MEASURE: SB 630
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Oral Testimony of Scott Rigdon CRNA MPH

On Behalf of the Oregon Association of Nurse Anesthetists (ORANA)

Before the Senate Health Care and Human Services Committee

April 1, 2013

<u>In Opposition of SB 630</u>

Chair Monnes Anderson and Members of the Committee:

My name is Scott Rigdon, and I am a nurse anesthetist (CRNA) and the current President of the Oregon Association of Nurse Anesthetists (ORANA). Thank you for the opportunity to appear before the committee and voice significant concerns in opposition to SB 630.

ORANA has represented the safety of citizens in Oregon and CRNA practice interests for more than 78 years and we stand in firm opposition to any form of SB 630. Overall, this proposed bill has the potential to significantly and negatively impact the quality of anesthesia care in our state and increase the risk of negative health care outcomes for the citizens of Oregon. While ORANA has many significant concerns related to SB 630, for brevity, I will highlight our most important concerns.

First, I am certain that those in support of SB 630 have nicely detailed the educational path, training and presumed safety of Anesthesiology Assistants (AAs). A Few important facts to keep in mind;

- CRNAs have a Masters or Doctoral degree upon completing their training. AAs have a Masters Degree upon graduation. That is the only weak similarity between us.
- AAs have been directly supervised for about 40 years in the United States and <u>there is no peer reviewed patient safety or outcome data published to date</u>. The American Society of Anesthesiologists (ASA), arguably the most powerful professional physician healthcare organization in the United States is the largest advocate of AA function. If favorable patient safety and outcome data related to AA practice existed, it would have been published in a peer reviewed journal by now. In contrast, the excellent, safe anesthesia care that CRNAs provide and associated anesthesia outcomes have been repeatedly demonstrated in peer-reviewed studies published in prominent journals.
- There are estimated to be around 1,800 AAs in the United States. There are over 40,000 CRNAs and approximately 35,000 Anesthesiologists.
- CRNAs have substantial direct patient care experience prior to beginning their Nurse Anesthesia training, which averages 30 months nationally. <u>AAs are not</u>

required to have direct patient care experience prior to starting their training and the entire AA training program is 24 months.

There is no Anesthesia Workforce Shortage

Why is SB 630 being presented to the Senate Health Care and Human Services Committee? There is no shortage of anesthesia professionals in our state. As is evidence by the lack of job postings and the weekly inquiries ORANA receives from highly qualified CRNAs wanting to practice here in Oregon. In fact, my independent CRNA clinical practice group received over forty highly qualified candidates in five days when filling a vacancy this past summer.

A review of job postings (excluding locum tenens coverage or "fill in") on 3/29/13 revealed a total of 8 anesthesia employment opportunities posted and 5 were for Anesthesiologists 3 were for CRNAs. I cannot speak for the Anesthesiologist situation, but after a phone call to the groups looking for CRNAs, it was determined that the jobs were essentially filled and the postings were a formality required by the organization. We have a great state with outstanding CRNA practice opportunities; Aside from the 5 Anesthesiologist job postings there are really no jobs available here in Oregon, so this is not an emergency workforce issue.

Under Oregon state law, CRNAs practice in collaboration with anesthesiologists, therefore the concept of supervision for CRNAs is a billing concept not a clinical function. However, Oregon is an opt-out state. This means that CRNAs can practice to the full extent of their education and training. In Oregon, patients who require the skill of a highly trained anesthesia professional may either have those services provided by a physician anesthesiologist or a nurse anesthetist. This may occur in a variety of staffing models based on the needs and culture of a particular facility or group.

Specifically, SB 630 allows a very minor and very poorly understood anesthesia provider type to begin functioning in our state. In fact, to date there is no peer reviewed, published quality or safety study related to Anesthesiology Assistants (AAs). By training and proposed law, an AA is not an independent clinician and when a clinical scenario arises which needs to be addressed immediately through rapid assessment and intervention the individual who is presumed to be at the bedside may be tied up with the other 3 patients they could be responsible for under SB 630. Where is the individual patient left in this scenario?

