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Honorable Melissa Wiklund, Chair  
Minnesota Senate Health and Human Services Committee  
2107 Minnesota Senate Building  
Saint Paul, MN 55155

March 8, 2023

Re: Keep Nurses at the Bedside Act (SF 1561/HF 1700)

Dear Chair Wiklund and Committee Members:

I am writing to express my deep concern regarding the Keep Nurses at the Bedside Act, both as a nursing leader in acute care at Methodist Hospital with a doctorate and board certification in nursing leadership and as a citizen of Minnesota. This proposed legislation removes our bedside and charge nurses' authority to make staffing decisions in real time in favor of inflexible government-mandated fixed ratios. Such legislation has the potential to reduce access and increase the cost of care for Minnesotans with no promise of improved quality of care or resiliency in our nursing workforce.

The Keep Nurses at the Bedside Act proposes unworkable mandates that will inhibit common sense flexibility in patient care and stifle innovations to reduce the cost of care. This thinly veiled attempt at mandated nursing ratios would immediately increase healthcare labor costs in Minnesota – an unaffordable increase that will be passed on to patients, taxpayers, and employers. Minnesota was recently ranked 4th in the nation for value in healthcare, while states with mandated ratios are historically at the bottom. Lawmakers should look to support value in care.

This bill would also unravel years of work encouraging all professionals to practice at the tops of their licenses. In response to mandated ratios in other states, health systems have been forced to eliminate positions among other important members of the care team to maintain financial stability and prevent massive increases in cost of care. While the mandated ratios are intended to improve workforce resiliency, instead the responsibilities of the lost allied health professionals will shift to nurses. Despite staffing cuts in ancillary departments, states with mandated ratios have experienced daily costs of hospital care that are up to \$1,000 more per day compared to costs in Minnesota – all with no evidence of improved health outcomes for patients.

Many professional nursing organizations call for acuity-based models of staffing that support the changing needs of our patients and dynamic nature of hospital departments. Hospitals like mine use flexible staffing models, informed by recommendations from professional nursing organization, to empower frontline nurses to make staffing decisions that make sense and ensure safety. Continued partnership among our nursing organizations, Minnesota hospitals, and the

Minnesota Department of Health ensures transparent reporting of quality and safety metrics that drive change and innovation to meet the healthcare needs of our great state. The nurses at my hospital are deeply involved in the development of our staffing plans. Despite long-standing consensus in the development of these staffing plans, and top decile staffing benchmarks for nursing hours per patient day, advocates for this legislation are making baseless claims that our staffing plans are inadequate. To the contrary, our plans meet industry standards, and our challenge remains recruiting and retaining the workforce to support our mutually developed plans.

Nurses are essential for ensuring patient safety and the health outcomes of our citizens. Pretending that unsafe staffing situations have not occurred in Minnesota would be foolish and irresponsible, yet we cannot allow passionate, misguided campaigns for mandated ratios to distract us from the larger issue: we need to explore patient care at a systems level and ensure that all disciplines are included and accountable in planning care delivery models that are effective, safe, and fiscally responsible. Mandated nursing ratio legislation is a myopic approach to care delivery that fails to address the value of the healthcare team. Hospitals cannot run on nurses alone just as they cannot run on physicians alone, or techs alone, or any of the other dozens of well-educated and highly competent professionals that show up to work each day focused on the best outcomes for our patients.

In my role as a nursing leader, it is my responsibility to ensure that the people working in this system and the patients we care for do not have the rug pulled out from under them – all while maintaining and inspiring hope for innovation that will lead to the birth of a better, more sustainable system. I put my heart into nursing the healthcare system back to health, but, just like for the patients in our ICU, a massive dose of the wrong medicine will lead to a crash; Article II of this bill is just such a harmful dose.

I am happy to meet with any committee members or sponsors of this legislation as well as offer my testimony before the Health and Human Services Committee.

Sincerely,



**Adam Karlen, DNP, RN, NEA-BC, CCRN-K** (he/him)

Clinical Nursing Director | Critical Care & Respiratory Therapy

2NS Med/Surg ICU | 3NS Advanced Care | 3East Cardiac Telemetry

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Enclosures:

1. Research article: Patient outcomes after the introduction of statewide ICU nurse staffing regulations.
2. Research article: Assessing the impact of California's nurse staffing ratios on hospitals and patient care.



# Patient Outcomes After the Introduction of Statewide ICU Nurse Staffing Regulations\*

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**Objectives:** To assess whether Massachusetts legislation directed at ICU nurse staffing was associated with improvements in patient outcomes.

**Design:** Retrospective cohort study; difference-in-difference design to compare outcomes in Massachusetts with outcomes of other states (before and after the March 31, 2016, compliance deadline).

**Setting:** Administrative claims data collected from medical centers across the United States (Vizient).

**Patients:** Adults between 18 and 99 years old who were admitted to ICUs for greater than or equal to 1 day.

\*See also pp. 1681 and 1683.

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**Interventions:** Massachusetts General Law c. 111, § 231, which established 1) maximum patient-to-nurse assignments of 2:1 in the ICU and 2) that this determination should be based on a patient acuity tool and by the staff nurses in the unit.

**Measurements and Main Results:** Nurse staffing increased similarly in Massachusetts ( $n = 11$  ICUs, Baseline patient-to-nurse ratio  $1.38 \pm 0.16$  to Post-mandate  $1.28 \pm 0.15$ ;  $p = 0.006$ ) and other states ( $n = 88$  ICUs, Baseline  $1.35 \pm 0.19$  to Post-mandate  $1.31 \pm 0.17$ ;  $p = 0.002$ ; difference-in-difference  $p = 0.20$ ). Massachusetts ICU nurse staffing regulations were not associated with changes in hospital mortality within Massachusetts (Baseline  $n = 29,754$ , standardized mortality ratio  $1.20 \pm 0.04$  to Post-mandate  $n = 30,058$ ,  $1.15 \pm 0.04$ ;  $p = 0.11$ ) or when compared with changes in hospital mortality in other states (Baseline  $n = 572,952$ ,  $1.15 \pm 0.01$  to Post-mandate  $n = 567,608$ ,  $1.09 \pm 0.01$ ; difference-in-difference  $p = 0.69$ ). Complications (Massachusetts: Baseline 0.68% to Post-mandate 0.67%; other states: Baseline 0.72% to Post-mandate 0.72%; difference-in-difference  $p = 0.92$ ) and do-not-resuscitate orders (Massachusetts: Baseline 13.5% to Post-mandate 15.4%; other states: Baseline 12.3% to Post-mandate 14.5%; difference-in-difference  $p = 0.07$ ) also remained unchanged relative to secular trends. Results were similar in interrupted time series analysis, as well as in subgroups of community hospitals and workload intensive patients receiving mechanical ventilation.

**Conclusions:** State regulation of patient-to-nurse staffing with the aid of patient complexity scores in intensive care was not associated with either increased nurse staffing or changes in patient outcomes. (*Crit Care Med* 2018; 46:1563–1569)

**Key Words:** hospital mortality; personnel staffing and scheduling; policy

Nurses are critical to ensuring the safe care of patients. However, studies investigating patient outcomes associated with nurse staffing have shown mixed results (1–8). Whereas multiple observational studies have identified associations between lower patient-to-nurse ratios (higher nurse staffing) and lower rates of complications within ICUs (1–3), interventions to increase nurse staffing on general wards have not shown improvements in patient outcomes (4–8). Observational findings from the ICU—where complex nursing

needs often differ from general wards—have not been explored using experimental or quasiexperimental study designs.

In response to concerns that unregulated patient-to-nurse ratios in the ICU may lead to patient harm (9); Massachusetts became the first state to mandate 1:1 or 2:1 patient-to-nurse staffing in the ICU guided by an acuity tool in March of 2016. The passage of the Massachusetts mandate created a natural experiment to evaluate the downstream effects of statewide policies applied to nurse staffing in the ICU. We hypothesized that Massachusetts ICU nurse staffing regulations would result in decreased complications and mortality for critically ill patients, when compared with patients admitted to ICUs across the country unaffected by Massachusetts regulations.

