The Impact of Breast Density Notification Laws on Supplemental Breast Imaging and Breast Biopsy

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BACKGROUND: Dense breast tissue increases breast cancer risk and lowers mammography sensitivity, but the value of supplemental imaging for dense breasts remains uncertain. Since 2009, 37 states and Washington DC have passed legislation requiring patient notification about breast density.

OBJECTIVE: Examine the effects of state breast density notification laws on use of supplemental breast imaging and breast biopsies.

DESIGN: Difference-in-differences analysis of supplemental imaging and biopsies before and after notification laws in 12 states enacting breast density notification laws from 2009 to 2014 and 12 matched control states. Supplemental imaging/biopsy within 6 months following an index mammogram were evaluated during four time periods related to legislation: (1) 6 months before, (2) 0–6 months after, (3) 6–12 months after, and (4) 12–18 months after.

PARTICIPANTS: Women ages 40–64 years receiving an initial mammogram in a state that passed a breast density notification law or a control state.

INTERVENTION: Mandatory breast density notification following an index mammogram.

MAIN MEASURES: Use of breast biopsies and supplemental breast imaging (breast ultrasound, tomosynthesis, magnetic resonance imaging, scintimammography, and thermography), overall and by specific test.

KEY RESULTS: Supplemental breast imaging and biopsy increased modestly in states with notification laws and changed minimally in control states. Adjusted rates of supplemental imaging and biopsy within 6 months of mammography before legislation were 8.5% and 3.1%, respectively. Compared with pre-legislation in intervention and control states, legislation was associated with adjusted difference-in-differences estimates of + 1.3% ($p < 0.0001$) and + 0.4% ($p < 0.0001$) for supplemental imaging and biopsies, respectively, in the 6–12 months after the law and difference-in-differences estimates of + 3.3% ($p < 0.0001$) and + 0.8% ($p < 0.0001$) for supplemental imaging and biopsies, respectively, 12–18 months after the law.

CONCLUSIONS: As breast density notification laws are considered, policymakers and clinicians should expect increases in breast imaging/biopsies. Additional research is needed on these laws' effects on cost and patient outcomes.

KEY WORDS: breast cancer; cancer screening; health communication; health policy; health services research.

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INTRODUCTION

Breast density refers to the comparative amounts of fibrous, glandular, and fatty tissue evident in the breast on mammography. Higher breast density indicates more fibrous and glandular tissue than fat. More than 40% of women aged 40–74 years have dense breast tissue (heterogeneously dense or extremely dense), particularly frequent among younger women.[1, 2] Higher breast density is associated with increased risk of breast cancer,[3, 4] with breast cancer risk for women with extremely dense breast tissue more than four times higher than for those with mostly fatty breast tissue.[5] Higher breast density is also associated with lower sensitivity of mammography for detecting breast cancer.[6]

Because dense breasts have implications for both breast cancer risk and the accuracy of mammograms, some have advocated for educating patients about their breast density. In 2009, Connecticut became the first state in the USA to enact a breast density notification law.[7] Connecticut's law requires notifying women with dense breasts about their breast density, the decreased sensitivity of mammography, and about supplemental breast imaging. Since then, 37 other states have passed similar laws,[8] and in February 2019 the U.S. Congress passed federal breast density notification legislation.[9]

The value of additional imaging for women with dense breast tissue is uncertain as evidence that supplemental screening improves clinical outcomes is lacking.[10, 11] Prior research suggests that supplemental ultrasonography, MRI, and tomosynthesis may identify additional cancers (4.4/1000, 3.5–28.6/1000, and 1.4–2.5/1000 examinations, respectively) while also increasing false-positive results.[11] Supplemental breast ultrasounds have been shown to lead to unnecessary biopsies.[12, 13] Current guidelines from the United States

Preventive Services Task Force (USPSTF) state that there is insufficient evidence to recommend supplemental imaging for women with dense breasts.[14] A comparative modeling study concluded that supplemental breast ultrasonography for women with dense breasts and otherwise average risk was not cost-effective, producing limited health benefits while greatly increasing expenditures.[15] In studies conducted in states that have implemented breast density legislation, these laws have been associated with increased use of breast ultrasounds or magnetic resonance imaging (MRI).[16–20] These studies primarily assessed one or both of these two supplemental imaging procedures, although some additional modalities are also available, and did not evaluate downstream breast biopsies or estimate incident breast cancers.

In this study, we used a difference-in-differences analysis to investigate the association of breast density notification laws in the USA from 2009 to 2014 with the utilization of supplemental breast imaging and breast biopsies. We compared use of supplemental breast imaging and breast biopsies in states that enacted laws versus matched control states without breast density notification laws. We hypothesized that states with breast density notification laws would experience larger increases in supplemental breast imaging and breast biopsies than states without laws. Additionally, we conducted an exploratory analysis to investigate the impact of breast density notification laws on breast cancer diagnoses.

METHODS

We used the Thomson Reuters' MarketScan® database from 2008 to 2015, which includes claims data for individuals with private employer-sponsored insurance.[21]

Breast Density Notification States and Matched Controls

We studied 12 states that passed notification laws from 2009 to 2014 (Table 1). For each state with legislation, we identified a nearby control state without breast density notification legislation at that time with similar U.S. Census population characteristics (median household income in 2014 dollars and proportions of the population living below the federal poverty level, who were high school graduates, and of white or black race/ethnicity) and similar baseline mammography rates from the 2014 Behavioral Risk Factor Surveillance Survey.[22] While no two states are exactly alike, matching each notification state with a close geographic neighbor sharing a similar profile of U.S. Census population characteristics increased the likelihood of comparable populations in breast density notification and control states. After matching, the group profiles of breast density notification states and control states were similar (Appendix, Table 4). Breast density notification states, controls, and key aspects of each state's notification law are listed in Table 1. The Connecticut law also required insurance plans to cover breast ultrasounds.

