

Decade of ‘Normal’ Mammography Reports—The Happygram

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Interest in breast density reporting legislation has accelerated in the past several years, driven primarily by patients turned advocates under the mentorship and leadership of Are You Dense, Inc, and Are You Dense Advocacy, Inc. The history of the density reporting movement and the birth of education and advocacy nonprofits are described, along with how legislative efforts began. The decades of scientific research on dense tissue’s masking effect and its being established as an independent risk factor for breast cancer are summarized. Finally, the opposition’s arguments against density reporting legislation are addressed.

Key Words: Breast cancer screening, dense breast tissue, interval breast cancer, patient advocacy, legislation, public policy

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INTRODUCTION

I ate healthy, exercised daily, examined my breasts regularly, and underwent yearly mammography. I had no family history of breast cancer. In 2003, my annual screening mammogram was reported as normal, just as the decade of reports before 2003. I was faithful to my health care regimen; my routine annual gynecologic examination was 6 weeks later. As my physician was examining my breasts, she felt a ridge in my right breast and ordered diagnostic mammography and ultrasound. The diagnostic mammogram revealed nothing, but the ultrasound examination revealed a 2.5-cm mass. A breast biopsy confirmed invasive cancer, which was later verified as stage IIIC breast cancer. At the time of diagnosis, my tumor was more than 1 inch in size, and it had metastasized to 13 lymph nodes. The American Cancer Society reports the 5-year survival rate for stage IIIC breast cancer as 49%, compared with stage I at 88% [1]. I expected, in the event of a cancer diagnosis, an early stage because of my faithful program of annual screening mammography. I questioned my doctors as to what had happened. This was the first time that I was told that I had extremely dense tissue and that, as breast density increases, the sensitivity of mammography decreases.

I was stunned that my doctors knew about dense breast tissue and its impact on the effectiveness of mammography but had never informed me. I also discovered that

my physician received reports generated by radiologists that included more details about my mammographic results and, as in most reports, my breast tissue composition. This information is usually not reported in the patient’s “happygram” report. My decade of radiologists’ reports, unknown to me, read, “Patient has extremely dense breasts...no change from prior exam.” My radiologist knew that I had dense breasts. My doctor knew that I had dense breasts. The only person who did not know was me: the woman with the dense breasts.

EXAMINING THE LITERATURE

Searching for information in lay publications and online, I found nothing about this “dense” condition that prevented an early breast cancer diagnosis by mammography. I turned to the medical literature and discovered a decade of scientific studies dating back from 2004, which concluded that 40% of women have dense breast tissue [2,3]; that breast density is one of the strongest predictors of the failure of mammographic screening to detect cancer [4,5]; that there is a direct correlation between tumor size at discovery and long-term survivability [6,7]; that women with the densest breasts are at a greater risk for having interval cancers [8-10]; that ultrasound, when added to mammography, significantly increases the detection of early-stage invasive cancers [5,11-15]; and that dense breast tissue is a well-established predictor of breast cancer risk [16,17].

Overwhelmed with the scientific data that explained the tragedy of my advanced diagnosis, I shared this information with my doctors and asked them to consider informing patients of their dense tissue. Each responded, “No, it is not the standard protocol.” Haunted by their responses and knowing that my delayed advanced-stage diagnosis represented the case for innumerable women

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Are You Dense, Inc, and Are You Dense Advocacy, Inc, are nonprofit organizations that receive sponsorships and grants from imaging facilities, device manufacturers, hospitals, and health care businesses.

across the nation and the globe, I turned to the Connecticut legislature.

FROM PATIENT TO LEGISLATIVE ADVOCATE

During the summer of 2004, after my surgery and during my chemotherapy treatments, my husband, Joe, contacted Senator Joan Hartley to share the scientific evidence about dense breast tissue and its impact on delayed diagnosis. Senator Hartley and Senator Joe Crisco introduced legislation to require insurance coverage of whole-breast ultrasound screening as an adjunct to mammography for women with dense breast tissue. With very little opposition, the bill passed in 2005 and was amended in 2006 with stronger language [18]. I now expected physicians to voluntarily communicate a woman's dense tissue composition to her, thus allowing an informed conversation about her screening protocol.