### METHODS

On June 30, 2014, Massachusetts General Law c. 111, § 231, “An Act relative to patient limits in all hospital intensive care units” was signed into law (10). The law established that 1) “in all intensive care units the patient assignment for the registered nurse shall be 1:1 or 1:2” and 2) that this determination should be based “on the stability of the patient as assessed by [an] acuity tool and by the staff nurses in the unit.” Regulations governing the implementation of the law were unanimously approved as 958 Code of Massachusetts Regulations 8.00 (11) on June 10, 2015. Academic medical centers, as defined by the Center for Health Information and Analysis (12), were given a compliance date of March 31, 2016. All other hospitals were required

to comply with mandate requirements by January 31, 2017. Hospitals were required to report on four ICU quality measures, including central line-associated bloodstream infections, catheter-associated urinary tract infections, hospital-acquired pressure ulcers, and patient falls with injury.

### Data Source and Cohort Definitions

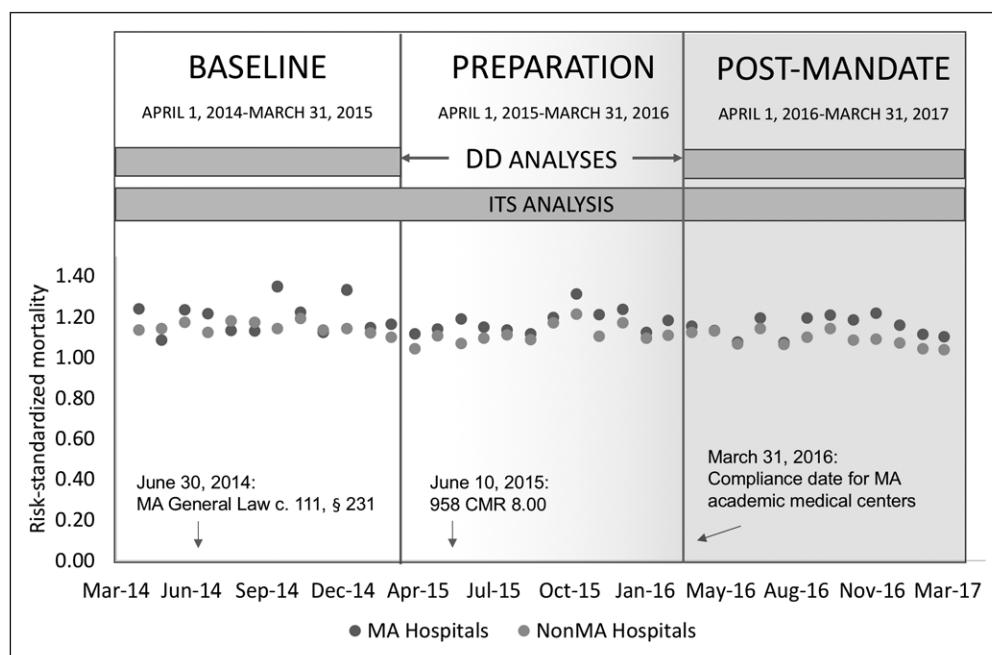
We conducted a retrospective cohort study of patients 18–99 years old admitted to ICUs at 246 medical centers and affiliated hospitals in the United States. Data were abstracted from Vizient (Clinical Data Base/Resource Manager and Action-OI databases), a collection of administrative claims and billing information from the largest network of healthcare systems in the United States. We used difference-in-difference methods to compare outcomes in academic Massachusetts and non-Massachusetts comparator hospitals during three time periods relative to the nurse staffing compliance date for academic hospitals: a “Baseline” period: April 1, 2014, to March 31, 2015; a “Preparation” period: April 1, 2015, to March 31, 2016; and a “Post-mandate” period: April 1, 2016, to March 31, 2017 (Fig. 1; Supplemental Methods, Supplemental Digital Content 1, <http://links.lww.com/CCM/D753>).

### Outcomes

The primary outcome was the change in risk-standardized mortality ratio during the Baseline and Post-mandate periods for patients hospitalized within Massachusetts academic

ICUs, when compared with patients hospitalized in non-Massachusetts academic ICUs. Risk-standardized hospital mortality was calculated by Vizient 2016 Mortality Risk Adjustment Models (13). To contextualize changes in standardized mortality ratios, we also reported changes in the component observed and expected mortality rates.

We evaluated two clinical secondary outcomes: 1) a composite in-hospital complication rate composed of four complications for which reporting was mandated (central line-associated bloodstream infections, catheter-associated urinary tract infections, hospital-acquired pressure ulcers, and patient falls with injury) (1–3); and 2) rates of do-not-resuscitate (DNR) orders. Previous studies showed associations between ICU staffing and DNR rates that may influence



**Figure 1.** Monthly risk-standardized mortality of patients receiving intensive care in the 24 mo before and 12 mo after Massachusetts (MA) legislation regulating ICU nurse staffing. Dates of legislation milestones (signing of MA General Law c.111, § 231, approval of 958 Code of Massachusetts Regulations [CMR] 8.00 governing implementation, and the official compliance deadline) are shown against the x-axis timeline. The 36-mo period was divided into three time periods for the purposes of study analysis and are shown above the plot. All difference-in-difference (DD) analyses compared two 12-mo time periods: a “Baseline” period from April 1, 2014, to March 31, 2015, and a “Post-mandate” period from April 1, 2016, to March 31, 2017. Primary analyses excluded the year immediately preceding the compliance date from April 1, 2015, to March 31, 2016, which was a “Preparation” period during which MA ICUs may have begun implementing changes to staffing. Interrupted time series (ITS) analyses included all time periods.



mortality (14). We also assessed for changes in nurse staffing before and after the mandate compliance date.

### Statistical Analysis

Difference-in-difference approaches can be used to evaluate effects of policy interventions introduced at a specific time and can achieve unbiased effect estimates when temporal trends are the same within the intervention and comparison groups (despite differences in group characteristics) (15). After establishing parallel baseline trends in mortality between Massachusetts and non-Massachusetts hospitals in the 2 years preceding the compliance date ( $p$  for difference in trends = 0.58), we investigated the effects of the nurse staffing mandate for risk-standardized mortality using generalized linear models with a Poisson distribution and the natural log of expected mortality as an offset variable (16). Difference-in-difference estimates were evaluated using similar methods for unadjusted hospital mortality, expected mortality, complications, and DNR orders. Three Massachusetts hospitals (11 ICUs) and 33 hospitals (88 ICUs) outside of Massachusetts reported nurse staffing data during both the Baseline and Post-mandate period; we calculated the ratio of total patient-days to the total nurse-days worked by licensed nurses to yield patient-to-nurse ratios for the Baseline and Post-mandate period and compared the change in nurse staffing using  $t$  tests.

### Sensitivity and Subgroup Analysis

We performed four sensitivity and subgroup analyses. First, we used a controlled interrupted time series approach (17, 18) to evaluate the change in unadjusted mortality after implementation of the nursing mandate among academic hospitals in Massachusetts when compared with outside of Massachusetts. The controlled interrupted time series design allowed an alternative approach to assess changes to mortality at the date of mandate implementation that did not depend on risk adjustment using a standardized mortality ratio. We assessed the difference in monthly mortality rates for MA and non-MA hospitals in the 2 years before and 1 year after the legislation compliance date. Due to the presence of first-order autocorrelation (Durbin-Watson test = 1.5;  $p = 0.026$ ), we used an exact maximum likelihood to account for autocorrelated errors and seasonality. Models included independent variables for time (i.e., number of months from start of follow-up), the onset of the policy intervention (i.e. pre- vs postimplementation), and time after the policy intervention (19). Polynomial models were also explored for best fit.

Second, we conducted a difference-in-difference analysis for risk-standardized and unadjusted mortality in nonacademic community hospitals. Previous analyses have shown that nurse staffing can vary between academic and community hospitals (20), and that state nursing mandates may affect hospitals differentially depending on prelegislation staffing levels (4, 5). Nonacademic community hospitals were required to comply with mandate requirements by January 31, 2017 date; therefore, two time periods were compared: February 1, 2015, to June 30, 2015, and February 1, 2017, to June 30, 2017, for

Massachusetts and non-Massachusetts comparator nonacademic hospitals.

Third, we examined the effect of the nurse staffing mandate in the subgroup of mechanically ventilated patients (using *International Classification of Diseases* [ICD], 9th Edition and ICD, 10th Edition procedure codes) (21). The presence of mechanical ventilation accounts for a significant increase in acuity score on a tool such as the Therapeutic Intervention Scoring System-76 (22), and therefore, patients requiring mechanical ventilation may be more likely to have nurse staffing increased as a result of the mandate.

