

## Special Article

## THE EFFECT OF LEGISLATIVE REQUIREMENTS ON THE USE OF BREAST-CONSERVING SURGERY

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**ABSTRACT**

**Background** We studied the effect of state legislation requiring the disclosure of options for the treatment of breast cancer on the use of breast-conserving surgery in clinical practice.

**Methods** The National Cancer Institute's Surveillance, Epidemiology, and End Results registry provided data on women from 30 through 79 years of age who underwent breast-conserving surgery or mastectomy for local or regional breast cancer from 1983 through 1990. We examined the trend over time in the use of breast-conserving surgery among patients in four sites (Connecticut, Iowa, Seattle, and Utah) where there were no state laws specifically requiring the disclosure of options for the treatment of breast cancer by physicians. For four additional sites (Detroit, Atlanta, New Mexico, and Hawaii) that had such legislation, we determined whether the rate of breast-conserving surgery after the legislation was different from the expected rate.

**Results** An attorney rated the legislation as giving most direction to physicians in Michigan, followed by Hawaii, Georgia, and New Mexico. The rate of breast-conserving surgery was up to 8.7 percent higher than expected in Detroit for six months after the passage of the Michigan law ( $P < 0.01$ ). The rate was up to 13.2 percent higher than expected in Hawaii for 12 months after that state's law was passed ( $P < 0.05$ ) and up to 6.0 percent higher than expected in Atlanta for 3 months after the passage of the Georgia law ( $P < 0.01$ ). After these transient increases, the surgery rates reverted to the expected levels. No significant effect was detected in New Mexico, where only a resolution without legal force was passed.

**Conclusions** Legislation requiring physicians to disclose options for the treatment of breast cancer appeared to have only a slight and transient effect on the rate of use of breast-conserving surgery. (N Engl J Med 1996;335:1035-40.)

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**C**ONTINUING medical education, peer-review organizations, consensus conferences, and practice guidelines have been advocated as ways of improving the quality of medical care. However, evidence of their effectiveness is lacking.<sup>1-6</sup> Another way to change medical practice is through legislation that requires certain

actions on the part of health care providers. Traditionally, legislation of this type has been restricted to public health measures, such as the reporting of cases of infectious diseases, but more recently it has been applied to other kinds of medical issues, such as the care of patients with the acquired immunodeficiency syndrome. Several state laws have been passed with the aim of promoting breast-conserving surgery for women with breast cancer in an early stage. The enactment of such legislation provides an opportunity to examine the effectiveness of legislative mandates in altering medical practice.

By 1985, several randomized trials had demonstrated the efficacy of breast-conserving surgery,<sup>7-10</sup> but the use of this treatment in clinical practice increased only minimally during the late 1980s.<sup>11-13</sup> The slow adoption of breast-conserving surgery and the identification of nonclinical factors that affect its use (such as geographic location and the type of hospital)<sup>14,15</sup> raised the question whether all women with breast cancer are adequately informed about their therapeutic options.

By 1990, 18 states had passed laws specifically addressing the disclosure by physicians of options for the treatment of breast cancer.<sup>16</sup> We assessed the effect of such legislation on the use of breast-conserving surgery in clinical practice.

**METHODS****Sources of Data**

The National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) registry data base<sup>17</sup> was the source of the clinical data we studied. The data were collected from nine geographically distinct, population-based tumor registries that include information on patients' demographic characteristics, the extent of disease, and initial treatment for approximately 10 percent of the patients with cancer in the United States. The sites in the SEER data base included the entire states of Connecticut, Hawaii, Iowa, New Mexico, and Utah and the metropolitan areas of Atlanta, Detroit, Seattle, and San Francisco and Oakland.

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Because social and demographic factors affect the use of breast-conserving surgery,<sup>14,15,18</sup> we obtained information regarding the urban or rural character and the mean per capita income of the county in which each patient resided from the Area Resource File.<sup>19</sup>

Copies of the relevant state legislation were obtained from Westlaw, an on-line service provided by the West Publishing Company.

### Patients

Data on women were selected from the SEER data base if the patients were given a diagnosis of breast cancer between 1983 and 1990 and were residents of any SEER site other than San Francisco and Oakland, California. Patients from the San Francisco area were excluded because California enacted a statute related to the treatment of breast cancer in 1980, before the period we studied.

