

Breast density notification: a systematic review on the impact on primary care practitioners (PCPs)

Running head: Impact of breast density notification on PCPs

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ABSTRACT

Background: In the last decade, there has been an unprecedented amount of advocacy and attention surrounding the issue of breast density (BD) in relation to mammography screening. It is largely unknown what impact notifying women of their BD has had on clinical practice for PCPs. This systematic review aimed to synthesise evidence from existing studies to understand the impact of BD notification on primary care practitioners' (PCPs) knowledge, attitudes and practice implications.

Methods: Empirical studies were identified via relevant database searches (database inception to May 2020). Two authors evaluated the eligibility of studies, extracted and crosschecked data, and assessed the risk of bias. Results were synthesised in a narrative form.

Results: Six studies of the 232 titles identified and screened were included. All studies were undertaken in the United States (US), with 5 conducted post-legislation in their respective states, and 1 study conducted in states which were both pre- and post-legislation. Five studies were quantitative including 4 cross-sectional surveys, and 1 study was qualitative. Findings consistently demonstrated PCPs' overall lack of knowledge about BD, low level of comfort in discussing and managing patients in relation to dense breasts, and limited consensus on the most appropriate approach for managing women with dense breasts, particularly in relation to supplemental screening.

Conclusions: This review highlights important gaps in PCPs' understanding of BD and confidence in having discussions with women about the implications of dense breasts. It identifies the need for high-quality research and the development of evidence-based guidelines in order to better support PCPs.

Keywords: breast density; mammography; notification; legislation; primary care; systematic review

INTRODUCTION

Breast density (BD) refers to the relative amount of fibrous and glandular tissue in a woman's breasts compared with the amount of fatty tissue, as seen on a mammogram. There are four categories of breast density as classified by the Breast Imaging Reporting and Data System (BI-RADS) Atlas:¹ almost entirely fatty, scattered areas of fibroglandular tissue, heterogeneously dense, and extremely dense. The latter two categories (classified as having dense breasts) are estimated to be prevalent in 40%–50% of women in the breast screening population in the United States (US).² Dense breast tissue independently increases the risk of breast cancer³ and, through its masking effect, lowers the sensitivity of mammography which can increase the chance of a cancer going undetected.⁴ The latter may lead to a higher frequency of interval cancers, breast cancers that are diagnosed after a clear mammogram and before a woman's next mammogram.⁵

In the last decade there has been an unprecedented amount of advocacy and attention in the US surrounding the issue of breast density in relation to mammography screening.⁶ Before this time, breast density was less frequently discussed in relation to the risk of developing and being diagnosed with breast cancer. However, as a result of a largely consumer-driven movement highlighting the importance of informing women about whether they have dense breasts, with the overall intention of improving healthcare decision-making, breast density legislation has now passed in the majority of the US. Since the enactment of such legislation,⁷ women are now routinely notified of their breast density after each mammogram.

Primary care practitioners (PCPs) are at the forefront of healthcare decision-making with patients. Their understanding of, and how, they communicate about a wide range of health issues is of the utmost importance in informing patients' decisions. Breast density is now one of these many health issues. With numerous states in the US now recommending that women receive their BD notification

follow-up with primary care, PCPs along with Obstetrician-Gynaecologists and Radiologists, may be faced with BD discussions with patients without adequate support and evidence to guide them in making BD-related recommendations.⁸ While the exact role of PCPs differs across health systems internationally, in the US PCPs, Obstetrician-Gynaecologists and Radiologists play a complementary role in the notification, discussion and recommendations around BD and the issue of supplemental screening. Radiologists are required by most states to inform women of their breast density and encourage conversation with their PCP or usual physician.

The issue of breast cancer risk and supplemental screening, in particular, is not straightforward. Firstly, BD is a risk factor that is not readily modifiable, which may make it challenging for women to understand what this means for them, and for PCPs to have discussions about risk-based strategies. Furthermore, while supplemental screening with imaging modalities such as ultrasound and MRI has been shown to enhance detection of cancer in dense breasts,⁹ the evidence is lacking to support long-term outcomes in terms of the rate of advance breast cancer diagnosis and mortality.⁹⁻¹¹ The potential benefit from increased detection of cancers through supplemental screening in women with dense breasts may not outweigh the associated downsides including false positives, overdiagnosis and overtreatment of breast cancer.

It is largely unknown what impact legislation for BD notification has had on clinical practice for PCPs, in particular in relation to their knowledge about BD, how they feel about the legislation and its implications for discussions with patients, and importantly recommendations for supplemental screening. This understanding is not only of central relevance for the care of women in the US moving forward, but is gaining importance for other countries currently considering implementing similar BD legislation or widespread notification. This systematic review aims to synthesise evidence from existing studies to understand the impact of breast density notification on PCPs' knowledge, attitudes and practice implications.