Fourth, we performed a post hoc exploratory analysis to evaluate changes in patient outcomes within Massachusetts alone using interrupted time series analysis (17, 18). This analysis was conducted to evaluate whether the changes in nurse staffing after implementation of state regulations were associated with changes in patient outcome, without relying on assumptions that Massachusetts was comparable to other states. Methods were similar to the controlled time series approach, with exact maximum likelihood used to account for autocorrelated errors (Durbin-Watson test = 1.4;  $p = 0.01$ ) and seasonality, independent variables for time, the onset of the policy intervention, and time after the policy intervention (19) and polynomial models explored for best fit.

All statistical testing was through SAS 9.4 (SAS Institute, Cary, NC), with two-tailed and performed with  $\alpha$  equals to 0.05. A sample size of 7,000 was required to detect a 10% relative change in mortality with  $\alpha$  equals to 0.05 and power of 0.90. A sample size of 10,000 was required to detect a 25% relative change in complications with  $\alpha$  equals to 0.05 and power of 0.90. This study of deidentified composite hospital data was deemed exempt from review by the Boston University Medical Institutional Review Board.

## RESULTS

### Cohort Characteristics

During the Baseline period, we identified 29,754 ICU admissions in the six academic hospitals in Massachusetts and 572,951 ICU admissions at 114 academic hospitals outside of Massachusetts. In the Preparation period between passage of the staffing law and mandated implementation date, we identified 29,553 ICU admissions in Massachusetts and 580,837 ICU admissions outside of Massachusetts. In the Post-mandate period, we identified 30,058 ICU admissions in Massachusetts teaching hospitals and 567,608 ICU admissions at Association of American Medical Colleges teaching hospitals outside of Massachusetts. Characteristics of the six cohorts are shown in **Table 1**.

### Nurse Staffing Changes

Patient-to-nurse ratios decreased in Massachusetts after nurse staffing legislation (Baseline:  $1.38 \pm 0.16$  to Post-mandate:  $1.28 \pm 0.15$ ,  $p = 0.006$ ) and outside of Massachusetts in the same time periods (Baseline:  $1.35 \pm 0.19$  to Post-mandate:  $1.31 \pm 0.17$ ,  $p = 0.002$ ), without significant difference-in-differences for change in nurse staffing ( $-0.05$  [95% CI,  $-0.03$  to  $0.13$ ];  $p = 0.20$ ).

**TABLE 1. Characteristic of Study Cohorts During Three Study Periods**

	Baseline Period, April 1, 2014, to March 31, 2015	Preparation Period, April 1, 2015, to May 31, 2016	Post-Mandate Period, April 1, 2016, to March 31, 2017
Massachusetts			
Total, <i>n</i>	29,754	29,553	30,058
Age, yr, <i>n</i> (%)			
18–50	7,060 (23.7)	6,829 (23.1)	7,057 (23.5)
51–64	8,818 (29.6)	8,785 (29.7)	9,042 (30.1)
65–79	9,398 (31.6)	9,529 (32.2)	9,807 (32.6)
≥ 80	4,478 (15.1)	4,410 (14.9)	4,152 (13.8)
Female, <i>n</i> (%) <sup>a</sup>	12,706 (42.7)	12,715 (43.0)	12,838 (42.7)
Race, <i>n</i> (%)			
White	22,305 (75.0)	21,980 (74.4)	22,293 (74.2)
Asian	958 (3.2)	1,004 (3.4)	957 (3.2)
Black	2,955 (9.9)	3,169 (10.7)	3,236 (10.8)
Other	2,364 (7.9)	2,101 (7.1)	2,210 (7.4)
Missing	1,172 (3.9)	1,299 (4.4)	1,362 (4.5)
Outside of Massachusetts			
Total, <i>n</i>	572,951	580,837	567,608
Age, yr, <i>n</i> (%)			
18–50	166,476 (29.1)	167,249 (28.8)	160,343 (28.2)
51–64	178,919 (31.2)	181,205 (31.2)	175,557 (30.9)
65–79	162,148 (28.3)	167,385 (28.8)	167,674 (29.5)
≥ 80	65,408 (11.4)	64,998 (11.2)	64,034 (11.3)
Female, <i>n</i> (%) <sup>b</sup>	247,284 (43.2)	249,391 (42.9)	244,318 (43.0)
Race, <i>n</i> (%)			
White	379,214 (66.2)	384,851 (66.3)	377,073 (66.4)
Asian	11,758 (2.1)	11,797 (2.0)	12,525 (2.2)
Black	116,404 (20.3)	120,979 (20.8)	116,154 (20.5)
Other	49,039 (8.6)	48,358 (8.3)	45,765 (8.1)
Missing	16,536 (2.9)	14,852 (2.6)	16,091 (2.8)

<sup>a</sup>Unknown sex in one patient (0.0%) in Massachusetts during the preparation period.

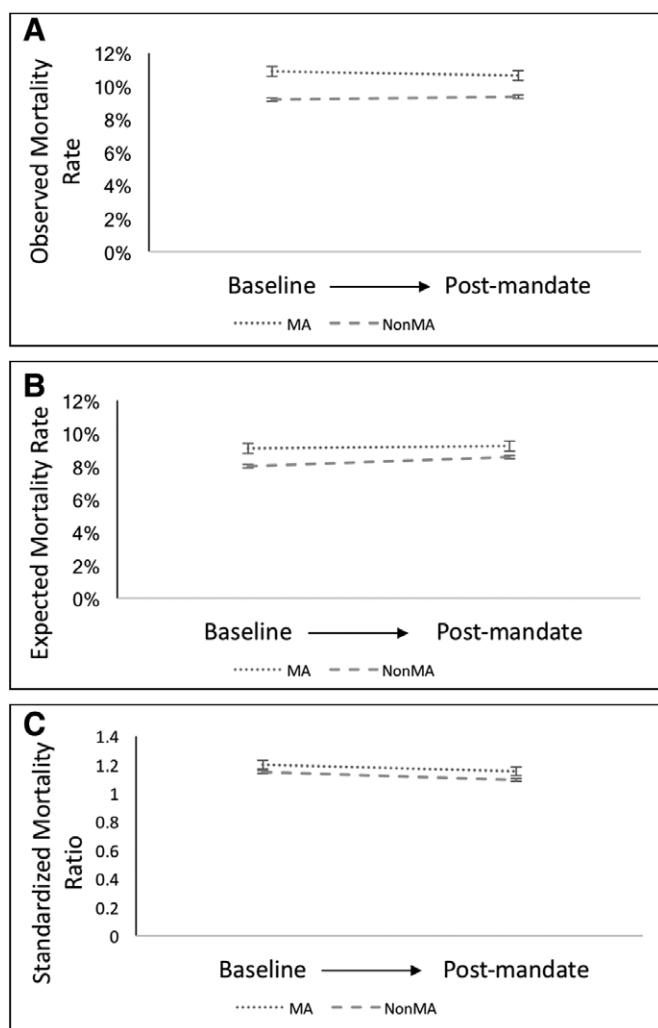
<sup>b</sup>Unknown sex in 43 patients (0.0%) during the baseline period, 53 patients (0.0%) during the preparation period, 106 (0.0%) during the Post-mandate period outside of Massachusetts.

### Mortality, Complications, and Advance Directives

After implementation of nurse staffing regulations, risk-standardized mortality remained stable in Massachusetts (1.20 [95% CI, 1.16–1.24] to 1.15 [1.11–1.19];  $p = 0.11$ ) but decreased outside of Massachusetts (1.15 [1.14–1.16] to 1.09 [1.08–1.10];  $p < 0.001$ ), without a significant difference-in-difference (odds ratio [OR], 1.01; 95% CI, 0.96–1.06;  $p = 0.69$ ) (Fig. 2). Observed mortality (OR, 0.96; 95% CI, 0.91–1.00;  $p = 0.09$ ) and expected mortality (OR, 0.95; 95% CI, 0.89–1.00;  $p = 0.06$ ) also did not change significantly in Massachusetts

after nursing legislation, when compared with outside of Massachusetts (Fig. 2).

The rate of complications was stable between the Baseline period and the Post-mandate period in Massachusetts (0.68–0.67%;  $p = 0.88$ ) and outside of Massachusetts (0.72–0.72%;  $p = 0.83$ ), with no significant difference in trends ( $p = 0.92$ ). The proportion of ICU patients with a DNR status increased in Massachusetts (13.5–15.4%;  $p < 0.001$ ) and outside of Massachusetts (12.3–14.5%;  $p < 0.001$ ), without a significant difference-in-difference ( $p = 0.07$ ).