Study Population

We identified women aged 40–64 years who lived in legislation or control states and had an index mammogram during any of four distinct time periods around when the legislation went into effect: (1) 6 months before, (2) 6 months after, (3) 6–12 months after, and (4) 12–18 months after. Each control states' time periods corresponded with its matched legislation state. MarketScan data were available through 2015; therefore, our analysis is limited to states that enacted notification laws by January 1, 2014, to permit a complete evaluation over at least three time periods following the law. We required women to be enrolled in an insurance plan with no mammogram in the 6 months before their index mammogram. We identified index mammograms using Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) procedure codes for two-dimensional mammograms or breast tomosynthesis. We included codes for both screening and diagnostic mammograms because standard quality metrics[23] incorporate both and procedure codes may not reliably distinguish screening and diagnostic mammograms.[24] We included tomosynthesis as index mammograms because of its increased use for breast cancer screening in recent years.[25–27] Tomosynthesis exams represented less than 3% of index mammograms in our study, and additional analyses (not shown) excluding tomosynthesis as index mammograms produced similar results.

Supplemental Breast Imaging, Breast Biopsies, and Incident Breast Cancers

We used CPT, HCPCS, and ICD-9 codes to identify supplemental breast imaging and breast biopsies performed within 180 days of an index mammogram (Appendix, Table 5). Supplemental imaging included breast ultrasound,[28, 29] MRI,[12] tomosynthesis,[30–32] scintimammography,[33] and thermography.[34, 35]

We used a modified version[36] of a previously validated algorithm[37] to identify incident breast cancers diagnosed within 180 days of an index mammogram from health claims data. This algorithm assesses procedure and diagnosis codes for screening tests, biopsies, breast surgeries, and radiation to identify incident breast cancers (Appendix, Table 5). Because of the limitations of identifying incident cancers using administrative data, we consider these analyses exploratory.

Statistical Analyses

We performed difference-in-differences (DID) logistic regression analyses using generalized linear models incorporating maximum likelihood estimation.[38–40] The independent variables included breast cancer notification law in effect, time period of index mammogram (6 months before the law, 0–6 months after law, 6–12 months after law, or 12–18 months after law), and the interaction of law by time period (our key coefficient of interest). We modeled any supplemental imaging, each individual test,

Table 1 Breast Density Notification States, Control Sates, and Content* of Breast Density Notification Laws by State, 2009–2014

Breast density notification states	Date law effective	Control states	Content of breast density notification laws				
			Decreased mammography sensitivity[a]	Increased risk of cancer[b]	Supplemental imaging[c]	Breast ultrasound and MRI[d]	Mandatory insurance coverage[e]
Connecticut	Oct 1, 2009	New Hampshire	+		+	+	+
Texas	Sept 1, 2011	Oklahoma	+		+		
Virginia	Jun 1, 2012	DC	+	+	+		
New York	Jan 19, 2013	Vermont	+	+	+		
California	Apr 1, 2013	Washington	+	+			
Alabama	Aug 1, 2013	Mississippi	+	+	+		
Maryland	Oct 1, 2013	Delaware	+	+			
Oregon	Jan 1, 2014	Colorado	+	+	+		
Nevada	Jan 1, 2014	Montana	+	+	+		
Hawaii	Jan 1, 2014	Alaska	+	+	+		
Tennessee	Jan 1, 2014	Kentucky	+	+			
North Carolina	Jan 1, 2014	Georgia	+	+			

*Notes: *Notification law requires: [a]mammography has a decreased sensitivity to detect breast cancer in women with dense breast tissue, [b]information about how breast density increases risk for breast cancer, [c]mention of the possibility of supplemental screening, [d]specific mention of breast ultrasound and MRI as supplemental breast imaging tests, [e]law includes mandatory insurance coverage for supplemental breast ultrasounds. Generic notifications (regardless of breast density) are provided to all women in CT, TX, and MD. All others could have different text depending on breast density.*

breast biopsies, and incident breast cancers. The DID study design compares the different trends in supplemental imaging over time between states with and without breast density notification laws. Although we lacked specific data about whether a supplemental imaging study was ordered because of dense breasts or to evaluate a mammographic abnormality, trends in the latter are likely to remain stable over time and the DID estimate can be interpreted as a difference in supplemental imaging related to the legislation.

All models were adjusted for patient age at the time of index mammogram, region (Northeast, South, West; no states were in the Midwest), health plan type, enrollee's relationship to the primary insurance beneficiary (employee, spouse, child), and index mammogram year. Variables were categorized as in Table 2. Patients for whom health plan type was missing were categorized separately (no other variables had missing data). We calculated covariate-adjusted estimates of the proportion with each dependent variable for patients in states with and without breast density legislation for each time period.

Supplemental imaging for women with dense breasts may not be covered by insurance, particularly if such coverage is not mandated by law. Lack of insurance coverage would limit our ability to ascertain use of supplemental imaging using insurance claims. Therefore, we also conducted analyses after stratifying by (1) women in Connecticut and New Hampshire (control state) versus (2) women in all other states because Connecticut's law also mandated that private health insurance cover supplemental breast ultrasounds for women with dense breast tissue.