METHODS

Review registration: The systematic review's protocol was prospectively registered with PROSPERO (an international prospective register of systematic reviews), registration number: CRD42020189628

Search strategy

In consultation with a literature search specialist, a comprehensive list of search terms was developed and tested for the return of potentially appropriate results (see supplementary material 1). The keywords, phrases and subjects-headings included in the database search strategy was informed by a similar systematic review on the topic of breast density notification conducted by study authors¹² and was further refined to specifically capture the population and outcomes of interest. The database search of Cinhal, Embase, Medline, Pre-Medline, PyscINFO, and PubMed was conducted from database inception to May 2020. A general search of the Cochrane Reviews database and extensive grey literature search using Google and Proquest to look for conference presentations and proceedings, dissertations and media, as well as a search in specific international grey literature databases for government publications and reports was also conducted. After removing any duplicates, the returned search results were screened by title and abstract independently by two researchers (BN and TC) for eligible articles. Study eligibility criteria (Box 1) was used by the authors to guide the selection of appropriate studies. Decisions regarding inclusion and exclusion of studies were then made independently by the same two researchers (BN and TC) and any disagreement was carefully discussed to reach consensus.

[Insert: Box 1. Systematic review eligibility criteria]

Criteria of inclusion and exclusion

Studies were included in the review if they empirically assessed the impact of breast density notification on PCPs' knowledge, perceptions, practice or recommendations. No restrictions were placed on country, year of publication or written language. Studies were excluded if they were protocols, reviews, editorials or commentaries. Studies were also excluded if they exclusively assessed the impact of breast density information or notification only on Radiologists, as the practice implications were deemed to be vastly different to those of PCPs.

Quality assessment and data extraction

All studies that met the inclusion criteria were appraised for study quality (risk of bias) by two authors (BN and TC) independently using the Joanna Briggs Institute (JBI) critical appraisal tools.¹³ Based on the scoring of the individual items used in each appropriate checklist, three categories of study quality (low, moderate, and high risk of bias) were identified according to each study's methodological characteristics. In high-quality studies (low risk of bias), the majority of criteria were fulfilled and done well, while in low-quality studies (high risk of bias), the majority of criteria were not addressed, unclear or addressed poorly.

Data from the final studies included in the review were extracted by one author (BN) into a standardised template in Excel and checked by a second author (TC). Results from the studies were synthesised in a narrative form, as the heterogeneity of the studies did not support the pooling of results.¹⁴

RESULTS

The initial search yielded 400 papers. After removal of duplicates (n=232) and screening by title and abstract, 10 papers from the search underwent full texts review. Six papers were then identified and agreed upon for final inclusion (Figure 1).

[Insert Figure 1. Flow diagram of included studies]

Characteristics of 6 included studies, are summarised in Table 1. There were 5 quantitative studies including 4 cross-sectional surveys (sample size (N) range=77-362),¹⁵⁻¹⁸ and one quasi-experimental study (N=63)¹⁹ assessing a workshop aimed at improving PCP's knowledge of BD, and increasing confidence in counselling patients about supplemental screening. The final included study was a qualitative interview study.²⁰ There were no randomised controlled trials. All studies were undertaken in the US.¹⁵⁻²⁰ Three of the 6 studies were conducted in Massachusetts^{16,19,20}, and there were no studies which included a national sample. Five of the studies^{15-17,19,20} were conducted in their respective states post-legislation, and one study¹⁸ was conducted in states which were both pre- and post-legislation. The main outcomes of interest across the studies were knowledge, attitudes and practice implications for PCPs.

Two studies^{16,20} were of higher quality with a low risk of bias; the other 4 studies^{15,17-19} had moderate to high risk of bias, as the overall quality of reporting was deemed to be low. The high-quality studies included one of the quantitative surveys¹⁶ and the included qualitative study¹⁶ (see supplementary material 2).

[Insert: Table 1. Characteristics of included studies]

Results from the studies are narratively synthesised below by PCPs' knowledge of BD notification and BD generally, PCPs' attitudes towards BD notification, and practice implications in relation to BD notification. Table 2 describes these findings in more detail by individual study.