Furthermore, a very well designed 2012 study published in *Anesthesiology*, the monthly Journal of the American Society of Anesthesiologists (ASA) highlights risk of lack of supervision (Anesthesiologist availability) in much greater detail. I have included a copy of the study with my testimony. For full disclosure this research was conducted and funded through university Anesthesia Departments and published by the ASA. Please refer to the blue text box on page 683, which states in bullet point number two, "lapses (in supervision) occurred commonly during first case starts even with a 1:2 supervision ratio". In addition, when the staffing ratios decrease from 1:2 to 1:3 the average frequency of lack of supervision increases from 13.9% to 61.9% and if one follows the extrapolated data (graph pg 690) a ratio of 1:4 with supervision is effectively not attainable. The data is clear; supervision even at a 1:2 ratio is commonly not possible given the demands of clinical anesthesia practice and the defined parameters of supervision. A reasonable person may conclude that Oregonians will be placed at significant risk by SB 630.

Recent Evidence of the Reality of Supervision

A recent 1.2 million dollar whistleblower case highlights the concept and clinical reality of supervision in anesthesia practice. (Statement summarized from article detailed in Outpatient Surgery Magazine http://www.outpatientsurgery.net/news/2013/03/16-1-2M-Settlement-in-Anesthesia-Supervision-Case)

"The California Board of Regents agreed to a 1.2 M settlement to resolve allegations of submitting claims which involved insufficient supervision of CRNAs and anesthesiology residents, which violates the Medicare and Medicaid policy as well as the federal False Claims Act. According to the plaintiff, Anesthesiologist presence was commonly documented and billed for while the charts were retrospectively signed and the anesthesiologists were not available for supervision or at times physically not present in the same building as the procedure".

There are other legal and financial ramifications of this case still pending.

Specific Concerns Regarding Patient Safety

While ORANA has identified numerous portions of SB 630 which decrease patient safety with vague language, clauses which allow for significant room for lack of supervision and provisions that specifically allow for individuals who are not certified to gain licensure. Specifically;

- Temporary license provision: which allows for AAs to receive temporary licensure until they pass the NCCAA certifying exam.
- Non-certified licensure provision: which allows and individual who has not met the NCCAA certification requirements to gain licensure.
- Supervision provision: no clear, concise definition of supervision of AAs.

In Summary

ORANA stands in opposition to SB 630 out of a deep professional concern for the safety of the citizens of Oregon. There is no substitute for the education and training CRNAs receive prior to entering the healthcare marketplace. When I think of the average reasonable Oregonian patient seeking anesthesia services at the facilities I work at, I am compelled to invoke the reasonable person standard related to the perception of how anesthesia care is delivered and how they would react with full disclosure about who is actually at the head of the table.

Scenario 1: (my everyday patient introduction)
Hello, my name Scott I am a nurse anesthetist and I will be keeping you safe during your surgical procedure today. From now until I deliver you to the highly specialized nurses in the post-operative care unit, I will be closely monitoring and personally performing every aspect of your anesthesia care here in our facility. Do you have any questions before I ask you questions?

Scenario 2 SB 630 may allow
Hello, my name is "Bill" I am an Anesthesiologist Assistant and I will be working under the supervision of Dr. ____X___. We will collaborate to keep you safe while you are in the operating room today. Dr. __X__ will be present during the important portions of the case and I will be present the entire case. If a serious situation should arise and Dr. __X__ is not busy with the other 3 patients under his/her supervision today, then he/she should be immediately available to quickly assess and intervene. After the case is over Dr. __X__ will be soley responsible for your care in the post operative period, unless he/she is involved with the other 3 patients under his/her care. Do you have any questions before I ask you a few questions?

In closing, I would like to convey and imperative clinical concept I impart on all the CRNA trainees who rotate through the facilities where I practice. I absolutely expect that they will gain all the necessary knowledge, clinical skills and anesthesia prowess to take care of my wife, children and close family. I tell each and every one of them that our profession demands and I expect that if I am ever involved in an event which lands me or my loved ones in your care, I expect nothing but the best from you no matter how you choose to practice. Anesthesiologist collaboration or not you are ultimately responsible for the welfare of your patient. Nothing else matters if you need more training in a specific area of practice get it, if you discover a knowledge deficit, fix it. The profession of Nurse Anesthesia is strong and relevant in healthcare transformation today because CRNAs always keep patient safety first.

Thank you for your time and I respectfully request SB 630 be dismissed and the committee consider taking up a bill which limits the addition of any new healthcare provider until a workforce need is established and peer reviewed patient safety data is published.

Scott Rigdon CRNA MPH

ORANA

OREGON ASSOCIATION OF NURSE ANESTHETISTS

OPPOSE SB 630: OREGON 2013 REGULAR SESSION

OREGON DOES NOT NEED ANESTHESIOLOGIST ASSISTANTS

Certified Registered Nurse Anesthetists (CRNAs) are well-established, proven-safe and cost-effective anesthesia providers. CRNAs have been caring for Oregonians for more than 100 years and continue to grow in number.