Two-sided p values < 0.05 were considered statistically significant. Analyses were performed with SAS statistical software, version 9.2 (SAS Institute, Inc., Cary, NC). The study protocol was considered exempt by the Harvard Medical School Institutional Review Board.

RESULTS

Table 2 includes characteristics of the study population in the 6 months preceding legislation for women in states with breast density laws and control states. More women had an index mammogram in states with breast density notification laws ($n = 2{,}600{,}370$) than in matched control states ($n = 920{,}785$), consistent with the larger populations in states with versus without legislation.

Any Supplemental Breast Imaging

During the 6 months before breast density laws were effective, the adjusted proportion of women with at least one supplemental breast imaging test within 6 months of mammography (Fig. 1, panel A) was similar in breast density notification and control states (8.5%). In legislation states, the adjusted proportion of women receiving supplemental breast imaging increased to 9.3% 0–6 months after the law, remained stable at 9.4% 6–12 months after the law, and increased to 10.1% 12–18 months after the law. In control states, there was a small increase in the adjusted proportion of women with supplemental breast imaging (9.4%) 0–6 months after the law but an overall decrease over time (8.1% 6–12 months after the law and 6.8% 12–18 months after the law). Compared with the 6 months before legislation, supplemental imaging rates in legislation and control states differed both in the 6–12 months immediately following the laws (difference-in-differences estimate + 1.3%, $p < 0.0001$) and the 12–18 months after the laws (difference-in-differences estimate + 3.3%, $p < 0.0001$).

Breast Biopsy

During the 6 months before breast density laws were effective, the adjusted proportion of women undergoing breast biopsy in

Table 2 Study Cohort Characteristics of Women Receiving Index Mammograms, 2009–2014

Patient characteristics	Breast density notification states		Control states	
	$n = 2,600,370$		$n = 920,785$	
	No.	%	No.	%
Age (years)				
40–44	433,990	16.7	147,678	16.0
44–49	507,312	19.5	170,207	18.5
50–54	589,408	22.7	202,963	22.0
55–59	572,904	22.0	208,318	22.6
60–64	496,756	19.1	191,619	20.8
Region				
Northeast	601,403	23.1	38,515	4.2
South	1,231,210	47.3	667,981	72.5
West	767,757	29.5	214,289	23.3
Type of health plan*				
Preferred provider organization	1,710,440	65.8	471,796	51.2
Health maintenance organization	337,641	13.0	82,223	8.9
Point-of-service plan	144,058	5.5	108,412	11.8
Consumer-driven or high-deductible health plan	216,087	8.3	222,307	24.1
Comprehensive	29,036	1.1	12,916	1.4
Relation to employee				
Employee	1,623,327	62.4	625,336	67.9
Spouse	976,028	37.5	295,161	32.1
Child/other	1015	0.0	288	0.03

*Notes: *Point-of-service (POS) includes non-capitated POS and POS w/ capitation. Health Maintenance Organization includes both HMO health plans and Exclusive Provider Organizations, which closely resemble HMO plans except their services are not paid by the plan on a capitated basis. None of the states that passed breast density notification laws that went into effect from 2009 to 2014 and none of the control states were located in the Midwest region.*
Source: Authors' analysis of data for 2008–2015 from the Truven Health MarketScan Commercial Claims and Encounters database.

the 6 months after an index mammogram (Fig. 1, panel B) was similar in legislation states and in control states (3.2%). The proportion of women with biopsies following an index mammogram in legislation states and control states differed both in the 6–12 months following the laws (difference-in-differences estimate + 0.4%, $p < 0.0001$) and in the 12–18 months after legislation (difference-in-differences estimate compared with pre-law + 0.8%, $p < 0.0001$) (Table 3).

Incident Breast Cancers

In exploratory analyses, we observed no statistically significant differences in the adjusted proportions of women newly diagnosed with breast cancer in states with breast density notification laws and control states in the 0–6 months and 6–12 months following the law (Table 3). There was a very small decrease in the number of incident breast cancers identified 12–18 months after the legislation.

Mandated Insurance Coverage for Supplemental Breast Imaging

In Connecticut, where insurance coverage of supplemental breast imaging for dense breasts is mandated, the adjusted proportion of women receiving supplemental breast imaging increased substantially following the legislation (Fig. 2, panel A). The adjusted proportion of women in New Hampshire (control state) with supplemental breast imaging decreased over time, resulting in an adjusted difference-in-differences in the proportion of women with supplemental imaging of + 5.0%, $p < 0.0001$, within 6 months; + 7.8%, $p < 0.0001$, by 6–12 months after the law; and + 8.6%, $p < 0.0001$, by 12–18 months after the law.

