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# Dense breast reporting laws in the USA

## What has been the impact?

A new study reports on the impact of breast density legislation in the USA on awareness of breast density and conversations between doctors and women about screening.



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Almost 10 years after the first breast density notification law was passed in Connecticut in 2009, 36 states in the USA now have such legislation. Research commissioned by Are You Dense, Inc., and Are You Dense Advocacy, Inc. set out to measure the impact of these laws from the patient perspective. The findings of the survey are published in the *Journal of the American College of Radiology* (JACR).

The results show that dense breast reporting laws in the United States significantly increase breast density awareness as well as prompt conversations between women and their healthcare providers about supplemental screening. And nearly 90% of women surveyed, regardless of the state's law status, completely or mostly agree that they would prefer to know their breast tissue type than not know.

Study results also show that women from states where density reporting laws have been in place longer are more likely to know their own density type and to report that their provider talked to them about supplemental screening.

The survey, conducted in February 2018, included 1,500 women in all 50 states, between 40 and 74 years old, who had a mammogram within the past two years. Survey results were compared across five groups based on law details and between women residing in states with laws versus without laws.

*HealthManagement.org* spoke to lead author Nancy M. Cappello, PhD, founder of Are you Dense, Inc. and Are You Dense Advocacy, Inc. and the inspiration behind the first density reporting law in the United States and co-author Christoph Lee, MD, MS, Professor of Radiology and Health Services at the University of Washington School of Medicine to find out more.

### What are the standout findings from this survey from your perspective?

**Nancy Cappello:** Regardless of a state's density

reporting status, the consumers of mammography, the patients, want to know their breast density status as part of their mammography reporting results.

Density laws are associated with increased breast density awareness (those in reporting states are more likely to know if they have dense breast tissue) and are more likely to have conversations with their providers about screening beyond the mammogram.

My state of Connecticut was the first state to enact a density reporting law (it took us 5 years of relentless advocacy). These results show that women in Connecticut are more likely than women in any other US state to know their tissue type AND, if heterogeneously or extremely dense, have conversations with healthcare providers about adjunct screening.

Our survey had several strengths. We surveyed women from all 50 US states with a diverse distribution of sociodemographic characteristics. We had a relatively large number (1,500 sample – 300 in each of the 5 groupings) and this large sample allowed for a robust 95% confidence levels for our statistics of +5.8% or smaller for each survey question.

### Has the discourse around breast density improved?

**Nancy Cappello:** Clearly patients who have been harmed by the limitations of mammography because of the impact of dense tissue on missed, delayed and advanced stage breast cancer, have led the discourse about dense breast reporting and its impact on access to an early breast cancer diagnosis. Right out of the gate, physician trade organisations were opposed to density reporting saying that we were mandating medicine through legislation.

There have been several peer-reviewed papers about the negative effects of dense tissue disclosure using overdiagnosis, patient and provider confusion and scaring women as reasons why women should not

receive this information through legislation. However, through research, starting in CT after the 2009 law, the significant yield of increased invasive cancer using ultrasound on otherwise normal mammograms has informed other practices across the USA.

Immediately upon enactment of the 2009 law, breast radiologist Dr. Jean Weigert, representing the Connecticut Society of Radiologists, who had testified a year before in opposition to the density reporting bill, began acquiring data to investigate whether screening breast ultrasound improves breast cancer detection in women with dense breast tissue and a recent normal mammogram result and her third research paper covered four years of screening women with dense breasts with bilateral ultrasound (Weigert 2017). Dr. Weigert spoke of her amazement in a recent article. "I pulled out the data from my five offices for the years 1 through 4. I tallied it all up, compared it, and found—much to my surprise—we continued to find 3.2 additional cancers per thousand in this cohort of patients with breast tissue density greater than 50%" (Green 2015). Additionally, the study demonstrated significant progress in reducing the false positive rate of biopsy, often cited as a harm of routine ultrasound screening, where ultrasound now equals the acceptable biopsy rate for mammography.

### Nearly 10 years on from the first state breast density legislation in Connecticut what are your reflections on the next steps?

**Nancy Cappello:** We need a national standard of density reporting. We are encouraged, under the leadership of U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb that density reporting, through changes in the Mammography Quality Standards Act (MQSA) is getting closer to becoming a reality across the US. On 18 October 2018, a communication was issued by the FDA concerning dense breast tissue reporting across the US. "The FDA intends to propose a new rule that will modernise mammography quality by recognising new technologies, making improvements

in facility processes and updating reporting requirements. The agency is proposing updates that incorporate current science and mammography best practices, including addressing breast density reporting by mammography facilities to patients and health care providers. These updates are intended to improve the delivery of mammography services" (U.S. FDA 2018).

### Why are some state laws time-limited?

**Nancy Cappello:** Even since the first density reporting law in CT in 2009, we have received huge resistance, mostly from physician trade organisations, using legislative efforts to communicate density reporting to the patient as part of the mammography reporting results. California became the first state in 2013 to use a "sunset" clause in the law where the existing law is eliminated on a certain date. The language of these laws is negotiated and for the bill to pass (the first one was vetoed by the Governor), a sunset clause date had to be part of the law or the opposition would not agree with its passage. A revised law was recently enacted which extended the sunset clause to January 1, 2025. There is a guide to the 36 state density reporting laws on our website at <https://iii.hm/oql>

### Do radiologists have effective tools for educating women about density and risk-based screening?

**Christoph Lee:** Radiologists are working with primary care physicians, policy makers, administrators, and patient advocates to effectively address density reporting laws. However, we have a long way to go. We need to generate better evidence regarding which women would benefit from which supplemental screening imaging examinations. Currently, the evidence suggests that there are both potential benefits and harms associated with additional testing beyond mammography. We also need to incorporate better risk stratification in an age of multi-modality screening options, and better inform women regarding their overall short-term and long-term risks for developing breast cancer. ■



## REFERENCES

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## FURTHER INFORMATION

Learn more about breast density and its relationship to breast cancer risk and legislative efforts across the U.S. at [areyoudense.org](http://areyoudense.org) and [areyoudensead-vocacy.org](http://areyoudensead-vocacy.org). You can also visit [mammography-saves-lives.org](http://mammography-saves-lives.org) and download the ACR Breast Density Brochure.