[Table 2. Key findings summarised by knowledge, attitudes and practice implications]

PCPs knowledge of BD and BD notification laws

General awareness of BD notification laws and knowledge surrounding the topic of BD was highly variable across the studies. Two studies^{17,21} reported just over half of the sample were aware of the laws and other 3 studies^{16,18,20} indicated that the majority of the PCPs were aware of the laws. However, in two of the three studies with higher awareness of the BD notification laws, knowledge of breast cancer risk was also measured and was notably lower than awareness.^{15 18}

PCPs attitudes towards BD and BD notification laws

There were a wide range of measures used to assess PCPs attitudes towards BD notification law and the concept of BD generally. In two studies^{16,20} it was shown that PCPs had mixed feelings about BD notification laws. In the survey conducted in Massachusetts the year following BD notification enactment¹⁶ it was found that only 38% of PCPs favoured the legislation. The qualitative interview study²⁰ conducted in Massachusetts around the same time period found that there were mixed attitudes around the utility of BD laws for patients and PCPs. PCPs in this study had relatively positive attitudes about how legislation might affect patient engagement, however PCPs also noted the lack of evidence informing next steps for screening patients with dense breasts and identified stress and anxiety as a possible negative consequence of informing patients.

In terms of level of comfort about discussing and answering questions about BD, again the findings were mixed. In two survey studies conducted at similar time points following enactments of BD notification, one study found only 6% of PCPs in California described themselves as being completely comfortable,¹⁷ while the other study conducted in Massachusetts found that over 80% of PCPs indicated “some level of comfort” in having these discussions and in answering questions in relation to density.¹⁵ In Maimone et al’s survey,¹⁸ conducted across 3 states (one pre-legislation and two-post legislation) PCPs were also split in their level of “comfort” in answering questions and providing management advice for patients. In all three studies PCPs highlighted the need for further education

and training about BD and how to manage patients, with Brown et al,¹⁵ finding that PCPs were more likely to report the need for more education about BD, relative to specialists ($p < 0.0001$).

Two studies^{16,19} assessed whether PCPs felt a responsibility to counsel women about BD. In the survey study,¹⁶ attitudes were split with less than half PCPs feeling it was their responsibility to counsel patients and around a quarter being neutral or unsure, believing it was the responsibility of Radiologists or breast health providers. In the quasi-experimental study,¹⁹ in the post-intervention survey compared to the baseline survey, more PCPs and residents in the intervention group agreed or strongly agreed that it was their responsibility to counsel women about BD, however this change was not significant.

Practice implications for PCPs in relation to BD notification

A number of different practice implications for PCPs in relation to BD notification were highlighted across studies. In the qualitative study²⁰ it was found that PCPs felt that the legislation failed to contextualise BD into a broader conversation about risk factors for breast cancer, and PCPs were particularly interested in discussion about modifiable risk factors such as exercise and alcohol intake. PCPs in this study felt that Radiologists should be the first point of information about BD followed by additional questions and contextualisation of the results from PCPs. In the survey study by Khong et al,¹⁷ about a quarter of PCPs discussed performing breast cancer risk assessments themselves, while the remainder referred women to a breast health clinic when they thought a risk assessment would be beneficial.

In two of the survey studies,^{15,18} practice implications for PCPs mainly focused on the issue of discussing and recommending supplemental screening. In the study by Maimone et al,¹⁸ there was large variability in whether PCPs indicated they offered supplemental screening to every patient with dense breasts and the choice of a particular supplemental screening modality also varied

greatly, with most respondents initially choosing digital breast tomosynthesis. Cost to the individual patient and breast cancer risk model results were the most common factors which most heavily influenced PCPs' decision to suggest supplemental imaging. In the study by Brown et al,¹⁵ there was a mix of responses for how they would proceed with management with 49% respondents feeling it necessary to order supplemental ultrasound, 7% supplemental breast MRI and the remaining 42% continuing routine screening or gave no clear recommendations. For the same women with heterogeneously dense breasts, the numbers followed a similar trend (59%, 3% and 13%, respectively).

It was flagged in a number of studies^{16-18,20} that PCPs would value additional support and resources to help alleviate confusion and improve the process of counselling patients about BD and supplemental imaging, including additional data and literature for PCPs, and patient information videos or pamphlets.

DISCUSSION

A small literature base exists from which to assess the impact of breast density information and notification on PCPs in clinical practice. Studies evaluating this issue are mostly low to moderate quality, with the majority being surveys with modest response rates conducted in the US with convenience samples. All but one of the studies were conducted in their respective states in the post-legislation period, with the other study not describing differences between states in the results despite being conducted across 3 states with varying pre- and post-legislation periods. Despite the small number of studies, findings from this systematic review highlight PCPs' overall lack of knowledge about BD. Although PCPs in states where BD legislation had been enacted the longest seemed to indicate greater awareness of BD and BD notification laws, there was still limited knowledge of breast cancer risk. Importantly, finding across the studies also highlighted the low level

of comfort in discussing and managing patients in relation to dense breasts, and limited consensus on the most appropriate approach for managing women with dense breasts. This review points to the need for high-quality research to assess the impact of BD notification on PCPs and how best to discuss the implications of having dense breasts with women.