News of my legislative victory brought numerous speaking invitations across Connecticut. My message was and still is a simple one: "Take control of your health: eat healthy, exercise, and, like me, have a yearly mammogram. Discuss your dense tissue composition, along with other risk factors, with your health care providers. If appropriate, supplement your mammogram with additional screening." Women reported to me that doctors diminished the importance of dense tissue, refused to prescribe additional screening, or denied that there was such a law. A few doctors, thanks to the insistence of their patients, ordered additional ultrasound examinations, which were later refused by imaging facility personnel, who stated, "We don't do screening ultrasound."

After the author reported to Senators Crisco and Hartley that the legislation did not get the issue of dense breast tissue to the person to whom it mattered most, the senators introduced legislation in 2007 to standardize the communication of findings of dense breast tissue in mammographic reports. It was at this time that Dr Gary Griffin, a radiologist from Torrington, Connecticut, contacted me to share his data since the 2005-2006 adjunct screening ultrasound coverage law. His compelling data confirmed a doubling of small, early invasive and node-negative cancers discovered by adding ultrasound to mammography for women with dense breasts [19].

Slogging through two legislative sessions before the notification bill was scheduled for a public hearing, Dr Griffin offered to testify at the 2008 hearing in support of the bill. Dr Jean Weigert, a radiologist representing the Radiological Society of Connecticut, testified in opposition to the bill. The reasons cited are still reported by our opponents 5 years later: there will be unnecessary screenings; the notices will panic women; mammography finds the smallest cancers; it is inappropriate for the government to prescribe what should be included in physicians' reports [20]. Dr Griffin's testimony included a report of an additional 9 or 10 cancers detected per 1,000 ultrasound examinations per year. He

reported that ultrasound is relatively easy to perform, relatively inexpensive, and fairly well tolerated by patients [19]. A subsequent unanimous committee and Senate vote sent the bill to the General Assembly. The bill survived a few more assembly committees but was never called for a vote. The bill died.

I was devastated. This defeat would become our watershed moment. Joe and I evaluated the session's setbacks, thoroughly assessing the all-encompassing toll of advocacy; we resolved to continue to relentlessly pursue density reporting to Connecticut women. Anticipating the endless outreach of a Web site, we launched *AreYouDense.org* a few months later. We also concurrently founded a non-stock-issuing corporation, *Are You Dense, Inc*, filing an application to the Internal Revenue Service as a 501(c)(3) nonprofit organization.

The 2009 session was different. The density notification bill became Senator Crisco's priority. Fortunately, the results of the ACRIN[®] 6666 trial had been published the previous spring [21]. Quoting ACRIN's results, the Radiological Society of Connecticut testified in support of density notification legislation [22]. The importance of dense breast tissue and the findings of ACRIN 6666 are best illustrated in the response to the following frequently asked question:

Why are these results from the first year being reported now if [ACRIN 6666] isn't complete? Because there is a potential benefit from early detection of small, node negative breast cancers seen only on ultrasound, we are announcing these results at this time so that women can consider these results when deciding whether or not to have ultrasound screening in addition to mammography [23].

However, how can a woman consider additional screening when she is unaware of her dense tissue composition and its potential impact on a delayed diagnosis?

On May 20, 2009, Connecticut governor Jodi Rell signed the first bill in the nation to standardize the communication of findings of dense breast tissue to patients in mammographic reports [24]. It would become the landmark legislation that birthed the density grassroots movement.

THE ROLE OF LEGISLATION

Through the Web site, I heard from women with stories similar to mine: yearly normal mammographic results but diagnosed with later stage cancers. The decades of scientific data concluding that breast density is the strongest predictor of the failure of mammography to detect cancer were illuminated in these women's stories [4,5]. It became their desire to prevent other women from the tragedy of a delayed diagnosis by advocating for state legislation. As a result of the flurry of interest in legislation, *Are You Dense Advocacy, Inc*, a 501(c)(4) nonprofit organization, was formed. As of August 2013, 12 states have enacted breast density notification legislation [25].

