

An Expert Discusses Breast Density Notification Laws: Are They Ahead of the Science?

John C. Hayes, Debra I. Monticciolo, MD

Dec 03, 2012

Editor's Note: *As of this writing, 5 states -- California, Connecticut, New York, Texas, and Virginia -- have enacted laws requiring that radiologists notify women who have dense breasts as observed on screening mammograms. Among those pushing this movement are patient advocates who argue that these women need additional screening, usually with ultrasonography, to reduce the possibility that cancerous lesions are missed. Medscape turned to Debra I. Monticciolo, MD, who practices breast imaging in Temple, Texas, for perspective on this issue. Dr. Monticciolo is President of the Society of Breast Imaging and Chair of the Board of Directors.*

Introduction

Medscape: Texas is among the states that have a breast density notification law. Can you describe briefly what it requires and how it came about, and were Texas radiologists and breast imagers involved in the discussion before it became law? If so, what was their position generally?

Dr. Monticciolo: The Texas law is a result of patient advocacy and breast imagers and radiologists in the state. My understanding is that the final law was a response to the need to make patients and referring physicians aware of the issues surrounding breast density. Breast imagers and other radiologists were involved, especially through the Texas Radiologic Society. I'm not sure what the different positions were, but they did work together on this law.

In Texas, the law requires us to inform a patient about density at the time of her mammogram. It lets women know about the risks that are associated with dense tissue, so overall we viewed it as a good thing.

Medscape: Can you tell me what impact this law has had on your practice? Have you noticed an increase in the number of women and referring physicians requesting breast ultrasonography?



**Debra I. Monticciolo,
MD**

Dr. Monticciolo: We were already including density information in our reports, including its effect on mammogram interpretation. So the most important impact for us is the additional steps we take to inform the patients, as well as our referring clinicians. In some states, the density laws are used to push ultrasonography a bit, which is not necessarily the best for patients; we have not chosen that path. There are limitations and potential harms to that approach.

Instead, we are promoting a dialogue with our patients, and we've made efforts to educate our referring physicians so that they can be comfortable with these conversations, because they ultimately will have the majority of the cancer discussions with their patients. In our practice, it's led to more overall risk assessments, which we think is a favorable outcome. In my own particular practice, we have not seen an increase in requests for screening ultrasonography.

Determining Cancer Risk

Medscape: You mentioned risk assessments. Can you describe that process?

Dr. Monticciolo: Breast cancer risk is multifactorial. So for any individual patient, just having dense breast tissue may not really change what she needs to do. Our concern is that many women will be told that they have dense tissue, without distinguishing how dense and without a clear indication of their own individual risk.

Right now, patients with heterogeneously dense and dense tissue get lumped together, but the effect of density is much less for those in the former category (heterogeneously dense). Patients feel like they absolutely must have further testing. What we're suggesting is they talk to their doctor and look at their overall risk, because density is only 1 element in a risk profile.

The Texas law gives us room on how to take the next step, and we're trying to do what is best on the basis of current science.

Risk assessment looks at other things -- family history, personal history, history of biopsy with certain types of pathology -- things that we know increase a patient's risk of getting breast cancer. At Scott and White, we have a high-risk clinic, and we have a physician who specializes in making these kinds of assessments. There are many risk assessment models available that have been validated in many different patient populations. Using these models, a physician can determine what a patient's lifetime risk is and suggest strategies to minimize the risk.

That's how we are using the breast density law. We treat density as 1 element, and we tend not to push patients toward ultrasonographic screening if they're on the low end of heterogeneously dense. The Texas law gives us a little bit of room to interpret how to take the next step, and we're trying to do what we think is best for the patient on the basis of current science.

A Connecticut Experience

Medscape: I'm sure you are aware that *Radiology* just published a study from one breast imaging practice that is based on a breast density notification law adopted in Connecticut in 2009.^[1] That study found an increase of 3.2 additional cancers per 1000 women screened. Would you expect to see the same sort of results in Texas, and why or why not?

Dr. Monticciolo: I believe the article you are referring to is by Hooley and associates.^[1]

Medscape: That is correct.

Dr. Monticciolo: The cancer detection rate in that study was similar to that seen in the ACRIN trials and other reports on screening ultrasonography. So I think that you could expect a similar study done elsewhere to produce similar results regarding the number of additional cancers detected. But there are additional issues to consider when you look at the data from that study and other studies very carefully. You will notice that these authors had a very high false-positive rate and a low positive predictive value for their biopsies.

