

# The Impact of Mammography Quality Improvement Legislation in Michigan: Implications for the National Mammography Quality Standards Act

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## ABSTRACT

**Objectives.** This study examined the impact of state legislation on mammography quality and access in Michigan.

**Methods.** The impact of state legislation was analyzed with respect to utilization, numbers of machines and facilities, and image quality.

**Results.** The legislation had a positive effect on image quality improvement, had no impact on utilization by women aged 50 years and above, and resulted in few facility closures.

**Conclusions.** Michigan's legislative intervention appears to have had a positive effect on efforts to improve mammography quality assurance with implications for other federal and state efforts to achieve quality assurance in health care delivery. (*Am J Public Health*. 1998;88:667-671)

## Introduction

Screening mammography was established as an effective means of controlling breast cancer morbidity and mortality in the 1980s. This has led to its widespread acceptance and promotion by primary care physicians, widespread use by women, and a marked increase in the number of mammography facilities.<sup>1-5</sup>

With more than 20 million US women receiving mammography examinations annually and quality standards and regulations varying from state to state, concerns have been raised over the potential for poor mammography. At the national level, this concern contributed to the formulation and passage of the 1992 Mammography Quality Standards Act.<sup>6-9</sup>

The Mammography Quality Standards Act establishes national baseline quality standards for mammography and requires that all mammography facilities be certified as meeting those standards in the areas of equipment, personnel, and overall quality assurance. It also requires that all facilities be inspected annually (Public Law No. 102-539).<sup>10</sup> While the act was welcomed by many as a means to ensure the quality of mammography in the US, others expressed concern that regulation of mammography might reduce access by increasing cost or by forcing some facilities out of business.<sup>10,11</sup>

With the passage of Public Law No. 56 in 1989, Michigan became the first state to implement stringent, comprehensive mammography quality assurance legislation. In many ways, the provisions of the Michigan law presaged the national Mammography Quality Standards Act by requiring accreditation standards, including clinical image review, regular state inspections, and annual surveys involving radiation dosimetry and other machine physics.<sup>6</sup>

## Methods

We set out to test whether the implementation and enforcement of mammography quality improvement legislation in Michigan would result in a decrease in mammography resources in Michigan, decreased access to and use of screening mammography, and an increased level of quality of mammography services.

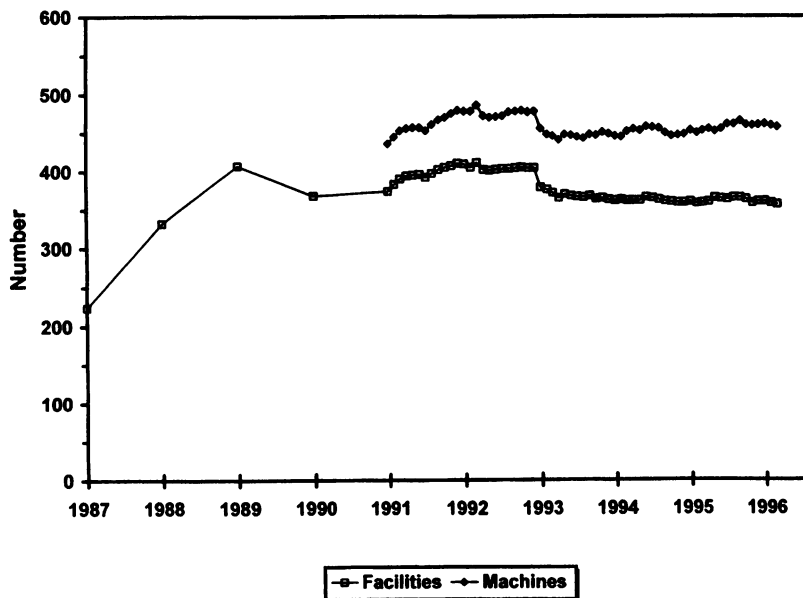
This test was undertaken by (1) comparing the levels of and trends in mammography machines and facilities in Michigan before and after implementation and enforcement of the legislation in Michigan; (2) comparing the levels of and trends in screening mammography use in Michigan with levels and trends in other states during the period in which the Michigan legislation was implemented and enforced; and (3) comparing data on mammography image quality in Michigan with data on image

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Note. In 1991, Michigan officials began collecting monthly data on both mammography facilities and mammography machines; prior to 1991, data were only collected on mammography facilities.