Uncertainty and variability on whether PCPs should discuss and recommend risk-based strategies or only offer supplemental screening was shown in this review. Since discussion about widespread BD legislation began over a decade ago in the US, the core of the BD notification controversy has largely been focused on whether or not to offer supplemental screening and if so, what type, to who and what frequency.²² Given the limited consensus in this area¹¹ and lack of guidelines, outside of Obstetrician-Gynaecologists and Radiologists, the ordering of supplemental screening modalities for women with dense breasts may be left up to the discretion of the PCP in individual consultations with their patients. Findings from the included studies highlight the need for the current uncertainty and variability around recommendations for supplemental screening to be factored into guidelines for PCPs. In settings where BD is not routinely notified, any contemplated change to potentially systematically notify women about their BD should engage PCPs, as well as Obstetrician-Gynaecologists and Radiologists, as key stakeholders in the decision about such notification. In two of the included studies^{16,20}, PCPs were split in support for BD notification legislation noting they were concerned about the current lack of evidence to inform decision-making for next steps and about providing BD information to patients without a clear course of action. This further highlights the need to involve PCPs in the initial decision-making process as well as the co-designing of future research in this area and management strategies.

Additional training opportunities for PCPs may also help to ensure they are provided with education and support for understanding BD, having discussions and managing women with dense breasts.

Although countries outside of the US do not currently have BD notification through population-

based screening programs, many private screening services in these countries are notifying women about their BD. Furthermore, given the recent developments in the US, there is now growing pressure from key breast cancer advocacy groups to inform women of their BD on a more wide-scale level.²³ Universally, PCPs will need to become more aware and receive training surrounding the issue of BD, the inconsistencies in current evidence and the implications this has for women to be able to have confidence in discussions around these topics. For now, PCPs discussions and future research could be best directed towards discussion of women's individualised risk factors and the possible benefits and trade-off for women in regard to options for supplemental screening.

This review has important strengths and limitations. First and foremost, this is the first systematic review to synthesise the impact that BD notification and legislation has had specifically on PCPs. This timely contribution to the literature highlights the need for further research and support for PCPs as they have been shown to be a crucial source of information and support for women in this area.^{20,24}

The review has been reported in accordance with the criteria in the PRISMA statement for systematic reviews (see supplementary material 3). Due to the variability of the measures used and reported outcomes in the included studies, authors were unable to conduct a meta-analysis and pool the effects of the data, and therefore the results are synthesised narratively.¹⁴ Furthermore, the small number of studies which were assessed were at various time-points in different locations across the US, so all have different notification processes and information about BD that is provided to both women and PCPs. Lastly, as all studies were conducted in the US where BD is legislated, the findings may not be generalisable to other healthcare systems. Given the lack of widespread notification in other countries it is likely that PCPs may have more limited knowledge and feel less comfortable with discussing BD and managing women with dense breasts.

CONCLUSIONS

Notwithstanding the limited literature base identified in this review, these studies highlight that PCPs are impacted by BD notification and they feel uncertain about their knowledge and how to best to manage their patients. These findings highlight important gaps in current understanding, and identify the need to develop, in consultation with PCPs and other healthcare professional involved in BD discussions and management, evidence-based guidelines. Such guidelines and inclusion of this information in training programs will enable PCPs to be better informed and supported. How PCPs discuss and manage women in relation to the issue of BD moving forward will significantly impact the benefit-to-harm trade-off of notifying women.²³ This understanding and how to improve it is not only crucial to support the current care of women in countries which have already implemented BD notification but also future care of women in countries which may be considering implementing widespread BD notification.

This would rather be HOW can we inform / train / involve PCPs and try to set up research regarding this topic in my opinion.

Author contribution statement: BN, KM and NH conceived the study. BN and TC screened title and abstracts. BN and TC completed the full text read and data extraction. BN completed the data synthesis with support from TC and NH. BN and TC conducted the risk of bias assessment. BN wrote the manuscript with input from TC, MB, RF, KM and NH.