**Figure 2.** Mortality in the Baseline period versus Post-mandate periods, comparing ICUs within Massachusetts (MA) and ICUs outside of Massachusetts (nonMA). **A**, The unadjusted mortality rate remained stable in Massachusetts (10.9–10.7%;  $p = 0.32$ ) and rose outside of Massachusetts (9.2–9.4%;  $p = 0.003$ ). The difference-in-difference in unadjusted mortality for patients in ICUs in Massachusetts when compared with outside of Massachusetts was not significantly different ( $p = 0.09$ ). **B**, The expected mortality remained stable in Massachusetts (9.1–9.2%;  $p = 0.53$ ) and increased outside of Massachusetts (8.0–8.6%;  $p < 0.001$ ). The difference-in-difference in expected mortality for Massachusetts compared with non-Massachusetts hospitals was not significantly different ( $p = 0.06$ ). **C**, The risk-standardized mortality ratio in Massachusetts was 1.20 (95% CI, 1.16–1.24) in the Baseline period and 1.15 (1.11–1.19) ( $p = 0.11$ ) in the Post-mandate period, whereas the mortality index outside of Massachusetts was 1.15 (1.14–1.16) in the Baseline period and 1.09 (1.08–1.10) in the Post-mandate control period ( $p < 0.001$ ). The difference-in-difference estimate for risk-standardized mortality associated with implementation of the Massachusetts nursing staffing mandate was not significant (odds ratio = 1.01; 95% CI, 0.96–1.06;  $p = 0.69$ ). Error bars represent 95% CIs.

### Sensitivity Analyses

Sensitivity analyses showed similar results to the primary analysis. Controlled interrupted time series analysis did not demonstrate a significant change in observed mortality in Massachusetts when compared with ICUs outside of Massachusetts following the Massachusetts policy implementation ( $\beta = -0.81$ ;  $p = 0.23$ ) (Supplemental Fig. 1, Supplemental Digital Content 1, <http://links.lww.com/CCM/D753>). Similarly, analysis of

nonacademic community hospitals did not show a significant difference-in-difference of risk-standardized mortality (OR, 0.99; 95% CI, 0.91–1.13;  $p = 0.89$ ). Risk-standardized mortality in Massachusetts decreased from 1.29 (95% CI, 1.21–1.37) to 1.14 (95% CI, 1.07–1.22) ( $p = 0.01$ ), whereas outside of Massachusetts, the mortality index decreased similarly from 1.10 (95% CI, 1.11–1.19) to 0.96 (95% CI, 0.93–0.99) ( $p < 0.001$ ) among nonacademic hospitals. Analysis of complication rates and DNR status revealed results similar to academic hospitals (Supplemental Results, Supplemental Digital Content 1, <http://links.lww.com/CCM/D753>). Mechanically ventilated patients also did not show a significant difference-in-difference in risk-standardized mortality (OR, 1.02; 95% CI, 0.96–1.08;  $p = 0.57$ ), rate of complications ( $p = 0.42$ ), or in rates of DNR orders ( $p = 0.31$ ). Analysis of interrupted time series within Massachusetts alone was also not associated with a significant change in observed mortality in Massachusetts (adjusting for first-order autocorrelation,  $\beta$  for immediate change in mortality =  $-1.13$ ;  $p = 0.18$ ), although some quadratic models suggested increasing mortality trends after implementation (Supplemental Fig. 2, Supplemental Digital Content 1, <http://links.lww.com/CCM/D753>).

### DISCUSSION

We performed an analysis of the effect of a Massachusetts law mandating the use of a risk score within ICUs to assign patient-to-nurse ratios of either 2:1 or 1:1, based upon patient acuity and anticipated care intensity. Increases in nurse staffing in Massachusetts after institution of statewide regulations were not significantly higher than staffing trends in states that did not pass ICU nurse staffing legislation. We did not identify improvements in patient outcomes associated with the Massachusetts nursing regulations. Results were robust to multiple sensitivity and subgroup analyses.

Our findings may be considered from two perspectives. First, the difference-in-difference analyses comparing changes in Massachusetts after the implementation of ICU nurse staffing regulations to changes in other states were analogous to an intention-to-treat analysis of the Massachusetts nurse staffing policy legislation. Our results suggest that the Massachusetts nursing regulations were not associated with changes in staffing or patient outcomes when compared with secular trends. Second, when examined apart from secular changes in other states, modest nurse staffing increases in Massachusetts (the change from 1.38 to 1.28 patients per nurse is approximately one extra nurse per 20-bed ICU per 12-hr shift) remained unassociated with changes in hospital mortality.

Few states have passed laws regulating nurse staffing. California previously mandated maximum patient-to-nurse ratios within acute care hospitals but did not use scoring systems to determine 1:1 staffing levels. Although California regulations were associated with an increase in nurse staffing, outcomes of hospitalized did not improve after the California law, findings similar to Massachusetts ICUs (4, 6, 8, 23).

Previous observational studies of nurse staffing have identified associations between lower patient-to-nurse ratios and improved outcomes (1, 2, 24, 25). However, these observational

studies were unable to distinguish the causal effect of nurse staffing on patient outcomes—patients in hospitals with a higher commitment to nursing staffing may also benefit from higher overall hospital commitment to a quality of care and nurse retention, improved nurse-physician collaboration, or other predictors of patient safety (1, 24, 26–29). In the absence of large randomized trials to determine the causal effect of nurse staffing on patient outcomes, studies of policy interventions provide natural experiments to evaluate the effectiveness of interventions. Whereas baseline demographic differences between Massachusetts and non-Massachusetts hospitals reflect existing underlying demographic differences in the population, the difference-in-difference analysis compares within state changes and therefore is likely robust to baseline demographic differences. Multiple factors may have contributed to the minimal changes in nurse staffing and observed lack of improvement in patient outcomes associated with Massachusetts' ICU nurse staffing regulations, including the following: 1) adequate nurse staffing and competent nurse assignment determination before the mandate; 2) significant leeway given to hospitals in both the determination of the acuity/severity tool to be used to guide nursing assignments and unclear implementation of the tool in guiding nursing assignments; 3) multidisciplinary staffing factors important for patient outcomes in addition to nursing care (pharmacists, respiratory therapists, among others); 4) secular trends of increased ICU nurse staffing outside of Massachusetts; and 5) a diluted effect on mortality due to unchanged or increased hospital-ward mortality as a result of earlier transfer from the ICU to the floor in the setting of ICU nurse staffing limitations. Hospitals used different tactics in designing or choosing acuity tools to determine nurse staffing, which may reflect uncertainty as to how to optimally distribute nursing resources.

Our findings should be interpreted in the context of limitations. First, although our analysis is based on deidentified individual patient data, risk-standardized mortality ratios were averaged across hospitals. However, interrupted time series analysis of observed mortality rates, which did not incorporate risk adjustment, corroborated the risk-standardized mortality findings. Second, nursing regulations may have had heterogeneous effects within certain patient populations or larger effects at hospitals with lower premandate staffing. However, results were similar in a subgroup of mechanically ventilated patients who were more likely to be affected by acuity score-based nurse staffing, as well as in nonacademic medical centers with generally higher patient-to-nurse ratios (5). Further studies may seek to evaluate for heterogeneity of policy effects across other patient populations, such as across type of ICU. Third, measured complications were rare (< 1% of patients), but sample size calculations suggested sufficient power to detect differences in complication rates. The complications chosen for the composite analysis were the four complications for which reporting to the state was mandated, but given rarity, were likely not ideal measures of improvements in nurse-staffing-sensitive ICU morbidity. The low rates of complications may reflect that other external forces aside from state legislation

