

EDITORIAL AND COMMENT

Breast Density Legislation and the Promise Not Attained

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Strong patient advocacy has resulted in widespread adoption of state legislation that requires notification of a finding of dense breast tissue on mammography. Approximately 40% of US women have dense breast tissue and could potentially receive legislatively mandated reporting about the role of breast density on “masking,” breast cancer risk, and the option for supplemental screening with ultrasound or magnetic resonance imaging (MRI).¹ Despite the well-intentioned goal of improving informed decision making, the impact of breast density legislation on understanding of breast cancer risk, awareness of the limitations of mammography as a screening test, or the timely diagnosis of breast cancer has largely not been demonstrated.^{2–5}

More than nine years have passed since the first breast density notification legislation was implemented in Connecticut, and we have experience with many state-specific “flavors” of density reporting requirements, including the provision of general information about the role of density in masking and breast cancer risk, notification limited only to women with dense breast tissue, and reporting of personal density to all women. Beyond the limited impact of the legislation on understanding and decision making, it is possible that the legislation has had unintended consequences, like diversion of attention from other important risk factors for breast cancer (e.g., family history), over-screening with supplemental screening for which there is insufficient evidence for most women, and perhaps over-diagnosis of cancer that would not have limited life expectancy. We also do not know the impact of this legislation on population health or health care costs; by supporting resource use based on legislation vs. evidence, it is possible that the legislation has diverted more costly, specialized screening tests, like MRI, from high-risk women (e.g., BRCA mutation carriers) for whom there is evidence to support use. In many states, insurance does not cover the costs of supplemental screening tests; unexpected out-of-pocket costs may discourage women from pursuing future evidence-supported breast cancer screening. In view of the ongoing legislative mandate, these potential adverse effects should be evaluated. Given our decade of experience with breast density

legislation and the lack of demonstrated benefit, it is time for us to accept that legislatively mandated notification letters alone have not achieved the desired goals.

Not surprisingly, women with limited health literacy may face additional challenges as the readability of the legislatively mandated language often exceeds both the recommended readability levels for health information and state literacy levels.⁶ The qualitative study by Gunn et al. in this issue of *JGIM* begins to explore how Spanish-speaking women with limited English proficiency (LEP) experience mandated breast density notification.⁷ These qualitative interviews were done approximately one year following the implementation of the density reporting requirement in Massachusetts. Importantly, only about one-half of these women reported receiving a notification letter in Spanish, suggesting broader limitations in how non-English-speaking women are notified of their test results. Themes that emerged from this qualitative work included notification-induced confusion, misinterpretation, seeking of information from other sources (e.g., internet, friends, family), and unrealized preferences for care. While it is critically important to understand the experiences of women with LEP, it is important to note that the experiences of these Spanish-speaking women were quite similar to qualitative work done with English-speaking women.⁸ Women with LEP or low health literacy may disproportionately benefit from discussion with their health care provider to promote understanding of complex concepts like future risk of developing disease and “masking.” Unfortunately, primary care providers and radiologists do not feel prepared to respond to patient questions raised by mandated density notification.⁸ While diverse populations of women face distinct challenges, a broad cross section of US women likely faces uncertainty because of this legislation.

Even if legislation has not resulted in the anticipated outcome, addressing the concerns that led to the wave of density legislation is essential. Improving women’s understanding of breast cancer risk and the limitations, and benefits and harms of breast cancer screening is necessary to improving the health and well-being of women. The failure of legislation to achieve the desired results suggests that providers and health systems should be allowed flexibility to try innovative approaches to address the underlying concerns about breast density raised by breast cancer advocates. We recently developed and evaluated whether a brief, personalized informational video about breast density and breast cancer risk following a normal mammogram result, in addition to a legislatively required letter, can

improve knowledge of breast density and breast cancer risk compared to a legislatively required letter alone.⁹ Relative to women who received the letter alone, women who also received a personalized video had greater improvement in their knowledge of both their personal breast density and their risk of breast cancer. The video format was well received. Similar videos could be developed in a variety of languages and may be more accessible than written information for women with limited health literacy. Importantly, these videos integrated information about other risk factors for breast cancer in addition to breast density.¹⁰

Another area in need of innovation is breast density assessment. The interpretation of breast density in current practice is subjective and inconsistent.¹¹ The likelihood that a woman is told she has dense breasts varies substantially according to which radiologist interprets her mammogram. The development of professional standards and training for breast density assessment may help to reduce this inconsistency. Additionally, the development, evaluation, and implementation of quantitative density assessment may improve the reliability of identifying women who may most benefit from supplemental screening. By not acknowledging the limited reliability of density assessment, mandated reporting may lead to unreliable decision making.

The ultimate goal of breast cancer screening should be the development of evidence-based strategies that can be successfully implemented in practice to promote shared decision making that maximizes the benefits and minimize harms of screening for an individual woman. Legislation has not moved us closer to this goal—it is time for us to re-evaluate the role of this legislation so that innovation and collaboration can promote evidence-based, informed decision making. The article by Gunn et al. reminds us to ensure that the additional needs of women with limited health literacy and LEP are addressed. While a wave of advocacy created needed impetus to pay

attention to breast density, it is time to realize that legislation has not gotten us where we want to be.

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