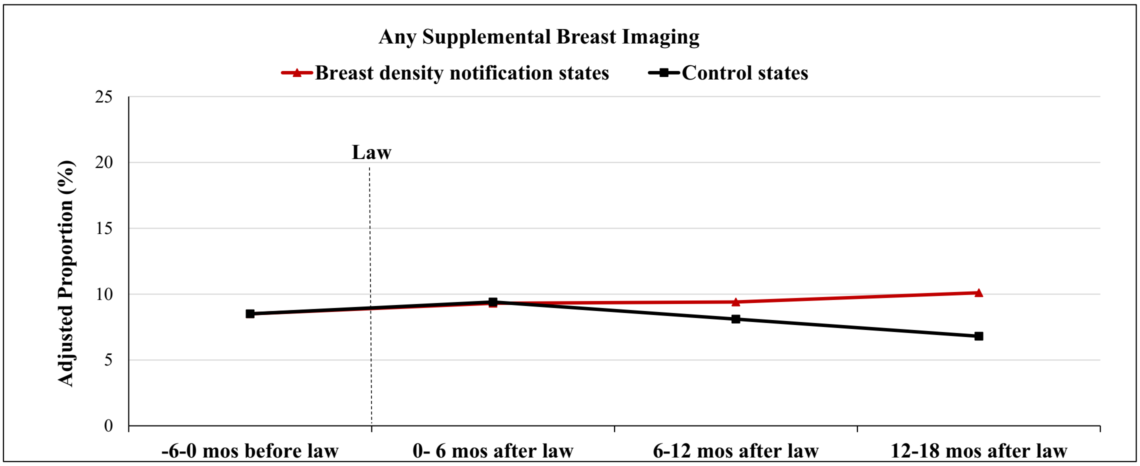
In states that implemented breast density notification laws without mandatory insurance coverage, there was a smaller increase in the adjusted proportion of women with supplemental breast imaging over time (Fig. 2, panel B). The adjusted proportion of women with supplemental imaging in states with breast density notification laws without mandatory insurance coverage differed from that in control states in the 6–12 months following the law (adjusted difference-in-differences + 0.9%, $p < 0.0001$) and in the 12–18 months after the laws (adjusted difference-in-differences + 2.0%, $p < 0.0001$) compared with the 6 months before legislation.

We observed similarly larger effects of breast density legislation on breast biopsies in Connecticut than in legislation states without insurance mandates (Fig. 3, panels A and B). We observed no association between breast density notification in Connecticut and incident breast cancers as measured in claims (data not shown).

DISCUSSION

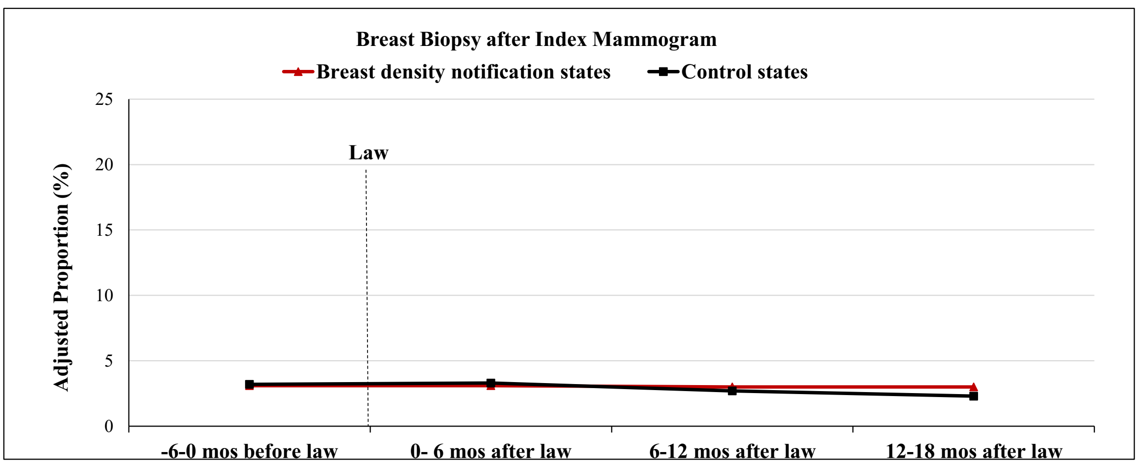
We assessed trends in use of supplemental breast imaging and breast biopsy following an index mammogram over time in states that enacted breast density notification laws compared with states without laws. We found higher proportions of women receiving supplemental breast imaging in states with breast density notification laws compared with control states during the first year after the law, with further increases during the 12–18-month period following legislation. While the proportion of women undergoing breast biopsies decreased slightly over time in notification and control states, a smaller decline was observed in states with breast density notification laws. In exploratory analyses, we observed no increases in incident breast cancers as measured from claims data in breast density notification states. These findings comparing differential trends in use of supplemental breast imaging and breast biopsies between multiple breast density notification states and control states expand on results from smaller, primarily single-state studies demonstrating that breast density notification laws were associated with increases in the use of supplemental breast ultrasounds and MRIs.

Although the observed increases in supplemental breast imaging were modest in size, since about 39.2 million mammograms are conducted in the USA each year,[41] increases of 3.3% and 0.8% by 18 months of enacting breast density notification legislation would translate to about 1.3 million additional women having supplemental imaging and 313,600 additional women having a breast biopsy procedure within 18 months by all states



a

Adjusted proportion with any supplemental breast cancer screening procedure pre-post notification law				
Time Period	**Breast density notification states (%)**	**Control States (%)**	**Difference-in-Differences (%)**	**P value for interaction of law*time period**
-6-0 mos before law	8.5	8.5	**reference**	**reference**
0- 6 mos after law	9.3	9.4	-0.11	0.34
6-12 mos after law	9.4	8.1	+1.3	<0.0001
12-18 mos after law	10.1	6.8	+3.3	<0.0001



b

Adjusted proportion with breast biopsy after index mammogram pre-post notification law				
Time Period	**Breast density notification states (%)**	**Control States (%)**	**Difference-in-Differences (%)**	**P value for interaction of law*time period**
-6-0 mos before law	3.1	3.2	**reference**	**reference**
0- 6 mos after law	3.1	3.3	-0.10	0.12
6-12 mos after law	3.0	2.7	+0.35	<0.0001
12-18 mos after law	3.0	2.3	+0.80	<0.0001

Figure 1 Adjusted* proportion of women with supplemental breast imaging and biopsy after an index mammogram pre-post breast density notification laws, 2009–2014. *Adjusted for all variables in Table 2 and year of index mammogram.

with national legislation, assuming our results can be generalized to women of all ages (these numbers may be lower if supplemental imaging and biopsy rates are lower for older women, who typically have less dense breasts). We observed larger increases 6–12 months after law and 12–18 months after law than in the first 6 months following the law. This increase over time may be related to a rising awareness among both patients and providers of the notification law, the association of breast cancer risk with breast density, the lessened sensitivity of mammography for women with dense breasts, and/or additional options for breast cancer imaging.