After contacting me in 2010 to acknowledge Connecticut's landmark density notification legislation, Connecticut congresswoman Rosa DeLauro introduced a

federal density reporting bill in 2011 [26], with plans for reintroduction in the 113th Congress. In 2010, we requested that FDA personnel consider revisions to the Mammography Quality Standards Act of 1992 (MQSA). The MQSA advisory committee agreed on November 4, 2011, to include a patient's dense tissue composition in the written lay summary of her mammographic results [27]. The FDA has projected December 2013 for the publication of the proposed regulations [28].

Many critics of state and federal regulatory efforts agree that dense breast tissue is an important component in the breast health of women because of its masking risk [5,11-15,21,29]. Some even acknowledge that dense tissue is an independent risk factor for breast cancer [30-34]. It is in how to standardize the communication of findings of dense tissue that we part ways. I often ask opponents what they recommend for standardization of the communication of findings of dense breast tissue to women. The response is a loud and uncomfortable sound of silence.

Using voluntary measures will not ensure that every woman receives this critical breast health information. When screening mammography was widely adopted for breast cancer detection in the 1980s, facilities across the country varied considerably with regard to image quality and radiation dose [35]. A voluntary accreditation program achieved limited gains, primarily because of low participation rates. Therefore, Congress intervened and passed MQSA in 1992 [36].

A little more than a year after Connecticut's breast density notification bill became law, I received news of Dr Weigert's data on the impact of the Connecticut legislation. Her multisite study yielded a significant increase in detection of small, node-negative cancers in women with otherwise normal mammographic findings [37]. Recently, the Yale University School of Medicine published research on the impact of CT legislation on its screening practices [38]. Dr Regina Hooley of Yale reported, "We're finding small, mammographically occult cancers at a significant rate, and we're able to do that and still be efficient" [39].

Although analog mammography is the only screening test that has shown a reduction in deaths in randomized controlled trials [40], there is no research to suggest that the invasive cancers not visible on mammography and detected by other screening tests are any different and, therefore, less clinically significant than those found by digital mammography.

COMMUNICATING WITH PATIENTS

The AMA's code of medical ethics states, "Withholding medical information from patients without their knowledge of consent is ethically unacceptable" [41]. The assessment of the potential benefits and harms of a specific test or treatment can be made rationally if the information given to the patient is complete, accurate, and true. The decision to withhold a woman's dense breast tissue

composition from her, which may affect her breast care, is denying her the right to make an informed decision. A patient can only act on the information given to her.

To accept the current protocol is to accept that patients should have only the information their doctors choose to reveal. The doctrine of informed consent exists independent of a consensus to the challenges of detecting early invasive cancers in women with dense breasts. Giving women information about their dense tissue, which is material to their health care, must not be dependent upon screening codes, workflow issues, reimbursement rates, and the myriad other reasons cited as to why the standardization of dense breast tissue notification through legislation is opposed.

ADDRESSING OPPOSING ARGUMENTS

The most cited reasons against density reporting are that the notices will cause unnecessary trauma [42,43] and confusion [39,43,44] and will scare [43,45] and frighten [44,46,47] women. Our organizations have not been presented with studies demonstrating that the notices are causing such deleterious effects, nor are we aware of studies or surveys that have been conducted or are currently in progress to support such claims. The results of two national surveys [48,49] and a survey conducted by Stanford University researchers [50] report that the majority of women do not know about their dense breast tissue and want to know. Women in the Stanford study also reported that interest in knowing about their dense breast tissue persisted despite the possibility of an increased likelihood of undergoing invasive procedures, an increase in false-positives, and additional out-of-pocket expenses. The only women I have met who are opposed to universal density reporting are those who are already knowledgeable about dense tissue's personal impact on their breast health and on mammographic screening accuracy.