(e.g., Center for Medicaid Services and the Joint Commission) have already maximally reduced occurrence rates. Further studies should evaluate other candidate measures of nurse-staffing-sensitive morbidity; for example, Kane et al (24) identified unplanned extubations as a measure potentially sensitive to nurse staffing. Unfortunately, few academic hospitals contributed data regarding nurse staffing and therefore power to detect changes in nurse staffing was limited—although effect estimates suggest small differences in staffing changes after the legislation. Fourth, Massachusetts instituted both maximum patient-to-nurse ratios and the use of patient severity scores in a bundled approach; we were unable to distinguish effects of the patient-to-nurse ratio mandate from the regulation of nurse staffing based upon patient severity scores. It is possible that our findings are the result of suboptimal nursing resource allocation as a result of the acuity tool alone, and that using other methods of nurse staffing distribution may yield different outcomes. Fifth, we did not have data on costs attributable to this legislation, although costs associated with development and implementation of severity score-based nurse staffing and reporting compliance in response to new mandates may be substantial (30). Sixth, other outcomes important to patients (such as patient and family satisfaction, emotional harms, or postintensive care syndrome) and nurses (job satisfaction or creation of a healthier work environment leading to higher nurse retention rates) may be sensitive to nurse staffing regulations and deserve further investigation. A longer follow-up comparison period may also reveal that state legislation similar to MA may prophylactically prevent decrease in nurse staffing or may more readily facilitate appropriate increases in nurse staffing in response to rising patient complexity. Conversely, unintended adverse consequences (longer emergency department wait times or floor-to-ICU transfer times due to limits on ICU staffing, reduction in staffing with more experienced nurses) should be investigated as well. Finally, results may differ among hospitals that chose not to submit information to the Vizient database. Participation in Vizient is voluntary in nature and may reflect a sample of improvement-focused hospitals; however, all MA academic centers submitted data to Vizient, decreasing the likelihood that our findings do not represent MA hospital academic medical center outcomes.

## CONCLUSIONS

In conclusion, Massachusetts General Law c. 111, § 231, which regulates the staffing assignments of nurses to patients in the ICU based upon patient acuity tools, failed to demonstrate improvements in patient mortality or complication rates among critically ill patients, potentially due to small effects on nurse staffing. Given the excess costs of enacting and enforcing statewide legislation to implement acuity-guided ICU nurse staffing, future efforts to regulate patient-to-nurse ratios should carefully first consider the extent of the effects of the mandate on nurse staffing levels. In line with previous studies outside of the ICU, our study of ICU nurse staffing adds further evidence suggesting that statewide legislation to mandate nurse staffing strategies may not effectively improve patient outcomes.



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# Assessing the Impact of California's Nurse Staffing Ratios on Hospitals and Patient Care

## Introduction

In 2004, California became the first state to establish minimum nurse-to-patient staffing requirements in acute-care hospitals. Little is known about how these regulations affected California's hospitals, the market for nursing labor, or the quality of hospital care. While research and news reports do indicate that hospital staffing of licensed nurses increased between 2002 and 2004 and employment of unlicensed nursing assistants dropped,<sup>1-3</sup> some hospitals did not meet the ratios in the first year of their implementation<sup>4-6</sup> and no significant impact on the quality of patient care has been measured.<sup>7-9</sup>

Prior studies have focused on average changes in staffing and patient outcomes across all California hospitals. This study, in contrast, examines how the minimum staffing regulations affected different types of hospitals, categorizing them according to ownership, financial position before the ratios were enacted, and mix of patients. The research then probes three issues:

- What strategies did hospitals use to meet the staffing requirements?
- Are the ratios associated with changes in hospital financial status?
- Did the ratios improve the quality of hospital care?

The results show that the nurse staffing legislation resulted in higher use of registered nurses in most California hospitals. Implementation of the staffing regulations could not be tied to changes in hospital finances; rather, changes in Medicare and Medi-Cal payment rates and demands to

address seismic building requirements had far greater effects on finances. Hospital administrators found that it was a challenge to meet the staffing requirements, particularly in ensuring that staff were available at all times, including during breaks and meals. Finally, many of the health care leaders interviewed for the study expressed an expectation that the minimum staffing ratios would increase the quality of care due to increased interaction with patients; however, there was no evident change in patient length of stay or adverse patient safety events. None of these findings were affected by hospital ownership, financial position, or patient mix.

## Background

In 1999, the California State Assembly passed AB 394, mandating that the state establish minimum nurse-to-patient staffing in acute-care hospitals. Between 1999 and 2002, the California Department of Health Services developed registered and licensed vocational nurse-to-patient ratios.<sup>10,11</sup> The law went into effect in January 2004 with specific ratios for different types of hospital units; for example, the minimum ratio in medical-surgical units was one nurse per six patients. The ratios were to be adjusted in January 2005 to require fewer patients per nurse in selected units; for example, the ratio in medical-surgical units would have dropped to one to five. This change was suspended in November 2004 by the Schwarzenegger administration, but the suspension was invalidated by the Sacramento County Superior Court in March 2005. Court challenges by the California Hospital Association proved unsuccessful, and the additional ratio regulations went into full effect on April 7, 2005.<sup>12</sup>

Licensed vocational nurses (LVNs) may make up half of the licensed nurses in this ratio, but whether they can be employed to this extent in practice depends on the needs of patients in the hospital. The legal scope of practice for LVNs, who must work under the direction of physicians or registered nurses (RNs), does not include administration of intravenous medications or the assessment of patients; thus, in most hospitals LVNs can have full responsibility for only a small share of patients. In addition, hospitals have tended to underuse LVNs by limiting their role to an even greater degree than the legal scope of practice requires.<sup>13</sup>

Little is known about how the minimum staffing regulations affected hospitals, nursing labor markets, or the quality of hospital care in California. In fact few studies had been conducted from which the state could develop the ratio requirements. A literature review conducted for the California Department of Health Services noted that only a handful of recent studies and reviews had demonstrated consistent relationships between staffing levels for licensed nurses and the quality of patient care, and none identified an ideal staffing ratio for hospitals.<sup>14,15</sup> The few publications that examined the effect of California's ratios reported that many hospitals did not appear to be meeting the standard in 2004—the first year of the regulation.<sup>16–18</sup> Recent research also found that licensed nursing staff increased notably between 2002 and 2004, while employment of unlicensed nursing assistants dropped; however, no significant improvement in the quality of patient care could be detected.<sup>19–21</sup>

Because the papers published to date have focused on average changes in staffing, patient outcomes, and hospital finances across all California hospitals, they may not capture the full impact of the ratios, since minimum staffing regulations may have had different effects on different types of hospitals. Previous studies have found that some hospitals—such as those with a high share of publicly insured patients—are more likely to report a shortage of nurses; these hospitals may have found it

particularly difficult to recruit and retain nurses to meet the staffing regulations. Hospitals that were in weak financial positions prior to the enactment of the ratio legislation may not have had the financial resources to pay for more nurses. Differences in hospitals' ability to respond to the regulations may in turn result in variation in the benefit to patients.

For the research reported in this issue brief, the methods used by hospitals to meet the staffing requirements were explored: Did permanent employment increase? Did hiring and retention change? Were more temporary agency nurses used? Changes in hospital financial positions were also examined. Finally, patient safety measures were compared to learn whether the implementation of the staffing regulations was associated with improvements in patient safety. For each of these three topics, hospitals were categorized by their ownership, financial position before the ratios were enacted, and mix of patients to learn whether the impact of minimum staffing ratios varied across hospitals.

## Methodology

This study combined quantitative analysis of several data sets with qualitative analysis of interviews conducted at 12 hospitals. Quantitative analysis of the impact of the regulations on staffing, fiscal, and health care outcomes was conducted for 410 general acute-care hospitals from 1999 through 2007. The main sources of data were three datasets collected by the California Office of Statewide Health Planning (OSHPD). With these data, changes in the hours worked by registered nurses, licensed vocational nurses, aides and orderlies, and agency-employed nurses were examined using the annual hospital disclosure reports. The fiscal health of each hospital was determined by comparing operating margins before and after ratios, using the quarterly hospital financial data. A set of nursing-sensitive metrics devised by the Agency for Healthcare Research and Quality (AHRQ) was calculated for hospitals reporting thirty or more patients at risk for

an incident during one time period, using the patient discharge data.

Changes in employment also were studied using the base wage file of the California Employment Development Department (EDD) from 1998 through 2007. These data compile wage and employment information that are primarily collected for unemployment insurance and disability insurance programs. The base wage file does not include occupation data, so it was not possible to identify registered nurses. Thus, all analyses of turnover were conducted for all hospital employees. Since RNs account for about one-third of hospital employees, it is expected that hospital-wide turnover rates will reflect proportional changes in nurse staffing. The final database included 244 employers. Due to the confidentiality of wage and employer information, all analyses of these data were performed by the EDD.