Connecticut's legislation included an insurance coverage mandate for supplemental breast ultrasound. The effect of legislation on rates of supplemental breast imaging in Connecticut was larger than for other states, suggesting that the impact of breast density notification laws on the use of supplemental breast

Table 3 Adjusted Proportion of Women with a Supplemental Breast Imaging Test After an Index Mammogram Pre-Post Breast Density Notification Laws, Overall and by Type of Supplemental Testing, 2009–2014

Panel A: Adjusted proportion with any supplemental breast imaging/biopsy after index mammogram pre-post notification law

	Breast density notification states				Control states			
	6 months before law (%)	0–6 months after law (%)	6–12 months after law (%)	12–18 months after law (%)	6 months before law (%)	0–6 months after law (%)	6–12 months after law (%)	12–18 months after law (%)
Any supplemental breast imaging	8.45	9.26	9.36	10.06	8.48	9.40	8.08	6.75
Ultrasound	7.06	7.89	8.10	8.79	7.26	8.07	7.10	5.86
Tomosynthesis	0.61	0.70	0.67	0.68	0.61	0.64	0.49	0.56
MRI	0.52	0.58	0.54	0.59	0.54	0.59	0.51	0.56
Other	0.74	0.71	0.81	0.89	0.53	0.66	0.62	0.66
Biopsies	3.07	3.14	2.99	3.04	3.15	3.31	2.71	2.30
Incident breast cancers	0.31	0.29	0.25	0.25	0.28	0.28	0.23	0.27

Panel B: Difference in difference estimates for any supplemental breast imaging/biopsy after index mammogram pre-post notification law

	0–6 months after law vs. 6 months before		6–12 months after law vs. 6 months before		12–18 months after law vs. 6 months before	
	(%)	*p* value	(%)	*p* value	(%)	*p* value
Any supplemental breast imaging	− 0.11	0.34	+ 1.31	< 0.0001	+ 3.34	< 0.0001
Ultrasound	+ 0.02	0.88	+ 1.20	< 0.0001	+ 3.13	< 0.0001
Tomosynthesis	+ 0.06	0.04	+ 0.18	< 0.0001	+ 0.12	0.0003
MRI	+ 0.01	0.76	+ 0.05	0.06	+ 0.05	0.10
Other	− 0.16	0.0001	− 0.003	0.93	+ 0.02	0.58
Biopsies	− 0.09	0.12	+ 0.36	< 0.0001	+ 0.82	< 0.0001
Incident breast cancers	− 0.03	0.09	− 0.007	0.68	− 0.05	0.02

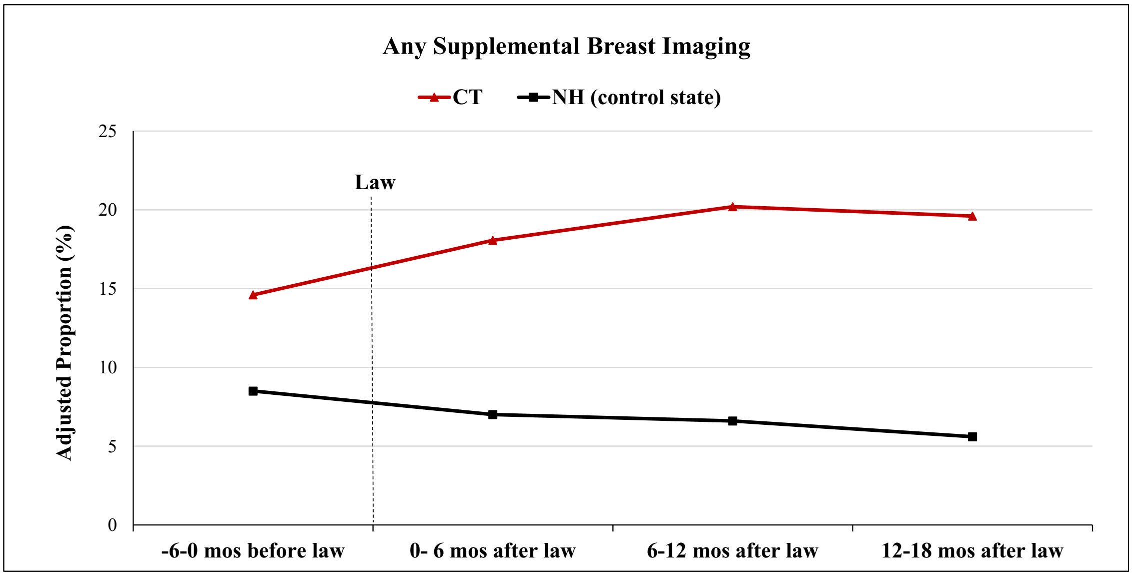
Notes: Table 3 includes supplemental imaging within 180 days following the service date of an index mammogram (2D or breast tomosynthesis). Any supplemental breast imaging includes breast ultrasound, tomosynthesis, MRI, scintimammography, and thermography. MRI refers to magnetic resonance imaging, and other includes scintimammography and thermography.
Source: Authors' analysis of data for 2008–2015 from the Truven Health MarketScan Commercial Claims and Encounters database.

imaging is amplified when coupled with mandatory insurance coverage. We also observed a greater impact on breast biopsies in Connecticut vs. other legislation states. Additional research on utilization and spending is needed as more states have mandated insurance coverage in their breast density notification laws. Our data do not allow us to differentiate supplemental imaging or biopsies performed only on women with dense breast tissue; however, our rigorous difference-in-differences design permits the estimation of variation in the performance of supplemental imaging or breast biopsies in states with mandatory breast density notification laws compared to states lacking notification laws.