Source. Data are from the State of Michigan Department of Consumer and Industry Services, Bureau of Health Systems, Radiation Safety Section.

**FIGURE 1—Total number of mammography facilities and mammography machines operating in the State of Michigan: 1987 through 1996.**

quality from other states before and after implementation of the Michigan law.

The number of facilities and units authorized to perform mammography in Michigan from 1987 to 1996 was obtained from state radiological health officials. As a result of more stringent legislation, state officials began systematically collecting machine and facility authorization data on a monthly basis in January 1991. The number of facilities and units operating in the state prior to 1991 is based on estimates from a variety of state sources.<sup>12</sup> All figures were confirmed against Food and Drug Administration (FDA) records.

Mammography utilization data for Michigan and other states were obtained from the Behavioral Risk Factor Surveillance System (BRFSS).<sup>13,14</sup> We then compared Michigan BRFSS utilization data for women aged 50 years and older who reported undergoing mammography in the previous 12 months and those who had never had a mammogram with similar data reported nationally. In addition, BRFSS data from Minnesota, Georgia, and California were selected for individual comparison and contrast, primarily because these states continuously participated in the BRFSS, because each state's mammography quality

assurance legislation and regulations varied during the time frame under study, and for demographic and geographic reasons.

We also examined changes in the quality of mammography in Michigan and other states, using data from the FDA's voluntary Nationwide Evaluation of X-Ray Trends (NEXT) program.<sup>15</sup>

Finally, the results of state inspections with regard to image quality performance from January 1988 through January 1996 were obtained from state radiological health officials. These quality indicators were then overlaid with legislative and regulatory milestones.

## Results

The increasing trend in the number of mammography facilities and machines in Michigan continued through March 1992, when the number of facilities reached 411 (see Figure 1); this was similar to growth trends observed in other states.<sup>4,16</sup> Estimates from Michigan officials indicate that there was a temporary decrease in mammography facilities and machines between 1989 and 1990, coinciding with the advent of the Michigan law. It is likely that this

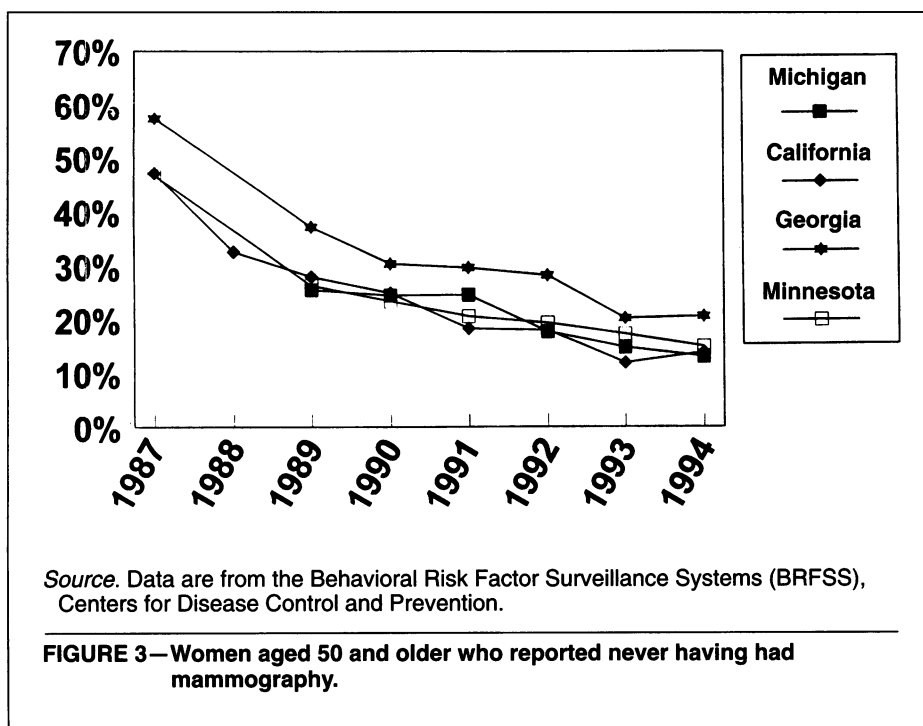
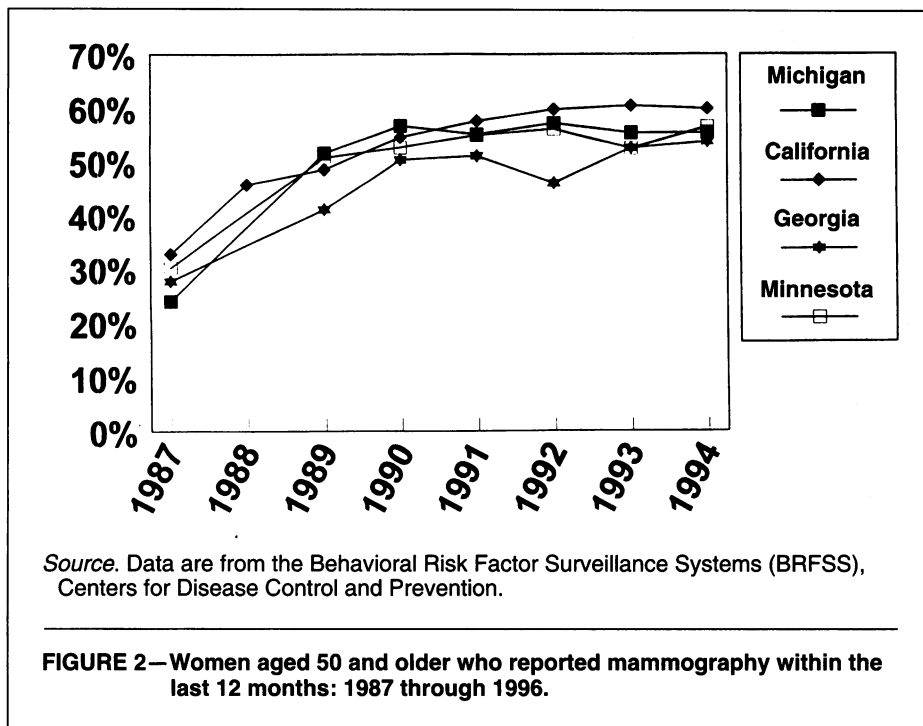
decrease was associated with the decommissioning of an estimated 30 general-purpose x-ray machines that had been used for mammography before they were banned under the 1989 Michigan law. The number of facilities and machines in Michigan evidenced a modest one-time decline of 8.5% in 1993, followed by a gradual, statistically significant increase ( $P < .05$ ) in the number of machines. The net long-term decline in the number of machines was approximately 5%, while the decline in the number of facilities from the peak 1992 level was approximately 9%. A reasonable interpretation is that facilities that remain open are equipping themselves to serve individuals who were served in the past by facilities that have now closed.