All quantitative data were first analyzed for all hospitals combined. The analyses were then repeated for three categorizations of hospitals: profit status (public, for-profit, and nonprofit), fiscal strength (fiscally strongest, fiscally weakest, and average fiscal position), and patient demographics (i.e., those serving higher-income populations with few recent immigrants; those whose patient mix includes a disproportionate share of lower-income, non-resident, or homeless patients; and average patient mix). Table 1 presents the number of each category of hospital included in this study.

**Table 1: Number of Hospitals in the Study, by Type**

Nonprofit	223
For-profit	125
District	41
Public	30
Fiscally Strong (average operating margin: 10.9 percent)	42
Fiscally Weak (average operating margin: -15.8 percent)	31
Lower-income Patients (average share of patients in public programs: 64.7 percent)	71
Higher-income Patients (average share of patients in public programs: 51.7 percent)	39
<b>TOTAL</b>	<b>410</b>

Interviews were conducted with 23 chief nursing officers, chief nurse executives, vice presidents of nursing, chief executive officers, emergency department directors, and other managers and directors. Hospitals selected for the case studies were chosen to represent a range of financial and recruiting positions from good to weak. Twenty hospitals were contacted for the study, with 12 agreeing to participate. Seven of the 12 hospitals are nonprofits, four are public hospitals, and one is for-profit. The researchers also interviewed several people currently or recently employed in the insurance industry to learn how the ratio regulations were addressed in contract negotiations between hospitals and payers.

**Findings**

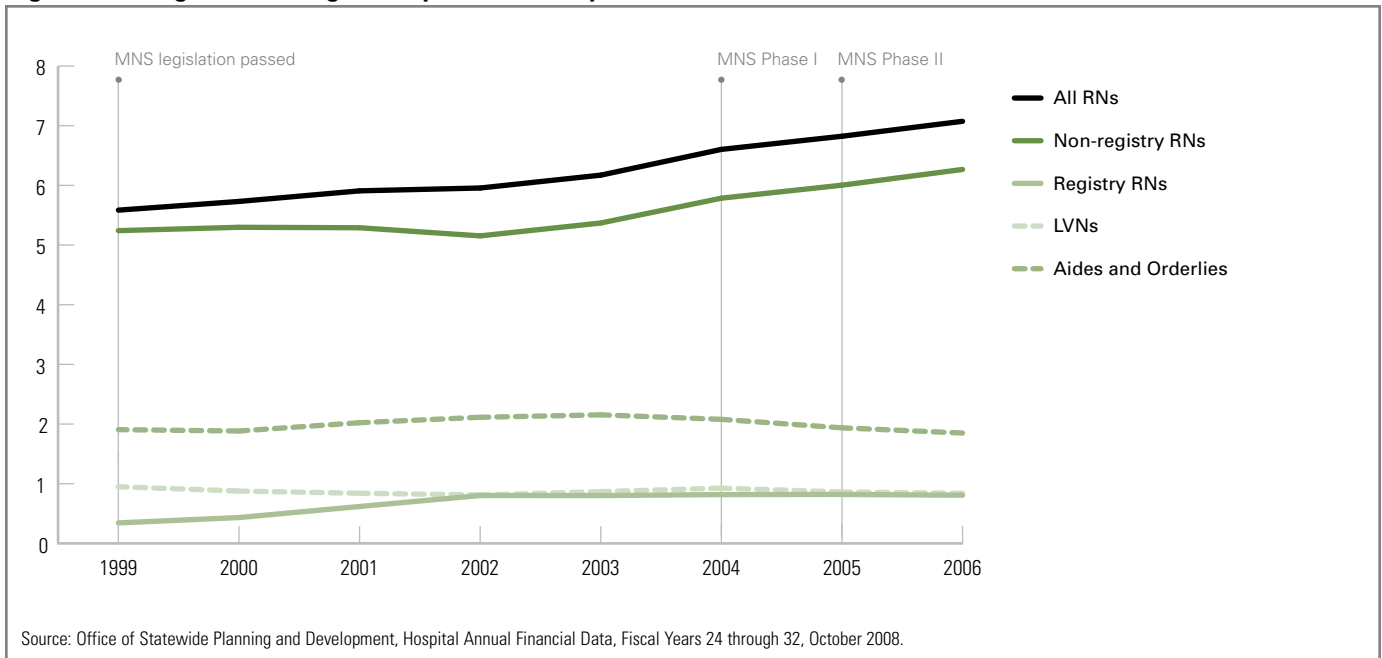
**Staffing Changes and Challenges**

The nurse staffing legislation resulted in higher employment of licensed nurses in most California hospitals. Figure 1 presents changes in hours worked by RNs, LVNs, and aides/orderlies between 1999 and 2006. The hours worked by regular RN employees and agency RNs also are indicated. RN hours per patient day increased throughout this period, with more rapid growth after 2002. Agency RN hours rose notably between 2000 and 2002. After 2002, RN hours per patient day for non-agency RNs increased. The levels of LVN and aide hours were fairly stable throughout the entire period.

Figure 2 compares RN hours per patient day before and after 2004, for all hospitals and by type of hospital. Prior to the enactment of the ratios, nonprofit hospitals had the highest number of RN hours per patient day, while district, for-profit, and fiscally weak hospitals had fewer RN hours per patient day. After the ratios were implemented, average RN hours per patient day increased for hospitals overall, as well as for each type of hospital. This growth varied by type of hospital. One might expect that staffing would have increased more among hospitals that had lower initial staffing; however, this is not the case for the groups presented in Figure 2. Less growth in RN



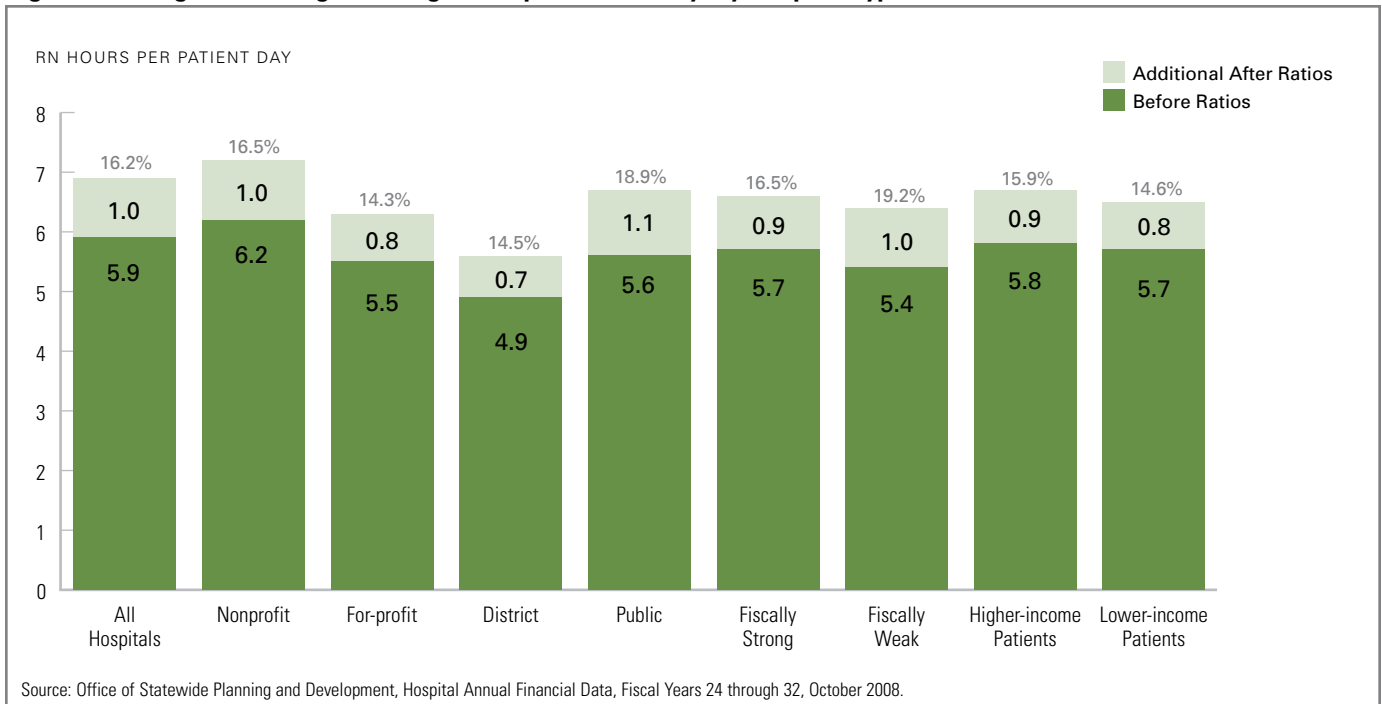
**Figure 1: Changes in Nursing Hours per Patient Day, 1999–2006**



hours per patient day was observed for district hospitals, for-profit hospitals, and hospitals with lower-income patients—all of which had initial staffing below the statewide average.