While prior studies of breast density notification laws evaluated a single type of supplemental breast imaging,[16–19] we assessed five different modalities. Our results showed that ultrasounds are the predominant form of supplemental imaging, with many fewer women undergoing tomosynthesis, breast MRI, or other imaging. Supplemental breast ultrasounds in particular may produce limited health gains for women with dense breasts, since although they increase cancer detection rates, false-positive rates are high.[15] Supplemental tomosynthesis increases cancer detection rates and decreases false positives, and thus may be more cost-effective than ultrasound.[42] Few data are available about other tests, which were used infrequently in our study. Additional research is needed to assess any potential differences in biopsies or cancer detection associated with different tests as well as the cost-effectiveness of various types of supplemental imaging.

At present, no evidence demonstrates that early detection with supplemental screening improves outcomes for women with dense breasts, and a recent study found no impact of breast density legislation in Connecticut on the incidence of late-stage breast cancer.[43] Our exploratory analysis demonstrated no significant impact of breast density legislation on new breast cancer diagnoses for women with dense breast tissue. Long-term studies are needed to fully understand the extent to which the increased use of supplemental imaging and breast biopsies following breast density legislation produces benefits (breast cancer mortality reductions) versus harms (false positives and overdiagnosis as well as costs to payers and patients).

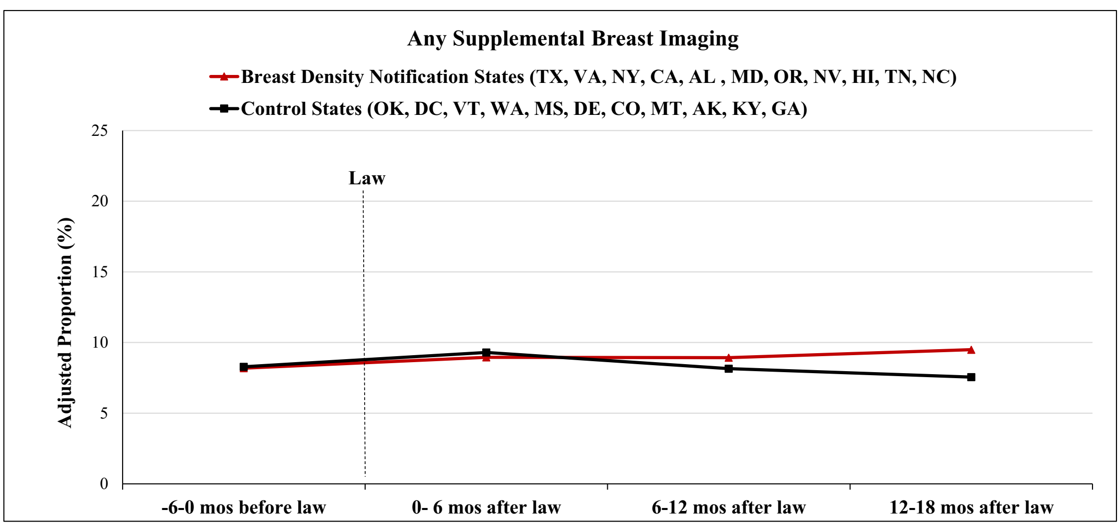
This study has several limitations. Our data included only supplemental tests that were reimbursed by insurers. If some women paid for supplemental imaging themselves, our analysis would underestimate the legislation's effect. We studied women aged 40–64 with employer-sponsored insurance; whether our findings are generalizable to older women or women with other types of health insurance requires further study. We also could not assess whether the increases in supplemental imaging were direct responses to a notification letter or greater general knowledge/understanding about breast density in notification states, nor could we determine whether patients or their clinicians prompted supplemental imaging or if there was a specific indication for supplemental imaging. Some supplemental ultrasounds we identified may have been ordered to investigate focal lesions noted on a mammogram, for example, rather than because of dense breasts. However, we would not expect rates of such diagnostic imaging to differ over time in states with versus without breast density legislation, so we would not expect their inclusion to affect our findings. Our exploratory analysis of incident breast cancers used a claims-based algorithm to identify incident breast



a

Adjusted proportion with any supplemental breast cancer screening procedure pre-post notification law

Time Period	Connecticut (%)	New Hampshire (Control state) (%)	Difference-in-Differences (%)	P value for interaction of law*time period
-6-0 mos before law	14.6	8.5	reference	reference
0- 6 mos after law	18.1	7.0	+5.0	<0.0001
6-12 mos after law	20.2	6.6	+7.8	<0.0001
12-18 mos after law	19.6	5.6	+8.6	<0.0001