Of the 100,207 women initially considered for the analysis, 38,661 were excluded because they had advanced disease (19,466 women), because the cancer in the data base for the study period was not the patient's first cancer (13,767 women), because mastectomy or breast-conserving surgery was not performed (5973 women), because the woman was less than 30 years of age (685 women) or more than 79 (11,574 women) at the time of diagnosis, because the cancer was not confirmed histologically (1614 women), because the cancer was bilateral (135 women), or because there was no valid county code in the data base (33 women). Some patients were excluded for more than one reason. A total of 61,546 women met the criteria of the study.

### Definitions of Variables

Patients were categorized by the SEER program as treated with breast-conserving surgery if they underwent segmental mastectomy, lumpectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, excisional biopsy, or partial mastectomy, either with or without axillary lymph-node dissection. All other patients underwent some form of complete mastectomy.

According to the conventions of the SEER program, the cancer was considered localized if it was confined to the breast tissue and regional if it had extended into surrounding tissue or regional lymph nodes. The patients were grouped according to their age at diagnosis (30 to 49 years, 50 to 64 years, or 65 to 79 years). Women were classified according to race as white, black, or "other." The mean per capita income in 1990 of the patient's county of residence and the size of the metropolitan statistical area in which the patient lived were obtained from the Area Resource File.

### Description and Ranking of Statutes

Without knowing the rates of use of breast-conserving surgery, an attorney summarized the relevant statutes and ranked them according to how much direction the laws gave physicians. The criteria included the legal requirements pertaining to the development and documentation of informed consent, as well as the inclusion of sanctions against physicians who failed to comply with the statute or protection for those who complied with it.

### Statistical Analysis

The period from 1983 through 1990 was broken into 32 three-month periods. The patients were assigned to periods according to the month of diagnosis. For Hawaii, where there were consistently fewer than 100 patients per three-month period, six-month periods were used. Logistic-regression models were used, with the dependent variable representing the receipt of breast-conserving surgery or mastectomy by individual patients.

Initially, we developed a model based on patients who lived at sites without relevant state laws regarding treatment for breast cancer (Connecticut, Iowa, Seattle, and Utah), in order to evaluate the trend over time in the use of breast-conserving surgery. The model included factors known to influence the use of breast-conserving surgery,<sup>13-15,18</sup> including age at diagnosis, race, stage of disease, SEER site, per capita income in the county, and size of

the metropolitan statistical area. The effect of time was modeled by allowing a unit step-function variable<sup>20</sup> to enter the model for each quarter from the second quarter of 1983 through the fourth quarter of 1990. This variable could increase or decrease the probability that a patient would undergo breast-conserving surgery, but it entered the model only during quarters when there were significant increases or decreases, as compared with the previous quarter, in the use of such surgery.

To test whether the trend over time was the same among the four SEER sites without relevant state laws, terms for the interactions of site with time and stage of disease with time were included in the model. A constant was also incorporated, allowing a different average base rate of use of breast-conserving surgery for each SEER site. The interaction of site with time was not significant at any site, indicating that the trend over time was essentially the same among the sites without state laws requiring the disclosure of treatment options.

We applied the model of the temporal trend to the sites at which a law requiring the disclosure of treatment options to patients had been enacted, in order to determine whether the rate of use of breast-conserving surgery in these sites differed from that expected from the temporal trend. After adjustment for the base-line use of breast-conserving surgery in each of the SEER sites, residual analysis<sup>21</sup> was used to identify which periods in the states with such laws deviated significantly from the temporal trend. This approach was used in preference to the simpler and more restrictive step-intervention model,<sup>20</sup> since the effect of the law could have been felt before the law's enactment (for example, because of publicity or debate about the law), the effect of the law could have been gradual or delayed (for example, if informational material was not immediately available), and the effect of the law could have been transient and have diminished over time.