## Mammography Use

Figure 2 shows the proportion of all women aged 50 years and older who reported undergoing mammography within the previous 12 months in Michigan and the comparison states between the years 1987 and 1994. Although this is the most convenient age group to compare across states, given the way in which BRFSS data are reported, we obtained virtually identical results when comparing rates for women older than 40 years. While there are some minor apparent differences in trends after 1989 (e.g., between Michigan and California), these are attributable to statistical fluctuations (95% confidence interval) of plus or minus 6 percentage points for individual state surveys. As Figure 2 shows, there was no sharp decrease in mammography utilization or change in overall trends from 1993 to 1994 coincident with the sudden decline in facilities and machines following 1993 emergency rules,<sup>17</sup> promulgated by the state of Michigan, which resulted in more stringent enforcement of legislative provisions governing mammography quality assurance.<sup>12</sup>

Figure 3 shows the proportion of women who reported never having had a mammogram. Public health programs have especially targeted this group for promotion of mammographic screening. Between 1989 and 1994, trends in overall mammography utilization in Michigan were similar to those in other states; implementation of Michigan's 1989 law had no apparent adverse effect on access to screening services.

We also conducted a more detailed analysis that examined average mammography utilization rates for all states participating in the BRFSS program except Michigan. US utilization rates for women older than 50 years increased from 26% in 1987 to 53% in 1993.



### Quality

Table 1 displays the variance of the distribution of total mammography image scores from 1988 and 1992 NEXT data for Michigan and for all other states. In 1988, the image quality scores for Michigan facilities were slightly lower than average ( $P > .05$ ). By 1992, after implementation of legislation in Michigan, scores for image quality in Michigan had improved significantly ( $P = .0001$ ).

The percentage of Michigan's NEXT sample that failed to meet the image quality criteria went from 23% (3/13) in 1988 to none (0/15) in 1992. The NEXT national sample, excluding Michigan, went from 15% (32/213) in 1988 to 11% (37/335) during the same time frame.