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Box 1. Systematic Review Eligibility Criteria

	Inclusion	Exclusion
Types of studies	Empirical studies (quantitative and qualitative e.g. surveys, interviews or focus groups) that consider the impact or effect of breast density information / notification / communication / legislation for PCPs	Protocols, review papers, editorials, commentary / discussion papers
Population / types of participants	Primary care practitioners (General practitioners/Medical doctors, practice nurses/nurse practitioners, physician assistants in internal medicine, family medicine and Obstetrics & Gynaecology)	Radiologists
Types of setting	Any type of medical or community setting	
Study factor (intervention)	Breast density information / notification / communication / legislation	
Outcome factor	Knowledge, perceptions, practice or recommendations impact/effect (including awareness and concerns)	

Supplementary material 1. Search strategy

OVID Medline	OVID Pre-Medline	OVID Embase	OVID PsycINFO	CINAHL	PubMed
1. breast*.mp 2. mammogr*.mp 3. dens*.ti 4. physician*.mp 5. practition*.mp 6. provider*.mp 7. doctor*.mp 8. clinician*.mp 9. perce*.mp 10. aware*.mp 11. understand*.mp 12. knowledge*.mp 13. attitude*.mp 14. attitude*.mp 15. recommend*.mp 16. impact*.mp 17. view*.mp 18. expereinc*.mp 19. 1 or 2 20. 4 or 5 or 6 or 7 or 8 21. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 22. 3 and 19 and 20 and 21	1. breast*.mp 2. mammogr*.mp 3. dens*.ti 4. physician*.mp 5. practition*.mp 6. provider*.mp 7. doctor*.mp 8. clinician*.mp 9. perce*.mp 10. aware*.mp 11. understand*.mp 12. knowledge*.mp 13. attitude*.mp 14. attitude*.mp 15. recommend*.mp 16. impact*.mp 17. view*.mp 18. expereinc*.mp 19. 1 or 2 20. 4 or 5 or 6 or 7 or 8 21. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 22. 3 and 19 and 20 and 21	1. breast*.mp 2. mammogr*.mp 3. dens*.ti 4. physician*.mp 5. practition*.mp 6. provider*.mp 7. doctor*.mp 8. clinician*.mp 9. perce*.mp 10. aware*.mp 11. understand*.mp 12. knowledge*.mp 13. attitude*.mp 14. attitude*.mp 15. recommend*.mp 16. impact*.mp 17. view*.mp 18. expereinc*.mp 19. 1 or 2 20. 4 or 5 or 6 or 7 or 8 21. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 22. 3 and 19 and 20 and 21	1. breast*.mp 2. mammogr*.mp 3. dens*.ti 4. physician*.mp 5. practition*.mp 6. provider*.mp 7. doctor*.mp 8. clinician*.mp 9. perce*.mp 10. aware*.mp 11. understand*.mp 12. knowledge*.mp 13. attitude*.mp 14. attitude*.mp 15. recommend*.mp 16. impact*.mp 17. view*.mp 18. expereinc*.mp 19. 1 or 2 20. 4 or 5 or 6 or 7 or 8 21. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 22. 3 and 19 and 20 and 21	S1 AB breast* OR AB mammogr* S2 TI dens* S3 AB physician* OR practition* OR provider* OR doctor* OR clinician* S4 AB perce* OR AB aware* OR AB understand* OR AB knowledge* OR AB attitude* OR AB pract* OR AB recommend* OR AB impact* OR AB view* OR AB experienc* S5 S1 AND S2 AND S3 AND S4	(((((breast*[Title]) OR mammogr*[Title])) AND dens*[Title]) AND (((((physician*[Title/Abstract]) OR practition*[Title/Abstract]) OR provider*[Title/Abstract]) OR doctor*[Title/Abstract]) OR clinician*[Title/Abstract])) AND (((((((perce*[Title/Abstract]) OR aware*[Title/Abstract]) OR understand*[Title/Abstract]) OR knowledge*[Title/Abstract]) OR attitude*[Title/Abstract]) OR pract*[Title/Abstract]) OR recommend*[Title/Abstract]) OR impact*[Title/Abstract]) OR view*[Title/Abstract]) OR experienc*[Title/Abstract])

Supplementary material 2. Study quality assessed using JBI critical appraisal checklists*