We sought evidence of an effect of the law on the use of breast-conserving surgery by determining the rate of use of such surgery around the effective date of the law and assessing whether that rate differed significantly from the use predicted on the basis of the model for trend over time. To address the problem of making many statistical comparisons, we used the k-ratio multiple-comparisons procedure, extended to the regression case.<sup>22</sup> This procedure provides strong protection against the finding of a significant difference when there is primarily random variation and provides high sensitivity when there are many significant differences.

In line with our previous description of geographic variation in the use of breast-conserving surgery,<sup>14</sup> we found that adjustment was required for a significant effect of the site. We accomplished this by adjusting the y intercept of the temporal trend to fit the average of the first two quarters of 1983 (in the cases of Detroit, Atlanta, and New Mexico) or, in the case of Hawaii, to fit the overall average for the state, since its law was passed at the beginning of 1983.

## RESULTS

### The Study Cohort

Table 1 shows the characteristics of the study cohort. There was a trend toward increasing numbers of patients with breast cancer over time. The states of Connecticut, Iowa, Washington, and Utah had not enacted relevant laws by 1990; 35,853 women (58.3 percent) were residents of these states. The remaining 25,693 women (41.7 percent) were residents of Michigan, Hawaii, Georgia, or New Mexico.

### Laws Requiring Disclosure of Treatment Options

Of the four states included in the SEER registry that passed legislation or a resolution specifically pertaining to the disclosure of options for the treatment

**TABLE 1.** CHARACTERISTICS OF THE 61,546 WOMEN IN THE STUDY POPULATION.

CHARACTERISTIC	No. (%)
Age at diagnosis — yr	
30–49	16,165 (26.3)
50–64	22,155 (36.0)
65–79	23,226 (37.7)
Stage of disease	
Local	37,766 (61.4)
Regional	23,780 (38.6)
Race	
White	54,571 (88.7)
Black	4,214 (6.8)
Other	2,478 (4.0)
Unknown	283 (0.5)
Year of diagnosis	
1983	6,355 (10.3)
1984	6,696 (10.9)
1985	7,234 (11.8)
1986	7,732 (12.6)
1987	8,405 (13.7)
1988	8,438 (13.7)
1989	8,119 (13.2)
1990	8,567 (13.9)
SEER site*	
Atlanta	5,791 (9.4)
Connecticut	12,068 (19.6)
Detroit	13,474 (21.9)
Hawaii	2,911 (4.7)
Iowa	9,649 (15.7)
New Mexico	3,517 (5.7)
Seattle	10,570 (17.2)
Utah	3,566 (5.8)
Residence	
Metropolitan statistical area†	
≥1,000,000 people	25,518 (41.5)
250,000–1,000,000 people	21,143 (34.4)
100,000–250,000 people	3,263 (5.3)
<100,000 people	1,772 (2.9)
Nonmetropolitan (rural)	9,850 (16.0)
Received breast-conserving surgery	
Yes	14,522 (23.6)
No	47,024 (76.4)
	<b>DOLLARS</b>
Per capita income of county	
Median	20,139
10th percentile	15,339
90th percentile	26,884

\*SEER denotes the Surveillance, Epidemiology, and End Results program.

†The categories are those used by the Bureau of Health Professions.<sup>19</sup>

of breast cancer, Michigan had the statute<sup>23</sup> that was rated the most strongly directive, followed by Hawaii,<sup>24</sup> Georgia,<sup>25</sup> and New Mexico (in that state only a resolution without legal standing was passed).<sup>26</sup>

Michigan's law (enacted in 1986) requires physicians to inform patients with breast cancer orally and in writing about alternative methods of treatment. This statutory requirement may be satisfied by distributing a brochure developed by the state public health department or a different brochure that contains substantially the same information. The patient must sign a form indicating that she has received a

copy of the brochure, and this form is to be included in the patient's chart. The statute includes protection for physicians who comply with the law, but no specific sanctions against physicians who fail to comply. The statute explicitly states that a physician's duty to inform patients does not require the disclosure of information "beyond what a reasonably well-qualified physician would know."

The Hawaii statute (enacted in 1983) requires the Medical Examining Board to establish informed-consent standards for mastectomy. These standards must cover the substantive content of the information to be given to women for whom mastectomy is recommended (including recognized alternative treatments), the manner in which the information is to be given, and the manner in which the patient's consent is to be given. This statute does not include specific requirements for documentation or specific protection of or sanctions against physicians.

