient decision-making.

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