Checklist for Cross-sectional (Prevalence) Studies (9-items)											
Study (author, year)	Checklist items										Overall study quality†
	<i>Was the sample frame appropriate to address the target population?</i>	<i>Were study participants sampled in an appropriate way?</i>	<i>Was the sample size adequate?</i>	<i>Were the study subjects and the setting described in detail?</i>	<i>Was the data analysis conducted with sufficient coverage of the identified sample?</i>	<i>Were valid methods used for the identification of the condition?</i>	<i>Was the condition measured in a standard, reliable way for all participants?</i>	<i>Was there appropriate statistical analysis?</i>	<i>Was the response rate adequate, and if not, was the low response rate managed appropriately?</i>		
Brown et al, 2019	+	-	?	+	+	N/A	+	+	+		Moderate
Gunn et al, 2018	+	+	?	+	+	N/A	+	+	+		High
Khong et al, 2015	+	+	?	-	+	N/A	+	+	+		Moderate
Maimone et al, 2017	+	+	?	+	+	N/A	+	?	+		Moderate
Checklist for Quasi-Experimental Studies (9-items)											
	<i>Is it clear in the study what is the 'cause' and what is the 'effect' (i.e. there is no confusion about which variable comes first)?</i>	<i>Were the participants included in any comparisons similar?</i>	<i>Were the participants included in any comparisons receiving similar treatment/care other than the exposure or intervention of interest?</i>	<i>Was there a control group?</i>	<i>Were there multiple measurements of the outcome both pre and post the intervention/exposure?</i>	<i>Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?</i>	<i>Were the outcomes of participants included in any comparisons measured in the same way?</i>	<i>Were outcomes measured in a reliable way?</i>	<i>Was appropriate statistical analysis used?</i>		
Casas et al, 2017	+	?	?	+/?	?	?	?	-	+/?		Low
Checklist for Qualitative Research (10-items)											
	<i>Is there congruity between the stated philosophical perspective and the research methodology?</i>	<i>Is there congruity between the research methodology and the research</i>	<i>Is there congruity between the research methodology and the methods used to collect data?</i>	<i>Is there congruity between the research methodology and the representation and analysis of data?</i>	<i>Is there congruity between the research methodology and the interpretation of results?</i>	<i>Is there a statement locating the researcher culturally or theoretically?</i>	<i>Is the influence of the researcher on the research, and vice-versa, addressed?</i>	<i>Are participants, and their voices, adequately represented?</i>	<i>Is the research ethical according to current criteria or, for recent studies, and is there evidence of ethical approval by an appropriate body?</i>	<i>Do the conclusions drawn in the research report flow from the analysis, or interpretation, of the data?</i>	

		<i>question or objectives?</i>									
Klinger et al, 2016	-	+	+	+	+	+	-	+	+	+	High

*The Joanna Briggs Institute. Critical Appraisal Tools. <https://joannabriggs.org/critical-appraisal-tools>.

†As decided on by study authors based on the explicit checklist items and other important study factors.

Supplementary material 3. PRISMA Reporting Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	53
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	5
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6 (Box 1)
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	6 (Supp. 1)
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	6
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	6-7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7

Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	7
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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	7 (Figure 1)
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	7-8 (Table 1)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	8 (Supp. 2)
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	8-11 (Table 2)
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	8-11
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	11-12
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	13
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13-14
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	14

Table 1. Characteristics of included studies

Study (author, year)	State	Pre or Post implementation of BD notification / legislation	Study aims	Study design	Sample	Setting	Main outcome measures*	Overall study quality†
Quantitative studies								
Brown et al, 2019	Sample was primarily from New York, however a few participants were from a number of other states (exact states not explicitly provided)	Post	To access physician views about breast density and their practices for breast cancer screening of women with dense breasts in light of breast density laws.	Cross-sectional online and hard-copy survey	N=155; PCPs (n=65) radiologists (n=42) n=6 geriatrics (n=6) gynecologists (n=26) n=14 other (n=14) missing (n=2)	Online, faculty meetings, and radiology conference in New York City	<p>Knowledge: assessed by asking whether they were aware of the BD laws in the state in which they practiced and whether they were able to correctly identify the 2–5 times increased risk of breast cancer associated with dense breasts.</p> <p>Attitudes: assessed through three questions: 1) comfort level discussing BD, 2) self-reported frequency of discussions about BD with women, and 3) perceived need for more education about BD.</p> <p>Practice implications: assessed by examining two hypothetical case scenarios regarding supplemental imaging for women with dense breasts.</p>	Moderate
Casas et al, 2017	Massachusetts	Post	To improve providers' knowledge about breast density risks and notification legislation and to increase confidence in counseling patients about supplemental imaging.	Quasi-experimental study including a pre/post survey	N=65 provider intervention group (n=13) provider referent group (n=21) residents (n=31): PCPs (n=14) radiologists (n=17) *no resident referent group	Workshop at Boston University Medical Center	<p>Knowledge: assessed by questions developed based on the results of a needs assessment conducted in the general internal medicine section, which showed that none of the 82 providers surveyed could identify the required components of the Massachusetts notification and less than half could identify that no current guidelines recommended the use of supplemental screening tests based solely on a finding of dense breasts.</p> <p>Attitudes: assessed by a range of questions from a review of the literature and in accord with the study's learning objectives.</p>	Low
Gunn et al, 2018	Massachusetts	Post	To describe the perspectives about the breast density legislation among PCPs	Cross-sectional online survey	N=80 PCPs	Online administered to two safety net hospitals in Boston Massachusetts	<p>Knowledge: assessed by 4 questions including 2 questions in relation to a patient vignette, response options for each question varied.</p>	High