The considerable improvement of Michigan's image scores suggests that those facilities with the poorest performance were likely to either close or take remedial action. Since a similar (though

less profound) trend was also found in other states between 1988 and 1992, it is likely that the increased interest of professional societies in quality issues may also have contributed to the improvement.

As Figure 4 shows, mammography image failure rates in Michigan from January 1988 through January 1996 appear to be coincident with legislative, regulatory, or enforcement milestones.

### Discussion and Implications

In this study we attempted to assess the impact of mammography legislation on both facilities and utilization. We found some evidence that legislative enforcement resulted in a temporary decrease in the number of mammography facilities when first initiated (1989) and a modest one-time decrease (1993) when enforcement was strengthened. The magnitude of the 1993 effect—a 5% reduction in machines and a 9% reduction in facilities—should be viewed with the knowledge that the annual exit of mammography facilities owing to normal market turnover is on the order of 5%. In addition, several studies have shown that the average mammography facility in the United States currently operates at one third to one half of capacity.<sup>4,5</sup> It is not clear that reductions in mammography resources of the magnitude seen in Michigan in 1993 should be expected to have any adverse impact on access and utilization. Therefore, it is not surprising that we found no obvious evidence of decreased mammography utilization (or adverse trends) in Michigan.

The data used in this study are limited in some respects. First, state-level BRFSS utilization data do not measure rates of mammography by intrastate geographic areas, for example, poor urban or sparsely populated rural areas. Thus, whether legislative intervention resulted in facility closures and reduced access to mammography in specific localities cannot be assessed with the data available. Nevertheless, if such adverse effects occurred, they were not large enough to be detected at the statewide level. Second, data on mammography quality are limited to a single measure of technical performance (image quality). In addition, data from the FDA's NEXT program involve relatively small samples intended to assess national mammography quality and as such are only suggestive of overall trends. This variable alone is an incomplete measure of overall mammography quality, which might include such factors as film interpretation, appropriate follow-up, and consumer satisfaction. However, good radiographic

imagery is a necessary prerequisite for accurate interpretation.

The image quality data from the NEXT survey indicate that Michigan's legislative intervention was successful, as anticipated. Between 1988 and 1992 average image scores increased more for Michigan than for other states. What is particularly notable about this increase is that it was driven primarily by the elimination of the lower quartile of the distribution of image scores, suggesting that legislative enforcement was successful in establishing baseline quality. It is likely that the 1993 reduction in Michigan's mammography units and facilities represented an additional elevation of this baseline.

To date, the evidence of legislative intervention's effect on mammography quality in Michigan appears to be positive. It is likely that the experience with the Mammography Quality Standards Act at the national level will be similar to the Michigan experience, although an exact parallel between the two cases cannot be assumed. There appears to be a synergistic relationship between the FDA's regulation of quality and the voluntary compliance first advocated by the American College of Radiology. A preliminary assessment of the Mammography Quality Standards Act found mammography facility closure in anticipation of the act and in the early stages of certification and inspection to be minimal.<sup>10</sup> Clearly, continued assessment will be necessary to determine the long-term impact of this legislation on mammography access and quality. □

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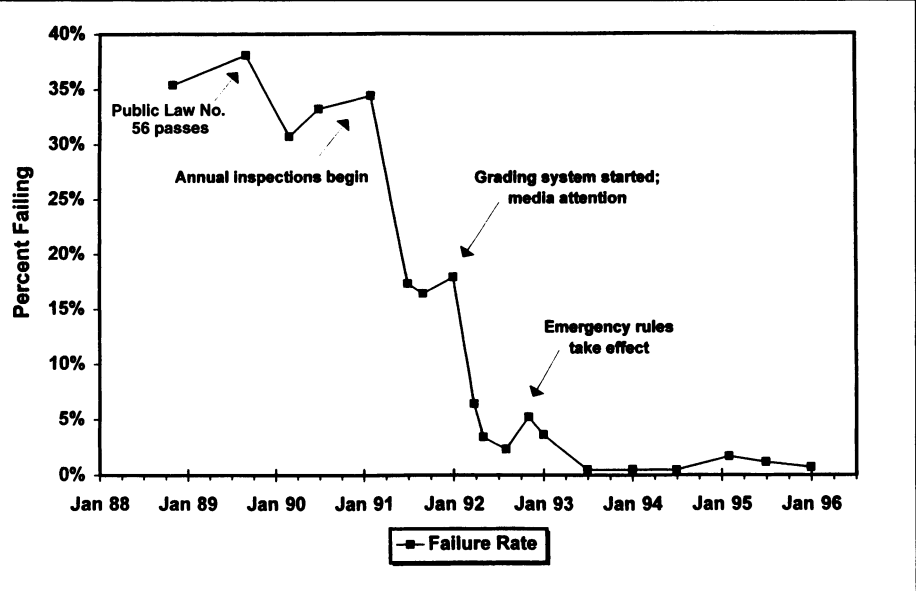
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**TABLE 1—Image Score Data for Mammography Facilities in Michigan and in all Other States**