This is the main problem with screening ultrasonography. In the Connecticut study, about 5% of patients were recommended for biopsy on the basis of their ultrasonography results, which is 4 to 5 times the rate for biopsies that we get from doing just standard mammography.

The cancer rate in the Connecticut study was similar to that seen in the ACRIN trials.

And when a biopsy was done for their ultrasonography-detected lesions, only 6% were positive -- which is good for those patients, but it's a very small percentage. It's not good for the 94% for whom you did a biopsy and it was negative. With mammography, about 30%-40% of recommended biopsies will be positive, which is a far, far better outcome.

So additional cancer is one part of that study, but there is a downside, and that is balancing those benefits and risks. It's really part of this issue.

Published Data on the Laws Are Scarce

Medscape: Except for the study in *Radiology* and a counterpoint editorial in the same issue,^[2] I haven't seen much of anything in the literature discussing breast density notification laws. Does this surprise you? Has there been a very robust discussion of this topic nationally?

Dr. Monticciolo: It's certainly on the national radar. I think it will take time for actual data to come out on this topic. Right now, it's probably a little bit soon for well-planned and well-documented studies to be in print.

The density law in Connecticut was first, so it's nice that somebody is presenting data from that state. There has been a national dialogue, but at this point it's not based on data because there are very few data on the overall effects of these laws, both positive and negative.

There has been some national discussion. I'm on the US Food and Drug Administration's National Mammography Quality Assurance Advisory Committee, and this type of notification has been discussed. There certainly is dialogue going on, but there isn't much dialogue at this point in the scientific literature because there aren't enough data to have that discussion.

Medscape: On balance, do you think laws like this are a good idea, and where do you think most breast imagers would fall on this issue? If there is a division, what are the main points of contention?

The risk/benefit ratio is probably the main point of contention.

Dr. Monticciolo: I think the risk/benefit ratio is probably the main point of contention. Better information for our patients is always a good idea, so I strongly support that. Whether that should be in

the form of a law for me is not clear. Laws are tricky when it gets down to the actual wording, and even if you think you know what the intent is, the way in which a law is worded can lead to unintended consequences.

In this case, I think the laws are ahead of the science because we don't have really enough information on this whole topic to be making the kind of decisions the laws are already making for us. Unfortunately, many of the laws are unfunded mandates, which is unhelpful. These are the downsides of bringing this into legislation before we really have a good handle on all the aspects of the issue.

An Appropriate Topic for Legislation?

Medscape: I've got a larger question here; it's the idea about legislators getting involved in patient care decisions in this way. You have a fairly broad experience in radiology. Could you see this extending into other areas as well?

Dr. Monticciolo: Again, my main concern is unintended consequences. Many things sound great in theory, until you start working on the details and looking at the data critically. New ideas are often accepted enthusiastically because we all want to do better for our patients. We want to diagnose more cancers earlier, but we should approach these things with caution or we're going to end up unsatisfied. That is my concern. There are many questions around this topic, such as how to consistently and accurately assign breast density in the first place, and yet we have a law. It may be well intended, but it's premature.

I think that it's possible that we'll see this extend to other areas, but if it does, I hope there are lessons taken from this experience. I would hope that more data and more thought are put in up front, so that the legislation will be streamlined to do just what it needs to do and not more. Understanding the legislative process is never easy. What grabs the attention of politicians is not always obvious to me.

Medscape: What is your advice to breast imagers in other states where this issue has or will come up?

Dr. Monticciolo: I would say that breast imagers and patients should work together for reasonable solutions that can be supported by real data. I would like to think that lawmakers will allow time for this to happen, and not respond to pressures from those who are simply promoting their own technology or their own agendas.

I think if we stick to science and keep a dialogue open and are responsive to our patients, then we can make progress in the fight against breast cancer. After all, we are on the same side. So my advice is to work together for solutions.

References

1. Hooley RJ, Greenberg KL, Stackhouse RM, Geisel JL, Butler RS, Philpotts LE. Screening US in patients with mammographically dense breasts: initial experience with Connecticut Public Act 09-41. *Radiology*. 2012;265:59-69. [Abstract](#)
2. D'Orsi CJ, Sickles EA. To seek perfection or not? That is the question. *Radiology*. 2012;265:9-11. [Abstract](#)

Medscape Radiology © 2012 WebMD, LLC

Cite this article: An Expert Discusses Breast Density Notification Laws: Are They Ahead of the Science? *Medscape*. Dec 03, 2012.