			practicing in two Massachusetts safety-net hospitals.				<p>Attitudes: assessed by 3 questions with the response options on a Likert scale from strongly disagree to strongly agree.</p> <p>Impact on clinical practice: assessed by 3 questions with the response options on a Likert scale from strongly disagree to strongly agree. 4 open-ended questions elicited additional comments and concerns about BD legislation and inquired what support providers felt was needed to assist them in dealing with issues arising from the new law.</p>	
Khong et al, 2015	California	Post	To investigate primary physician awareness of the California Breast Density Notification Law and its impact on primary care practice.	Cross-sectional online survey	N=77; internal medicine (n=30) family medicine (n=36) OBG (n=7) missing (n=4)	Online administered to a single academic medical facility	<p>Awareness: assessed using yes/no question.</p> <p>Impact on patient concerns: assessed using yes/no, multiple-choice and select all questions.</p> <p>Physician comfort level in discussing issues of BD: assessed using yes/no, multiple-choice and Likert-style questions.</p>	Moderate
Maimone et al, 2017	Minnesota, Arizona and Florida	Pre (Florida) / Post (Minnesota and Arizona)	To survey primary care providers in an effort to gauge awareness of and familiarity with dense breast legislation and supplemental screening.	Cross-sectional online survey	N=362; internal family medicine (n=214) family medicine (n=112) OBG (n=36)	Online administered to Mayo Clinic (Minnesota, Arizona, Florida and satellite clinics)	<p>Knowledge: assessed by a range of common questions provided to all participants. 6 additional more detailed questions were presented to those who endorsed receiving inquiries from their patients regarding BD.</p>	Moderate
Qualitative study								
Klinger et al, 2016	Massachusetts	Post	To understand perspectives on BD and inform best practices are implementation	Qualitative interviews	N=7 PCPs	Face-to-face or telephone with women recruited from Brigham and Women's Hospital-affiliated practices	Qualitative understanding of BD, legislation, and implications and preferred methods for delivering BD information to women.	High

*as reported in the paper.

†As decided on by study authors based on the explicit checklist items in The Joanna Briggs Institute Critical Appraisal Tools (<https://joannabriggs.org/critical-appraisal-tools>) and other important study factors.

Table 2. Key findings summarised by knowledge, attitudes and practice implications