	n	Average Score	Variance ( $\sigma$ )	Range (r)
1988 <sup>a</sup>				
Michigan	13	9.38	4.09	6-12
All others	213	10.47	4.02	5-15
1992 <sup>b</sup>				
Michigan	15	12.13	0.41	11-13
All others	335	11.16	2.45	4-14

*Source.* Data are from the Food and Drug Administration, National Evaluation of X-Ray Trends (NEXT) Program.  
<sup>a</sup>In 1988 the image quality insert was the RMI Model C insert, which required a gross passing score of 8.  
<sup>b</sup>In 1992 the image quality insert was the RMI Model D insert, which required a gross passing score of 10.



**FIGURE 4—Michigan phantom image failure rates: 1988 through 1996.**

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## Reporting Sexual Risk Behavior for HIV: A Practical Risk Index and a Method for Improving Risk Indices

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### ABSTRACT

**Objectives.** As a means of enhancing public health efforts to control sexual transmission of human immunodeficiency virus (HIV), methods were developed to report on risk behavior in a manner that is comparable and widely interpretable.

**Methods.** An elementary sexual behavior risk index (the vaginal episode equivalent index) that is in accord with some of the essential knowledge about sexual transmission of HIV is described, and a multivariate ordinal risk (MOR) method that can be used to improve such risk indices is introduced.

**Results.** An example shows that these approaches are applicable to observational studies of seroconversion.

**Conclusions.** The MOR represents a powerful new tool to develop valid comparable measures of sexual risk behavior and, thereby, to advance HIV prevention research. (*Am J Public Health*. 1998;88:671-674)

### Introduction

In public health efforts to control the HIV epidemic, it is vital to assess the efficacy of strategies designed to reduce sexual transmission of HIV.<sup>1,2</sup> Yet, there is no reliable and accepted way of judging one strategy against another in terms of effects on sexual risk behavior. This paper first describes an elementary sexual behavior risk index that was heuristically defined, and then introduces a method for using the data of observational seroconversion studies to improve upon such risk indices.

### The Vaginal Episode Equivalent Risk Index

The prevailing approaches to reporting sexual risk behavior pose dilemmas.<sup>3,4</sup> Focusing on a specific behavior (e.g., episodes of unprotected vaginal sex) evades the most critical question, that is, whether overall sexual risk behavior was affected; a decrease in one behavior may be associated with an increase in another. For instance, decreased vaginal sex may be associated with increased anal sex. If, instead, one examines the proportion of sexual episodes that were unprotected, an awkward paradox may be created: When the total number of episodes decreases, this proportion can increase even though the total number of episodes and risk of HIV transmission decrease. Finally, traditional approaches that classify individuals according to category of risk (e.g., high, medium, or low) tend to be arbitrary and thus vary from one study to another.

Faced with these dilemmas in reporting the results of our own clinical trials<sup>5</sup> and

observational studies,<sup>6</sup> we have developed an elementary risk index that is compatible with some of the essential knowledge about sexual transmission of HIV and, specifically, with empirical findings showing anal sex to have higher risk and oral sex to have lower risk than vaginal sex.<sup>7,8</sup> The vaginal episode equivalent (VEE) risk index was defined by the following simple linear function: Risk Score = (number of unprotected vaginal episodes) + (2 × number of unprotected anal episodes) + (0.1 × number of unprotected oral episodes). Risk is reported in units of a vaginal episode equivalent (VEE), equivalent to the risk associated with one episode of vaginal unprotected sex, which is an intuitively meaningful unit. The VEE is eminently practical when data on sexual behaviors and/or HIV status are limited, as they are in the great majority of intervention studies.

The VEE can be refined when the data are extensive. In complex data sets, one might differentiate further, for instance, among types of sex or partners. When the number of anal, vaginal, and oral episodes

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