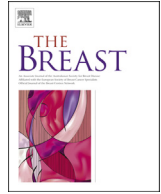




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Review

The impact of legislation mandating breast density notification – Review of the evidence



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ABSTRACT

Breast density (BD) is an independent risk factor for breast cancer and reduces the sensitivity of mammography. The enactment of BD legislation in a majority of states in the USA mandating notification of risks associated with BD directly to women undergoing mammography has catapulted interest in BD among women, physicians, and policymakers. We therefore report a descriptive review of the evidence on the impact of enactment of BD legislation. Based on 22 eligible studies, we identified four broad themes of research: studies of the impact on screening rates, most showing increased utilisation of supplemental screening; studies exploring the effect on women, radiologists, or primary physicians (reporting heterogeneous effects on knowledge, awareness, perceptions, attitudes and behaviour; and changes in practice); few studies assessing the population impact (effect on screening outcomes or breast cancer stage); and studies of costs highlighting the economic burden from supplemental screening. Given that many of the studies were retrospective single institution studies (comparing pre- and post-legislation) or small surveys with a paucity of population-level studies, we highlight areas meriting additional research. The information described in this review can inform research priorities where BD legislation has been introduced and can be used to guide world-wide policy or practice decisions where BD legislation may be under debate or contemplation.

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1. Introduction

1.1. Contemporary issues regarding breast density

A large body of research has been dedicated to breast density (BD) over the past 40 years, from elucidating its role as a risk factor for breast cancer [1,2] to screening trials using density categorisation to triage women for supplemental screening [3,4]. However, this decade's unprecedented enactment of legislation in some parts of the USA mandating notification of risks associated with BD directly to women undergoing mammography has catapulted interest in (and discussion of) BD among women, physicians, and policymakers [5–10]. While more than 70% of all states in the USA now have density reporting laws enacted [5,7,11,12], resorting to legislative measures in the routine breast cancer screening setting is likely to have broader implications beyond the USA. For example, Australia does not have BD-specific legislation and Australia's national breast screening program (BreastScreen) does not routinely provide BD information to women having screening. However, in 2018, the Australian Government's Department of Health commissioned a public survey to inform discussion of whether BreastScreen's position statement on BD requires modification [13]. Although there are no published reports on whether BD legislation is being considered or is in the process of being enacted in countries other than the USA, it seems likely that the ripple effect of enactment of BD legislation in the USA may have world-wide reach.

1.2. Scientific issues on breast density and the detection capability of supplemental screening

Mammographic BD is an independent risk factor for breast cancer [1,2], and separate from this inherent risk, high BD also increases the risk of having a cancer missed on screening mammography (ie, increases the risk of an interval cancer in screened women) [14]. **Box 1** summarises some of the key scientific facts regarding BD. Early evidence suggests that supplemental (adjunct) screening in women with dense breasts detects additional breast cancers not detected on mammography [4,15,16]. Specifically, there is early evidence that breast ultrasound and digital breast tomosynthesis detect additional cancers following 'negative' mammography screening; estimates of increased cancer detection and the associated increase or decrease in recall rates from supplemental imaging for women with dense breasts varies by imaging modality as summarised in systematic reviews [4,16]. The variability in estimated additional cancer detection from supplemental imaging is in the broad range of an additional 1.4 to 28.6 cancers per 1000 screens in dense breasts [4], and is partly driven by selection of study populations, with studies often including women with risk factors other than high BD due to clustering of risk factors in some women. Of equal importance is acknowledgement that routine supplemental screening for women with dense breasts has not been sufficiently evaluated to allow any conclusions about long-term health benefit. Therefore, recommendations about supplemental screening for women with dense breasts build on an assumption that additional cancer detection (above that from mammography) will transfer into additional clinical benefit and assume that the potential benefit outweighs the potential harms from supplemental screening.

Box 1

Current evidence regarding breast density as a risk factor.

More than 40% of the screening population have dense breasts (heterogeneously or extremely dense) [43], making it one of the most common breast cancer risk factors

Box 1 (continued)

Breast density is subjectively categorized into four groups by radiologists (with significant inter-reader and intra-reader variability) [44], with the top two groups considered to have dense breasts

The relative risk for developing breast cancer when comparing women with extremely dense breasts to those with almost entirely fatty breasts is 4.64 (95% CI 3.64–5.91) [1]

Both sensitivity and specificity of mammography for detecting breast cancer decreases with higher breast density (88.2% sensitive and 96.5% specific for women with fatty breasts compared to 62.2% sensitive and 89.9% specific for women with extremely dense breasts) [45]

High mammographic breast density is associated with higher likelihood of an interval breast cancer in mammography screening [14]

1.3. Aims of this review

In this complex and evolving landscape of BD legislation, we undertook a review of the evidence to describe and summarise evidence on the impact of enactment of legislation mandating notification of BD information to women. Insights into the impact or potential impact of BD legislation is needed to guide the path forward with research and evaluation where BD legislation has been introduced (or is in the process of being enacted), and to inform world-wide policy or practice decisions where BD legislation may be under debate or contemplation.

2. Methods

2.1. Literature search and eligible studies

A literature search was performed (June 2018) as shown in online [Appendix 1](#). This review does not attempt to address the broader literature on the detection capability of supplemental screening in women with dense breast tissue on mammography, which has been covered in systematic reviews and meta-analyses [4,15,16]. The present review focuses on describing and summarising the evidence related to the impact of introducing or enacting BD legislation, and aims to identify a broad scope of research themes. Eligible studies were those that (a) stated that a purpose of the study was to assess or report on the impact of BD legislation, and (b) reported any quantitative information on the observed, perceived, or estimated effect of the enactment or potential enactment of BD legislation. The literature search consisted of a Medline search (exploded "breast neoplasm", combined with "density" and "legisla\$" or "mandatory" or "notification" in the title; repeat search using "laws" instead of "legisla\$"), searching reference lists of eligible studies, and contact with content experts. Literature searching and identifying relevant studies was performed by both co-investigators: selection of eligible studies is shown in a flow-chart (online [Appendix 1](#)).

2.2. Extracted information

Information was extracted into an evidence table to summarise the scope of research evidence on the impact of BD legislation, as follows: purpose of the study, design and methods, source population or subjects, and the main findings. Extraction from eligible studies was performed by both investigators (NH, CL), using discussion and consensus to collate the information and to resolve disagreement. The information collated in the evidence table was used to define the main themes of research that have emerged in response to BD legislation and to summarise their findings.

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