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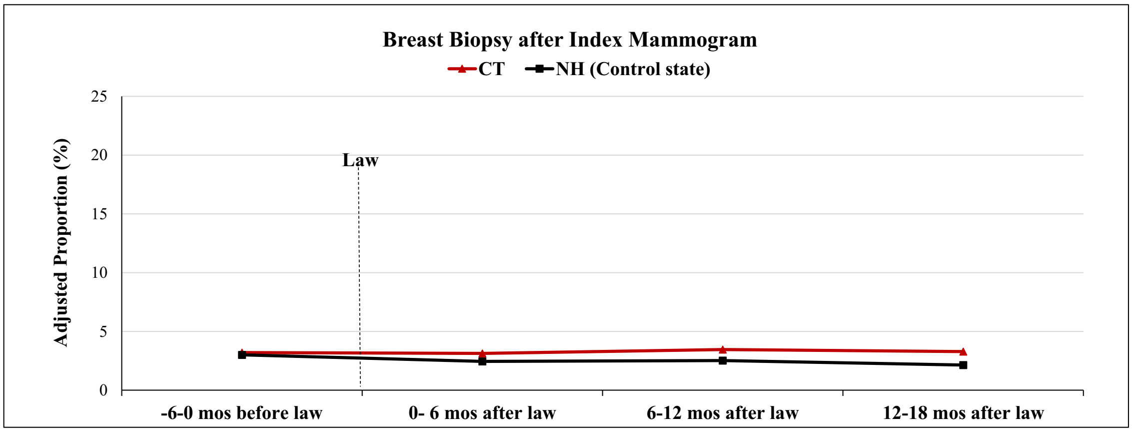
Adjusted proportion with any supplemental breast cancer screening procedure pre-post notification law

Time Period	Breast Density Notification States (TX, VA, NY, CA, AL , MD, OR, NV, HI, TN, NC) (%)	Control States (OK, DC, VT, WA, MS, DE, CO, MT, AK, KY, GA) (%)	Difference-in-Differences (%)	P value for interaction of law*time period
-6-0 mos before law	8.2	8.3	reference	reference
0- 6 mos after law	9.0	9.3	-0.2	0.03
6-12 mos after law	8.9	8.2	0.9	<0.0001
12-18 mos after law	9.5	7.6	+2.0	<0.0001

Figure 2 Adjusted* proportion of women with a supplemental breast cancer screening procedure after an index mammogram pre-post breast density notification laws, 2009–2014, stratified by presence of mandate requiring ultrasound coverage. *Adjusted for all variables in Table 2 and year of index mammogram.



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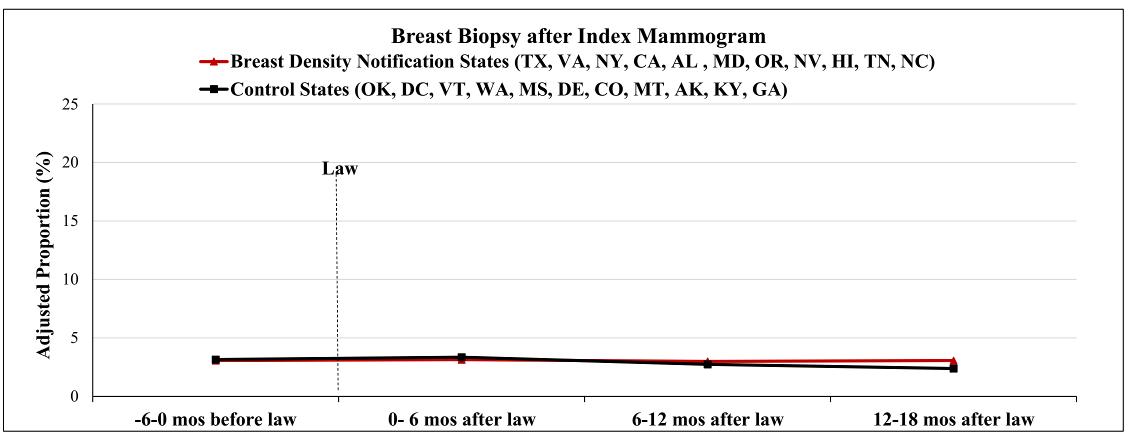
Adjusted proportion with breast biopsy after index mammogram pre-post notification law

Time Period	Connecticut (%)	New Hampshire (Control state) (%)	Difference-in-Differences (%)	P value for interaction of law*time period
-6-0 mos before law	3.2	3.0	**reference**	**reference**
0- 6 mos after law	3.1	2.5	+0.5	0.2
6-12 mos after law	3.5	2.5	+0.7	0.03
12-18 mos after law	3.3	2.1	+0.9	0.0007



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Adjusted proportion with breast biopsy after index mammogram pre-post notification law

Time Period	Breast Density Notification States (TX, VA, NY, CA, AL , MD, OR, NV, HI, TN, NC) (%)	Control States (OK, DC, VT, WA, MS, DE, CO, MT, AK, KY, GA) (%)	Difference-in-Differences (%)	P value for interaction of law*time period
-6-0 mos before law	3.1	3.2	**reference**	**reference**
0- 6 mos after law	3.1	3.3	-0.1	0.08
6-12 mos after law	3.0	2.7	+0.3	<0.0001
12-18 mos after law	3.1	2.4	+0.8	<0.0001

Figure 3 Adjusted* proportion of women with breast biopsy after an index mammogram pre-post breast density notification laws, 2009–2014, stratified by presence of mandate requiring ultrasound coverage. *Adjusted for all variables in Table 2 and year of index mammogram.

cancers. This algorithm has been previously used to study care for women with probable early-stage breast cancer but not to estimate rates of cancer diagnosis across a population of patients. Finally, we did not adjust for multiple comparisons.