There are NO current workforce issues facing Oregon in the area of anesthesia.

Anesthesiologists and CRNAs together provide 100% of the care needs.

Anesthesiologist Assistants (AAs) are rare throughout the United States and possess a limited scope of practice that would not help promote access to healthcare or maintain a cost-effective anesthesia care model in Oregon.

ACCESS TO CARE IN OREGON

CRNAs provide anesthesia care anywhere it is needed in both rural and urban settings. CRNAs practice in every setting in which anesthesia is delivered: traditional hospital surgical suites and obstetrical delivery rooms; critical access hospitals; ambulatory surgical centers; the offices of dentists, podiatrists, ophthalmologists, plastic surgeons, and other medical professionals; and U.S. Military and Veterans Administration healthcare facilities.

- **LIMITED UTILIZATION:** Because AAs cannot practice without anesthesiologist supervision, AAs do not practice in rural areas where CRNAs working without anesthesiologist involvement are the primary providers of anesthesia care. The AA model's focus, i.e. on only practicing where anesthesiologists practice, greatly limits their utilization. Thus, AAs cannot help solve problems of inadequate access to anesthesia care in rural and underserved communities.

- **FAILS TO MEET DEMAND:** If for any reason an AA's supervising anesthesiologist is not available – for example, off-site, on vacation, or simply home for the day – the AA may not provide anesthesia care. The AA/anesthesiologist-driven mode of practice, therefore, is inflexible and fails to adequately meet the needs of patients, hospitals, ambulatory surgical centers and other healthcare settings.

- **NO PROVEN OUTCOME DATA:** No peer-reviewed studies in scientific journals have been published regarding the quality of care of AA practice or AA anesthesia outcomes. AAs are explicitly recognized in state laws or regulations in only 13 states and the District of Columbia. Louisiana actually passed legislation that has the effect of prohibiting AA practice, declaring that "CRNAs receive a much higher level of education and training than do AAs."

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ORANA

OREGON ASSOCIATION OF NURSE ANESTHETISTS

OREGON DOES NOT NEED ANESTHESIOLOGIST ASSISTANTS

continued...

ECONOMIC IMPACT

Independent studies have shown that CRNAs acting as the sole anesthesia provider is the most cost-effective model for anesthesia delivery. This model is used in many of our hospitals in rural communities and in our top rated critical access hospitals in Oregon. The second-most cost effective model is the CRNA/anesthesiology care team model, which is similar to the well-established models used at Kaiser and OHSU.

- **COSTLY MODEL OF CARE:** With an AA model, two healthcare providers must be educated and then utilized, i.e. a supervising anesthesiologist and an AA, to provide anesthesia care to one patient.
- **ANESTHESIOLOGISTS REPORT DIFFICULTY WITH SUPERVISION:** AAs must be supervised by anesthesiologists. The Society of Anesthesiology reports that even with an appropriate ratio of anesthesiologists to providers, lapses of supervision during critical portions of anesthetic cases would occur. In a review of one year of data from a tertiary hospital, supervision lapses occurred commonly during first-case starts even with a 1:2 supervision ratio.

EDUCATION/SCOPE OF PRACTICE

CRNAs are trained and educated to deliver anesthesia care regardless of anesthesiologist involvement. CRNAs are qualified to make independent judgments regarding all aspects of anesthesia care, based on their education, licensure, and certification. CRNAs have experience as critical care nurses and can assess and treat a broad range of health problems before even beginning anesthesia training.

- **LIMITED SCOPE OF PRACTICE:** AAs administer anesthesia solely under the medical direction of physician anesthesiologists. AAs, therefore, have a much more limited scope of practice than CRNAs. AAs are NOT physician assistants (PAs).
- **NOT A FULL SERVICE ANESTHESIA PROVIDER:** The AA program curriculum is characterized by training that only allows AAs to assist anesthesiologists in technical functions. For example, one of the largest AA programs, Emory University, does not even provide clinical instruction in the administration of regional anesthesia.
- **LACK HEALTH CARE EXPERIENCE:** AAs are not required to have any prior healthcare education or experience (e.g., nursing, medical, anesthesia or healthcare education, licensure, or certification) before they begin their AA educational programs.