Figure 3 examines hospital hiring of new employees from 1999 through 2007, as calculated from the EDD’s base wage file. Hiring peaked in 2002 for all hospitals, with an average of 29 percent of employees being new to their

**Figure 2: Changes in Average Nursing Hours per Patient Day, by Hospital Type, Before and After 2004**



**Figure 3: Percent of Employees New to Hospitals Each Year, by Hospital Type**



hospitals that year. For-profit hospitals increased their hiring earlier, in 2001. This is not surprising because staffing levels at for-profit hospitals were below the statewide average before the ratios were implemented, which meant they had a greater need to hire to meet the regulations. Hiring by nonprofit hospitals was comparatively stable over time, though it decreased somewhat after 2001. Hiring by public hospitals, which in Figure 3 includes district hospitals, also was fairly stable between 1999 and 2007. Hospitals that served a greater proportion of higher-income patients engaged in more hiring throughout this time period, with hiring rising notably in 2003, dropping in 2004, and then rising again through 2007. Hospitals that served more lower-income/non-resident patients increased hiring somewhat in 2001 and 2002, but decreased hiring after 2004. Fiscally strong hospitals did more hiring than fiscally weak hospitals, but the difference was not large. (In the interest of clarity, the data tracking patient demographics and financial strength were not included in Figure 3.)

The hospital leaders interviewed for this study reported that they faced many challenges as the staffing regulations were put in place. Prior to the implementation of the

ratios in 2004, most hospitals had completed financial and staffing assessments. A few interviewees reported that staffing ratios at their hospitals or units were already at or above the mandated levels, but most reported that they needed to hire more RNs to meet the requirements, particularly to cover meals and breaks. California's labor code regulates how many meal breaks employees must receive based upon shift length, and the interaction of this regulation with the minimum staffing requirement posed a particular challenge.

The majority of the individuals interviewed for this study, both at high-performing and under-performing hospitals, discussed the problems associated with meeting the "at all times" requirement of the ratios law in conjunction with meal breaks for staff. This challenge was addressed with a wide variety of solutions. Many created "float pools" to have a supply of staff to cover meal breaks. Charge nurses and nurses from registries are also used to cover meal breaks. One hospital created a position whereby a nurse works a truncated shift for the sole purpose of providing meal breaks. Several interviewees noted that the need to cross-train staff increased, particularly in specialty areas, in order to increase float coverage. Some interviewees

thought the implementation of the ratios increased tension between management and staff, and associated this with rules regarding meal breaks. The combination of meal break and staffing regulations was perceived as reducing the ability of staff nurses to use their professional judgment in determining the best time to take a break, and interviewees believed that nurses found this loss of autonomy frustrating.

Nine of the 12 hospitals that participated in the interviews reported that 90 percent or more of their nursing staff were RNs, and six hospitals said they employ traveling or agency nurses to meet staffing requirements. Many hospital leaders reported difficulty finding specialty nurses or experienced nurses holding bachelor's or master's degrees, noting that new graduates are not appropriate for some positions. Interviewees also noted that they could not readily use LVNs to meet the staffing regulations due to their limited scope of practice. Because only RNs can assess patients and administer intravenous medications those few hospitals that used LVNs had to partner them with RNs; some of the nursing managers reported that their RN staff thought this arrangement increased their workload, since they had to provide care to both their own and the LVN's patients while supervising the LVN. A reduction of ancillary staff support was reported at several of the hospitals. These reductions resulted in additional primary care duties for the RNs, such as giving baths to patients. Managers reported hearing from their RN staff that they were unhappy with these additional job tasks and the shift in their role in patient care. These issues were of equal importance among both high-performing and under-performing hospitals.

Overwhelmingly, interviewees said they want some flexibility in applying the ratios. particularly the removal of the "at all times" language. The lack of flexibility was singled out as the reason hospitals have trouble remaining in compliance, since it is expensive and challenging to maintain the mandated ratios at all times and in all contingencies, such as days when too many nurses call

in sick. Another recommendation focused on using acuity-based ratios, so as to avoid situations where the minimum staffing regulations dictate a lower ratio than was generally thought of as necessary, or vice versa. The night shift and patients waiting to be discharged were both cited as examples of situations requiring fewer nurses than the ratios prescribe. On the other hand, caring for patients with complex conditions, such as multiple and chronic illnesses, was cited as an example of an area where the staffing ratios fell short of meeting the patient's needs.

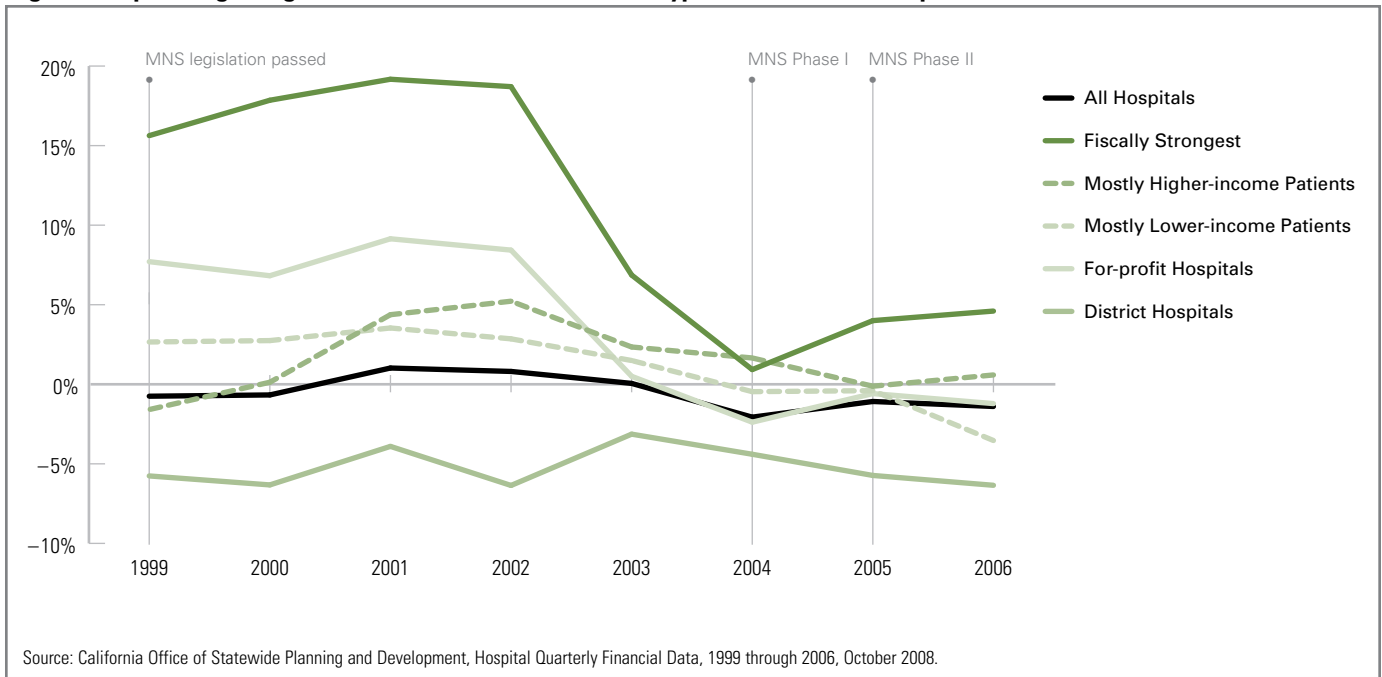
### Fiscal Stability and Change

Over the eight years examined in this study, California's hospitals experienced decreasing operating margins; however, these changes could not be tied directly to the nurse staffing legislation. A variety of financial policies had a substantial effect on hospitals from 1999 to 2007.