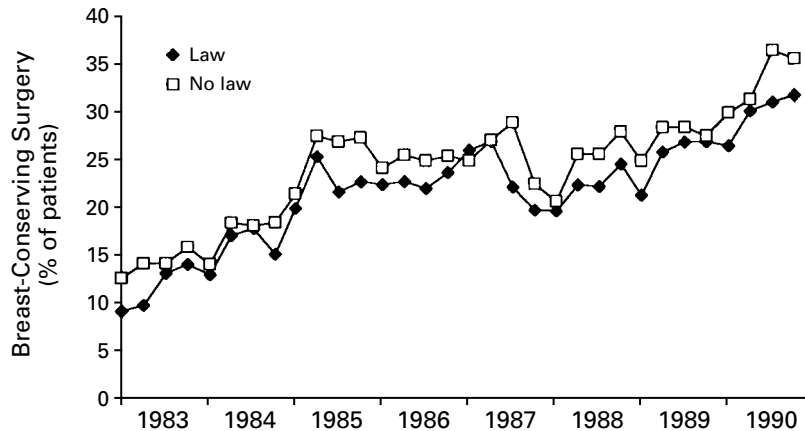
The Georgia statute (enacted in 1984) states that "when funds are specifically appropriated for such purpose," the Board of Medical Examiners is to publish and make available to physicians an informational booklet on treatments for breast cancer, and to urge them by letter to distribute a copy of the booklet to patients with breast cancer. Informed-consent standards are not addressed, and there are no requirements for documentation or protection and no sanctions for physicians.

New Mexico's legislature passed a resolution in 1984 that urged physicians to inform patients with breast cancer about options for treatment, using a brochure to be developed by the state health department, in conjunction with the medical societies and the University of New Mexico Medical School. Since this resolution had no force of law, it was considered the least directive.

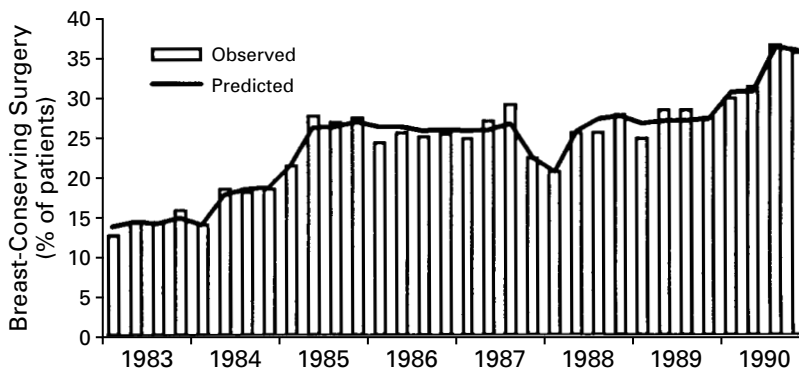
Pursuant to all the states' laws and the New Mexico resolution, an informational brochure detailing alternatives for the treatment of breast cancer was developed by each of these states.

#### Use of Breast-Conserving Surgery over Time

Figure 1 shows the use of breast-conserving surgery according to quarter, from 1983 through 1990, for women residing in the states with laws regulating the disclosure of alternative treatments for breast cancer and in the states without such laws. Logistic regression was used to model the trend over time in the use of breast-conserving surgery among patients residing in the sites without relevant laws. The logistic regression included terms for all the covariates shown in Table 1. Figure 2 depicts the observed rates of breast-conserving surgery in these sites and the rates predicted by the model. A chi-square test for lack of fit of the model was not significant ( $P=0.37$ ), indicating that the model was fitted adequately to the observed data. There was a gradual increase in



**Figure 1.** Use of Breast-Conserving Surgery for Local or Regional Breast Cancer in Four States with Laws Requiring the Disclosure of Treatment Options and in Four States with No Such Laws as of 1990. Data shown are unadjusted data from the registry of the Surveillance, Epidemiology, and End Results program.



**Figure 2.** Observed Rates of Breast-Conserving Surgery and Temporal Trends Predicted by the Logistic-Regression Model in Four States without Laws Requiring the Disclosure of Treatment Options. Data are from the registry of the Surveillance, Epidemiology, and End Results program.