Study (author, year)	PCPs knowledge of BD and BD notification laws	PCPs attitudes towards BD and BD notification laws	Practice implications for PCPs in relation to BD notification
Quantitative studies			
Brown et al, 2019	<ul style="list-style-type: none"> - 48% of respondents (PCPs and specialists) were unaware of their state's BD laws - 62% were unaware of the increased risk of breast cancer associated with dense breasts - Compared to specialists, PCPs were: less aware of BD laws ($p<0.0001$) and less knowledgeable about the increase in breast cancer risk with dense breasts ($p<0.0001$) 	<ul style="list-style-type: none"> - 67% of all respondents felt they needed more education about BD and supplemental imaging, with 18% reporting they were "not comfortable" answering patients BD questions - PCPs were less likely than specialists to report feeling "comfortable" answering patients BD questions ($p<0.0001$), less likely to have discussions about BD with their patients "often" ($p<0.0001$) and more likely to report the need for more education about BD, relative to specialists ($p<0.0001$) 	<p>Case scenario: 50-year-old woman with a BIRADS1 (normal) screening mammogram and extremely dense breasts:</p> <ul style="list-style-type: none"> - 49% of all respondents would order supplemental US (38% immediately, 11% at next screening), 7% would order a supplemental MRI, 26% would continue routine screening and 16% had no clear recommendations <p>When case scenario had heterogeneously dense breast tissue:</p> <ul style="list-style-type: none"> - 59% would order supplemental US (50% immediately), 3% a supplemental MRI, 26% would continue routine screening, and 13% had no clear recommendations
Casas et al, 2017	<ul style="list-style-type: none"> - PCP's knowledge scores were significantly higher postintervention compared to baseline ($p<0.0001$), no further change at 3-month follow-up ($p=0.06$) - Primary care residents had significantly higher knowledge scores postintervention compared to baseline ($p<0.0001$) 	<ul style="list-style-type: none"> - Compared to baseline, more PCPs (intervention group) post-intervention agreed/strongly agreed with 3 attitudes regarding responsibility to counsel women about BD, comfort in counselling women about BD (sig increase $p=0.03$) and knowledge of referring women with dense breasts for supplemental screening ($p=0.02$) 	Not assessed.
Gunn et al, 2018	<ul style="list-style-type: none"> - 80% of PCPs were somewhat/very familiar with the Massachusetts legislation - PCPs could not identify all eight components of the specific mandated elements for notification - 41% correctly identified that no current guidelines recommend supplemental screening solely based only on dense breasts - 57% responded to the scenario knowledge question correctly 	<ul style="list-style-type: none"> - PCPs' perceptions of the BD mandate varied – 38% favoured the legislation, 38% did not and 24% were neutral - 25% of PCPs felt the legislation would promote informed decision-making about breast cancer screening - 43% felt counselling women about BD is a PCP's responsibility, 29% were neutral, and 28% felt it was the responsibility of other clinical specialties (e.g., radiologists, breast health providers) 	<p>When asked whether BD notification laws has changed the discussion of mammography results with patients:</p> <ul style="list-style-type: none"> - 42% responded yes, 28% no and 29% neutrally - 49% did not feel prepared to discuss requests about dense breasts - 85% were somewhat/ very interested in further training on how to manage women with dense breasts
Khong et al, 2015	<ul style="list-style-type: none"> - 49% of PCPs were not aware of the BD legislation before taking the survey 	<ul style="list-style-type: none"> - 6% of PCPs described themselves as "completely comfortable" discussing BD 	<ul style="list-style-type: none"> - 49% of PCPs reported rarely answering patient questions regarding BD letter, and 20% reported never answering questions related to BD - More female PCPs (43%) compared with male PCPs (19%) noticed a change in patient concern about BD in the past 6 months ($p=0.05$) - 32% indicated referring patients to a breast health clinic to discuss questions related to their BD after a mammogram - When participants thought a BC risk assessment would be beneficial, 26% reported performing it themselves, whereas 74% referred to a breast health clinic - 75% were interested in attending a BD educational presentation
Maimone et al, 2017	<ul style="list-style-type: none"> - 68% respondents were aware of BD notification laws, 32% had no knowledge of this legislation - 41% of residents and fellows, 30% nurse practitioners and physician assistants, and 27% staff physicians were unaware of BD laws - 21% of respondents were unfamiliar with the concept of supplemental screening 	<ul style="list-style-type: none"> - Comfort level in answering questions about BD and providing management advice varied considerably amongst PCPs: 17% very comfortable, 36% moderately comfortable, 30% slightly comfortable, and 17% not comfortable 	<ul style="list-style-type: none"> - 26% of PCPs indicated they offered examination to every patient with dense breasts, 47% offered it dependent on unique patient or risk factors, 15% did not offer supplemental examinations, 11% other - Choice of supplemental screening modality varied greatly – most (32%) chose digital breast tomosynthesis

			<ul style="list-style-type: none"> - Costs to the patient (20%) and breast cancer risk models (19%) were the most common choices for influencing factors in suggesting supplemental imaging - Solution for alleviating confusion/improvement of counselling: a synopsis of available data/literature for referring providers, followed closely by informational pamphlets/documents for patients.
Qualitative study			
Klinger et al, 2016	<ul style="list-style-type: none"> - Overall, PCPs indicated that they were knowledgeable about the BD law 	<ul style="list-style-type: none"> - PCPs had mixed attitudes about utility of BD laws for patients and providers: PCPs had relatively positive attitudes about how legislation might affect patient engagement, but noted the main limitation as the failure to contextualize BD into a broader conversation about risk factors for breast cancer - PCPs noted and expressed concern over lack of evidence informing next steps for screening patients with dense breasts, and were concerned about providing information without a clear course of action - PCPs frequently identified stress and anxiety as possible negative consequences of informing patients - PCPs recognised the complexity and trade-offs resulting from limitations of healthcare coverage 	<ul style="list-style-type: none"> - Some PCPs thought women preferred to hear about BD from their PCP - Most PCPs thought the information should be reported first by the radiologist face-to-face, with the PCP available to answer additional questions/contextualise the results - PCPs noted that a video might be a good way to present this information and should include information about overall risk - PCPs were particularly interested in discussion of modifiable risk factors like exercise and alcohol intake