Medicare margins severely declined as the Balanced Budget Act of 1997 constricted government payment rates and Medicare significantly changed its billing procedures and payment streams.<sup>22,23</sup> After a series of emergency state funding bills, California had fewer hospitals reporting operating deficits in 2005 than in 1999. However, in late 2005, the state began enacting a series of changes in Medicaid funding that, along with new changes in Medicare funding, sought to decrease government transfers to safety-net hospitals.

As a result of these policies and trends, by 1999, the first year examined in this study, California hospitals had experienced significant declines in operating margins. Hospitals started to recover from these fiscal woes in 2001, but by 2004 margins had declined again. These declines occurred primarily in district hospitals, for-profit hospitals, hospitals serving higher-income or lower-income patients, and hospitals that prior to 2002 were fiscally strongest (Figure 4). Public, nonprofit, and the fiscally weakest hospitals experienced increases in operating margins over the same period, while public hospital margins declined after 2004. Due to

**Figure 4: Operating Margins Prior to Ratios for Selected Types of California Hospitals**



these pre-ratio trends, most hospital types experienced statistically significant variation in operating margin after ratios. (The two exceptions were district hospitals and those serving mostly higher-income patients.) While the ratio regulations may have influenced the amount of change experienced by each hospital type, this analysis cannot isolate any such effect. In fact, it is likely that the staffing requirements had at most a marginal impact on hospital financial stability.

Several of the nursing executives and managers reported that the staffing legislation made it easier to secure additional funding or avoid budget cuts within their own hospitals, particularly for hiring nursing staff. However, CEOs at both high- and under-performing hospitals said that it was difficult to absorb costs related to the ratios. They noted that they needed to find funds from other budget areas, which in some cases involved the reduction of some services. A small number reported that their hospitals successfully obtained higher insurance reimbursement rates from insurers to defray some of the increased costs. The insurers interviewed for this study indicated that hospitals have cited the minimum ratios as

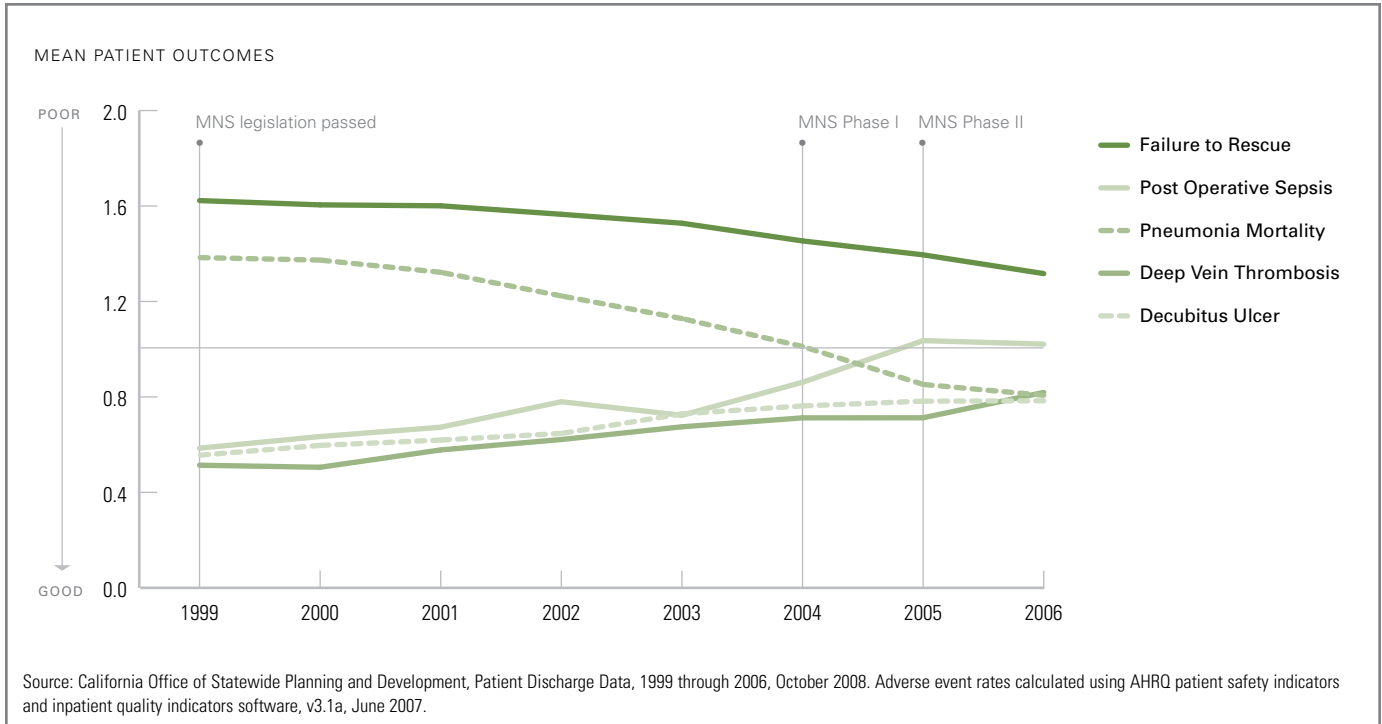
one reason for rising costs, and that these costs are likely passed on to the consumer.

### Quality of Care

The desired outcome of minimum nurse staffing legislation was the improvement of patient outcomes; however, most of the quality measures analyzed for this study do not appear to have been directly affected by the increase in RN staffing. For example, one of the metrics sensitive to nursing care, average length of patient stay, showed very low rates of change during the study period. Average length of stay did not change for nonprofit hospitals, increased significantly in public hospitals, and decreased significantly among for-profit hospitals. As a result, the overall level of average length of stay in California has stayed the same since the ratios were imposed. Other nursing-sensitive measures such as decubitus (pressure) ulcers, failure to rescue after a post-surgical complication, deep vein thrombosis/pulmonary embolism (DVT), pneumonia mortality, and postoperative sepsis show similar results. Figure 5 shows the average ratio of observed patient incidents over expected patient incidents for all California hospitals.



**Figure 5: Trends in Patient Safety Measures for California Hospitals, 1998–2006**



Ratios greater than one indicate poorer quality, whereas rates less than one indicate better quality. California performed better than expected through the entire period for rates of DVT and decubitus ulcer. All California hospitals performed worse than expected for rates of pneumonia mortality and failure to rescue, but these rates improved throughout the study period and were improving well before the minimum staffing requirements were implemented.

Many of the healthcare leaders we interviewed expressed an expectation that the minimum staffing ratios would raise the quality of care due to increased interaction with patients. However, only a few interviewees felt that the ratios had resulted in such an improvement. Some expressed concern about the break in the continuity of care resulting from maintaining compliance between both the ratios and the meal break rules. Some interviewees reported that the ratios affected patients in their emergency departments. In those hospitals, emergency department waiting times increased, patients occasionally had to be held in the emergency department due to lack

staffing, or, in rare cases, the emergency departments were put on diversion so patients had to be transported to other hospitals. Very few hospitals had conducted any analysis of data related to the ratios. While many hospitals conduct regular patient satisfaction surveys, most of the leaders we interviewed said they did not believe there had been a significant change in patient satisfaction as a result of the nurse staffing regulations.

### Conclusion

Staffing changes have created challenges and adjustments for some hospitals, particularly with regard to the logistics of meal break compliance and the roles of RNs. The leaders we interviewed did not notice significant changes to the quality of patient care, though emergency departments became bottlenecks at some hospitals. Leaders reported difficulties in absorbing the costs of the ratios, and many had to reduce budgets, reduce services, or employ other cost-saving measures. The interviews did not reveal any important differences in the effects of the ratios upon high-performing and under-performing hospitals.

The minimum nurse staffing regulations did achieve one goal of the legislation: skill mix increased in California hospitals. The hours worked per patient by RNs and registry RNs significantly increased. These improvements in skill mix did not have a clear impact on hospital finances. While overall margins declined between 1999 and 2007, there was no clear relationship between those declines and the start of staffing ratios. This is likely due to other fiscal challenges facing California hospitals. Ratios did not appear to affect most nursing-sensitive outcomes. While the average length of stay changed after 2004, trends in rates of decubitus ulcer, failure to rescue, and deep vein thrombosis, were not changed. More detailed analysis of this and other nursing-sensitive outcomes is needed to fully explore the effect of nurse staffing ratios on the quality of patient care.

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## ENDNOTES

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