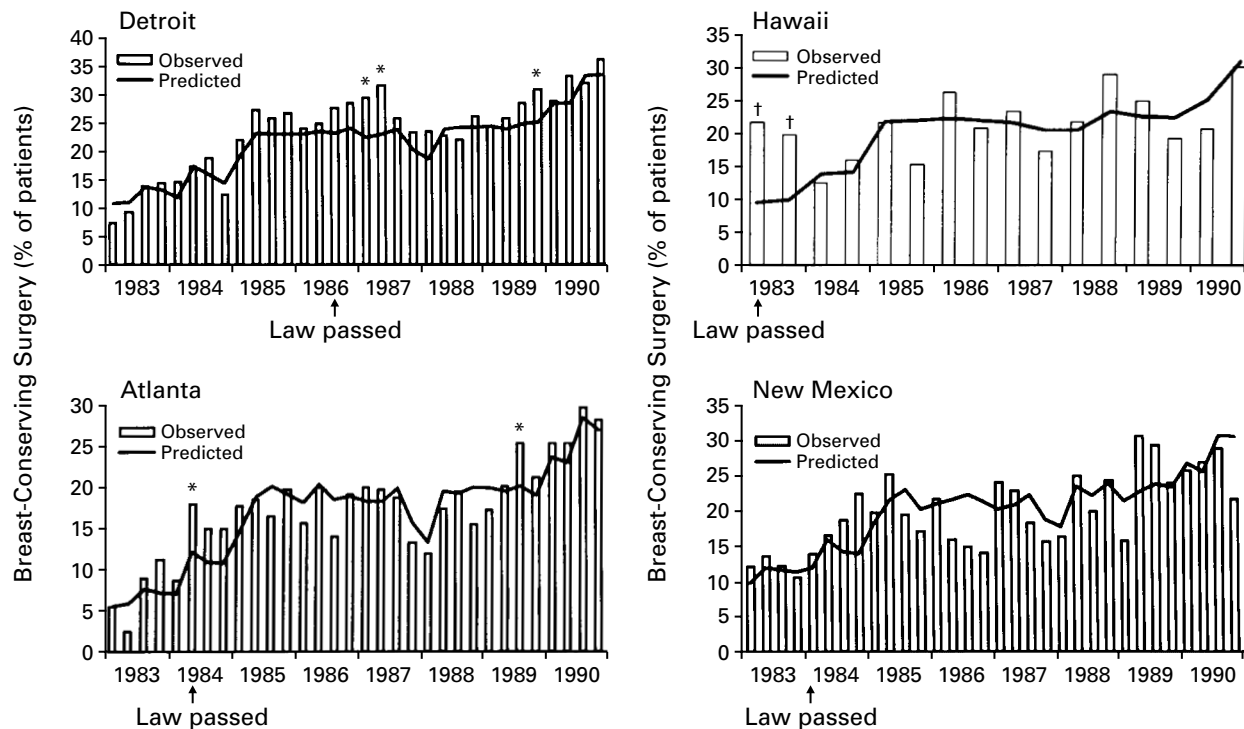
the use of breast-conserving surgery from 1983 to 1985, followed by relative stability through mid-1990, with the exception of a dip in late 1987 and early 1988.

**Use of Breast-Conserving Surgery at Sites with Relevant Laws**

Figure 3 shows the observed rate of breast-conserving surgery in each of the sites with laws regarding the disclosure of options for treatment. Superimposed is the expected rate of breast-conserving surgery for each period, adjusted for the covariates in Table 1, according to the logistic-regression model of the trend over time.

The Michigan law took effect in July 1986, but physicians were not subject to the terms of the leg-

islation until November 1986, by which time the informational brochure had been published. The use of breast-conserving surgery in Detroit showed a small but steady increase from mid-1986 through mid-1987. The surgery was significantly more frequent than expected during the first half of 1987, reaching a maximum of 8.7 percent more use than expected (standard error, 2.4 percent). The rate of use of breast-conserving surgery was also higher than expected during the fourth quarter of 1989. Interestingly, in a different statute,<sup>27</sup> a program to reduce mortality due to breast cancer was established in Michigan in the third quarter of 1989. It included programs of professional education regarding breast-cancer screening, diagnosis, referral, treatment, and rehabilitation, as well as public education regarding



**Figure 3.** Observed Rates of Breast-Conserving Surgery at the Sites with Laws Requiring the Disclosure of Treatment Options, as Compared with the Rates Predicted on the Basis of the Trend over Time in Four Sites without Such Laws.