Another common argument against legislation is that density assessment is subjective. Yet breast density reporting by radiologists is consistent whether using digital or film-screen mammography [51]. The variability for breast density is no different from other BI-RADS[®] features in mammographic interpretation [52,53]. There is moderate to substantial intrareader and interreader agreement in the assignment of BI-RADS density categories, and research demonstrates that training radiologists dramatically reduces density assessment variability [53-55]. Adding computer methods also improves interreader agreement [56]. Moreover, there are currently two FDA-approved volumetric density assessment tools that are commercially available [57,58].

Many of the critics of mammography's benefits and the utilization of additional screening tests expound about the harms of false-positives. These comments imply that it is acceptable to disregard the findings of scientific studies that added tests find small, invasive cancers that are mammographically occult in dense

breast tissue. The facts underscore that the real threat for women with dense breast tissue is false-negatives on mammography. Furthermore, the literature suggests that women are willing to be recalled for noninvasive or invasive procedures if they might increase the chance of detecting cancer earlier [59]. Moreover, ultrasound screening has traditionally bypassed the callback process that is standard procedure for screening mammography, proceeding directly to biopsy upon discovery of suspicious lesions on ultrasound. Ultrasound examinations that required callbacks with full diagnostic examinations before biopsy demonstrated a similar false-positive rate as mammography [60,61].

Legislative critics report the good news that women with dense breast tissue are not at a greater risk for dying than women with fatty breasts, referring to Gierach et al [62]. What critics fail to mention is the fundamental conjunction “when” in the study’s conclusion that women with dense breast tissue are not at increased risk for death, given that there was equality in all other patient and tumor characteristics, including age, tumor size, grade, lymph node stage, and stage at diagnosis. One of the limitations of Gierach et al’s study was its length of patient follow-up, with a mean of 6.6 years. Breast cancer recurrences or metastases may develop decades after initial diagnosis, and treatment and death from breast cancer have been reported up to 20 years after diagnosis [6,63–65]. The elevated hazard rate from death and recurrence in patients with estrogen-positive breast cancer persists beyond 10 years after diagnosis [66–68]. Seventy-eight percent of women in Gierach et al’s study had estrogen receptor-positive tumors.

The unequivocally not-so-good news rarely mentioned by opponents is that women with dense breast tissue, compared with those with fatty breasts, have a greater likelihood of interval cancer, delayed diagnosis, and advanced disease [4,5,8–10,21,29], which carry fewer treatment options and worse survival outcomes [6,7,69]. These scientific facts are not reassuring to women with dense breast tissue who experience delayed diagnoses despite yearly normal mammographic results.

CONCLUSIONS

There is plenty of scientific evidence to demonstrate that more early invasive cancers would be found if the masking risk of dense breasts were reduced, thus decreasing the frequency of later stage cancers. The unsolicited interest in our mission from across the globe is a testament to the fact that there is no shortage of women diagnosed with later stage invasive cancers because of their dense tissue. These women, faithful in their mammographic screening regimens yet denied equal access to early detection, have fewer treatment options and worse survival outcomes. Consumers have a right to know about this risk.

All the issues that are concerning to the profession cannot be solved by withholding a woman’s dense tissue

composition from her. Her breast health and access to an early diagnosis are compromised by delaying this communication. Short of a MQSA regulatory change or a national law, our work with patients and physicians for mandated density disclosure through state legislation will continue.

The Association for Medical Imaging Management and the American Society of Breast Disease have communicated their support for breast density education and advocacy efforts [70,71]. ACR and Society of Breast Imaging leadership have an opportunity to join their members and partner with breast density advocates for universal density reporting. Together, we would maximize the benefits of early detection, reduce the incidence of regional and distant disease, and improve life outcomes for women. It’s time this became our collective mission.

TAKE-HOME POINTS

- Breast density is the strongest predictor of the failure of mammography screening to detect cancer.
- To withhold a woman’s breast density composition from her, which may affect her health care, is denying her the right to make an informed decision.
- The doctrine of informed consent exists independent of a consensus to the challenges of detecting early invasive cancers in dense breasts.
- There is no research to suggest that cancers, not visible by mammogram and detected by other screening tests, are less clinically significant.
- Voluntary measures will not ensure that every woman receives this critical breast health information.

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