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Influence of Supervision Ratios by Anesthesiologists on First-case Starts and Critical Portions of Anesthetics

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ABSTRACT

Background: Anesthesia groups may wish to decrease the supervision ratio for nontrainee providers. Because hospitals offer many first-case starts and focus on starting these cases on time, the number of anesthesiologists needed is sensitive to this ratio. The number of operating rooms that an anesthesiologist can supervise concurrently is determined by the probability of multiple simultaneous critical portions of cases (*i.e.*, requiring presence) and the availability of cross-coverage. A simulation study showed peak occurrence of critical portions during first cases, and frequent supervision lapses. These predictions were tested using real data from an anesthesia information management system.

Methods: The timing and duration of critical portions of cases were determined from 1 yr of data at a tertiary care hospital. The percentages of days with at least one supervision lapse occurring at supervision ratios between 1:1 and 1:3 were determined.

Results: Even at a supervision ratio of 1:2, lapses occurred on 35% of days (lower 95% confidence limit = 30%). The peak incidence occurred before 8:00 AM, $P < 0.0001$ for the hypothesis that most (*i.e.*, >50%) lapses occurred before this time. The average time from operating room entry until ready for prepping and draping (*i.e.*, anesthesia release time) during first case starts was 22.2 min (95% confidence interval 21.8–22.8 min).

Conclusions: Decreasing the supervision ratio from 1:2 to 1:3 has a large effect on supervision lapses during first-case starts. To mitigate such lapses, either staggered starts or additional anesthesiologists working at the start of the day would be required.

What We Already Know about This Topic

- The most appropriate ratio of anesthesiologists to providers would avoid lapses of supervision during critical portions of anesthetic cases. A simulation study suggested this occurs most commonly with simultaneous first starts.

What This Article Tells Us That Is New

- In a review of 1 yr of data from a tertiary hospital, lapses occurred commonly during first-case starts even with a 1:2 supervision ratio.
- These data suggest that either staggered starts or additional anesthesiologists working at the start of the day would be needed to reduce lapses during critical periods.

ANESTHESIOLOGISTS often function in anesthesia care teams (*e.g.*, supervising concurrently two or more certified registered nurse anesthetists).[1–7] Many anesthesia groups perceive an incentive to decrease their supervision ratio.[8–10] Because a ratio lower than 1:2 does not satisfy accreditation requirements of the American College of Graduate Medical Education, ratios lower than 1:2 apply to nurse anesthetists, not anesthesia residents.‡ Because many hospitals focus on tardiness of first-case starts[11,12] and offer many such starts,[13–16] anesthesiologist staffing is sensitive to the supervision ratio.

The number of operating rooms (ORs) that an anesthesiologist can supervise is limited by the probability of occurrence of two or more simultaneous events (*i.e.*, critical portions) requiring either physical presence or a time-sensitive, nonpreemptive interaction. The probability of supervision lapses is also influenced by the availability of other anesthesiologists to cross-cover. The consequence might be limited to a case delay, but patient safety could be affected when there are coincident critical physiologic events.

In the United States, invoicing Medicare for professional anesthesia services requires that the anesthesiologist "personally participates in the most demanding procedures in the anesthesia plan, including induction and emergence, where indicated."§ However, to reduce the risk of substandard

◇ This article is featured in "This Month in Anesthesiology." Please see this issue of ANESTHESIOLOGY, page 9A.

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‡ ACGME Program Requirements for Graduate Medical Education in Anesthesiology. Available at: http://www.acgme.org/acWebsite/downloads/RRC_progReq/040_anesthesiology_07012008_u03102008.pdf. Accessed December 7, 2011.

§ CMS Manual System, Pub 100–04 Medicare Claims Processing, Transmittal 1324 Available at: https://www.cms.gov/transmittals/downloads/R1324CP.PDF. Accessed December 7, 2011.

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care,[17] many institutions do not reveal patient insurance information. Consequently, all patients are supervised in accordance with Medicare rules. Furthermore, anesthesiologists' time before induction likely will increase from implementation of the World Health Organization surgical safety checklist.[18]

Paoletti and Marty[19] used simulation to estimate the risk of a supervision lapse in surgical suites with various numbers of ORs (2–18) performing a mix of elective cases of various durations (0.8–4.5 h) and a range of anesthesiologist supervision ratios (1:1, 1:2, 1:3). Their model parameters were based on data from several French hospitals. The simulated risk of a supervision lapse peaked at the start of the day. Risks ranged from 14% to 87% for inability to supervise all critical portions of cases at a 1:2 ratio, depending on case length (higher with shorter cases) and the size of the suite (lower with more ORs). Increasing the supervision ratio to 1:3 markedly increased the risk. Providing an unassigned "floater" anesthesiologist greatly reduced the risk.