In conclusion, using a rigorous difference-in-differences study design, we observed a modest increase in use of supplemental breast imaging and breast biopsies following breast density notification legislation in 12 states. In 2019, federal legislation requiring breast density notification, was enacted by Congress [44] and the U.S. Food and Drug Administration has released a proposed rule requiring reporting of breast density by mammography facilities.[43] As breast density notification laws are implemented, policymakers and clinicians should be aware of the potential effects on care and the cost burden to payers and patients associated with these laws. More research is needed to understand the effects of these laws on cancer outcomes, including stage at breast cancer diagnosis, potential overdiagnosis of breast cancer, and cancer-related mortality. The national impact of breast density notification will require consideration as policies are instituted to promote value and improve the quality of breast cancer screening in the US health care system.

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Compliance with Ethical Standards:

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APPENDIX

Table 4 State Characteristics After Matching, 2009–2014 (including CT and NH)

	Breast density notification states	Control states
State-level census variables		
Median household income	$56,983	$55,949
Percent below poverty	15%	15%
High school graduate or higher	86%	88%
College or higher	30%	31%
Percent Black	14%	14%
Percent White	58%	66%
Mammography rates*	75%	72%

Note: All values represent averages for all states in each group. Median household income values are presented in 2014 dollars
*Sources: US Census data for the year each state law was effective. *Mammography rates are from the Behavioral Risk Factor Surveillance Survey (BRFSS) 2014*

Table 5 CPT, HCPCS, and ICD-9 Procedure Codes for Breast Cancer Screening, Breast Biopsy Procedures, and Breast Cancer Incidence Analysis

	CPT/HCPCS	ICD-9
Type of breast cancer screening		
Mammography	77051, 77052, 77055, 77056, 77057, G0206, G0204	V76.11, V76.12, 87.36, 87.37
Ultrasound (ultrasonography)	76645	88.73
Magnetic resonance imaging (MRI)	77058 (+0159T), 77059 (+0159T), C8903, C8904, C8905, C8906, C8907, C8908, 76498 (unlisted MRI), S8042 (MRI low-field)	88.96, 88.97
3D mammogram/digital breast tomosynthesis (DBT)	76499 (+G0202), 76376 (+G0202), 76377 (+G0202)	
Molecular breast imaging (MBI)/breast specific gamma imaging (BSGI)/ scintimammography	S8080, 78800, 78801, 78802, 78804, 78803, A4641, A4642, A9500	92.19
Thermography/digital infrared thermal imaging (DITI)	93740, 99429	88.85
Breast biopsy		
Fine needle aspirate	19000, 19001, 10021, 10022	85.91
Core needle biopsy	19100, 19102	85.11, 85.12
Excisional biopsy	19120, 19125	85.20, 85.21
Other codes	19002, 19003, 19020, 19081, 19082, 19083, 19085, 19086, 19101, 19103, 19126, 19281, 19282, 19283, 19284, 19285, 19286, 19287,19288, 19290, 19291, 19295, 76095, 76942, 77021, 77031, 77032	85, 85.1, 85.2, 85.19
Surgery		
Lumpectomy	19120, 19125, 19126	85.20, 85.21, 85.25
Partial mastectomy	19160, 19162	85.22, 85.23
Lymph node dissection	38740, 38745, 38525	40.3
Mastectomy	19180, 19182, 19200, 19220, 19240, 19303–19307, 19110, 19301, 19302	85.41–85.48
Radiation therapy	77400–77499, 77520–77525, 77750–77799	92.2–92.9

Note: The study period of the analysis covered the transition from ICD-9 to ICD-10 effective October 1, 2015. All relevant codes here were converted to ICD-10 when the analysis overlapped with their temporal use

Description of an algorithm using claims data to identify women with incident breast cancer

The algorithm Nattinger and colleagues developed uses Medicare claims data to identify women with incident breast cancer. This algorithm involves a four-step process:

In step 1, women with both a breast cancer diagnosis code and a breast cancer procedure code, on the same or different claims, are identified in the Medpar, Outpatient, or Carrier Claims records.

In step 2, women identified from step 1 must meet two main criteria:

First, women must have a mastectomy claim in any file or a lumpectomy or partial mastectomy claim in any file followed by at least one Outpatient or Carrier claim for radiotherapy with a breast cancer diagnosis.

Second, women must have at least two Outpatient or Carrier claims on different dates containing breast cancer as the primary diagnosis.

Women meeting both of these criteria were classified as possible incident breast cancer cases. Subjects failing to meet both of the criteria outlined in step 2 were further analyzed in step 3.

In step 3, primary breast cancer cases are differentiated from women undergoing lumpectomy/partial mastectomy for benign disease or for another cancer that had metastasized to the breast. Without primary breast cancer, some of these patients have claims with erroneous primary breast cancer diagnosis codes, resulting in their inclusion into the cohort that passes step 1 of the algorithm.

Finally, step 4 removes prevalent breast cancer cases. This step uses prior years of claims of subjects classified as an incident breast cancer case in step 2 or step 3. Claims for women from these prior years are subject to step 1 of the algorithm and assessed for containing a diagnosis of previous history of breast cancer; when either of these conditions are met in the prior claims data, the subjects are removed.

The algorithm was validated through comparisons with the SEER cancer registry. Algorithm results had a positive predictive value (PPV) of 89% when compared to the SEER registry. In terms of sensitivity, the algorithm identified 83.0% of the women in the SEER cohort who underwent lumpectomy/partial mastectomy and 81.8% of the women in the SEER cohort who underwent mastectomy.