Data are from the registry of the Surveillance, Epidemiology, and End Results program. The asterisks indicate  $P < 0.01$  and daggers  $P < 0.05$  for the comparison of the observed and expected rates, after adjustment for multiple comparisons. The observed and expected rates did not differ significantly in New Mexico. Six-month periods were used in Hawaii, and three-month periods at the other sites.

the options available for the treatment of breast cancer, among other topics.

The Hawaii law was passed during the spring session of 1983 and was signed into law in June 1983. The Medical Examining Board's informed-consent guidelines for mastectomy were released on September 21, 1983. The rate of use of breast-conserving surgery in Hawaii was significantly higher than expected throughout 1983, reaching a maximum of 13.2 percent higher use than expected (standard error, 3.8 percent). The rate of use of breast-conserving surgery returned to the expected level by 1984.

The Georgia statute was signed into law on April 5, 1984, and went into effect on July 1, 1984. The informational brochure was published by late 1984. The rate of use of breast-conserving surgery was significantly higher than expected in Atlanta in the second quarter of 1984, with a maximum of 6.0 percent higher use than expected (standard error, 3.3 percent). The rate of use of breast-conserving surgery was also significantly higher than expected in the third quarter of 1989.

The New Mexico resolution was passed in February 1984, and the written brochure on alternatives for breast-cancer treatment was published by No-

vember 1984. There was some increase in the use of breast-conserving surgery over the expected level during the last six months of 1984, but the difference was not statistically significant.

## DISCUSSION

We found that state laws requiring the disclosure of alternatives for the treatment of breast cancer were temporally associated with slight increases (6 to 13 percent) in the use of breast-conserving surgery in the states with the most directive laws. The increases were transient, however, lasting from 3 to 12 months, after which the use of breast-conserving surgery reverted to the level expected on the basis of the trend in states without specific legislation.

Why was the apparent effect of these laws so small? The assumption underlying these statutes was that women with breast cancer were not being fully informed of their choices and that measures to increase the discussion of alternative treatments would lead to increases in the use of breast-conserving surgery. However, a major determinant of the choice of therapy appears to be the recommendation of the surgeon,<sup>28-31</sup> which would not be expected to be affected by the legislation. Also, research by Nayfield

et al.<sup>16</sup> suggests that only a minority of patients with cancer pursue a decision-making process that is enhanced by additional information; for some patients such information may complicate the process.<sup>31</sup>

A number of factors may explain the transient increases in breast-conserving surgery, which were temporally related to the passage of the laws we studied. It is possible that the laws did influence physicians to discuss alternative treatments. However, patients might have been more aware of these alternatives because of publicity surrounding the passage of the laws. If such publicity was important, increased public awareness could have spilled over into states without legislation, thereby affecting the use of breast-conserving surgery in those states as well. This process could explain the transient increases in the use of breast-conserving surgery in the states with relevant laws, because the effect in states without such legislation would have been incorporated into the model of the temporal trend in the use of breast-conserving surgery that we used to assess the effect of the laws.

Legislation to require specific clinical actions on the part of physicians is unusual. Critics of such legislation claim that it can introduce an adversarial component into the doctor-patient relationship by suggesting to the public that physicians must be coerced to behave appropriately.<sup>32,33</sup> Moreover, even in the absence of specific legislation, the development of the informed-consent doctrine in common law has established the legal requirement for full disclosure by physicians of alternative treatments. Many contend that such legislation should therefore be pursued only for compelling reasons, when the benefit of improved patient care clearly outweighs the potential harm to the physician-patient relationship. The lack of a clinically important or sustained effect of legislation designed to increase the use of breast-conserving surgery should serve as a warning against the passage of such legal requirements in the future.

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