We explored predictions of the French simulation study using real data captured from an anesthesia information management system to determine the incidence and timing of simultaneous critical portions of cases.

Our first hypothesis was that, as predicted,[19] on one-third of days, there would be supervision lapses even with a supervision ratio of 1:2.

Our second hypothesis was that, as predicted,[19] the peak incidence of supervision lapses occurred at the start of the day (*e.g.*, not during lunch breaks). If true, a supervision ratio less than 1:2 would require an increase in first-case start delays; first-case starts staggered sufficiently to allow the later first case to start on schedule[20]; additional anesthesiologists available at the start of the day; or anesthesiologists not present for all critical portions of cases.

If the first and second hypotheses were true, then the mean anesthesia release time would determine the average delay when two patients, supervised by the same anesthesiologist, were simultaneously ready for induction and all other anesthesiologists were occupied. We previously published how to use such mean times for anesthesia group economic analyses of first-case starts.[12,13]

Our third hypothesis was that anesthesia release times for first-case starts would average 22 min, in the midrange of values determined at Yale-New Haven Hospital.[21]

Materials and Methods

After Thomas Jefferson University Institutional Review Board (Philadelphia, Pennsylvania) approval with waiver of informed consent, we reviewed all 15,656 records in the hospital's anesthesia information management system on nonholiday weekdays between May 3, 2010 and May 1, 2011‖ that took place in the 24 ORs comprising the two largest surgical suites. Inpatient and outpatient procedures are performed in these suites, but not cardiac surgery or diagnostic gastrointestinal procedures. The times of events and descriptive information listed in table 1 were obtained. Heart rate, oxygen saturation, and invasive and noninvasive blood pressure values were retrieved from the anesthesia information management system database, recorded at 1-min intervals. Actual room locations where procedures took place were determined as previously described.[22]

We considered the anesthesia providers (*i.e.*, those individuals delivering direct anesthesia care) to be busy during the interval from the beginning to the end of anesthesia. The duration of breaks and lunch relief was considered as the interval from the documented start of the break to the documented end of the break, or lasting the mean duration of documented breaks if only the start time of the break was recorded in the anesthesia information management system, which is typical practice (72% of cases) for our providers. Where the end time of the break was not documented, the mean lunch break duration (30 min, based on 1,998 documented breaks) was substituted (presumed for breaks occurring between 11:00 AM and 1:30 PM, which is when lunch is offered). For breaks outside this period with a missing end time, the duration was set at the mean duration of such breaks (*i.e.*, 15 min, based on 2,776 documented breaks).

Each day was divided into 1,440 1-min intervals, during each of which the total number of providers who were busy was determined. We considered anesthesiologists to be occupied in tasks that cannot be preempted (*i.e.*, unable to leave the patient being cared for) during the periods listed in table 2. For each day, the number of anesthesiologists who were occupied as specified was determined during each 1-min interval.

Table 3 lists the physiologic events (hypoxemia, hypotension, and hypertension) considered critical portions of cases. The physiologic event definitions were based on published manuscripts demonstrating adverse outcomes and represent prolonged alarm conditions, as opposed to transient or false alarms. The duration of each such event corresponded to when the threshold for the critical event occurred (*e.g.*, after 10 min with systolic blood pressure less than 70 mmHg), until when the alarm trigger no longer was in effect (*e.g.*, systolic blood pressure ≥70 mmHg). The events we included deliberately underestimated the critical portions of cases to take a conservative approach with respect to the incidence of supervision lapses, increasing the chance of rejecting Hypothesis 1 (discussed in the Statistical Methods section). For example, a blood pressure of 220/140 lasting 20 min during a case scheduled for 1 h was not classified as a critical physiologic event in our analysis, although such instances would almost certainly trigger a call to the supervising anesthesiologist. The same goes for a systolic blood pressure of 75 in a patient undergoing carotid endarterectomy, or a

‖ The data interval was selected to allow binning by 13 4-week periods and to include a representative sample of anesthesia residents at all levels of training. A year of data was required to produce a confidence interval of 1 min, making survey methods to determine the anesthesia release time impractical.

Table 1. Data Obtained from Cases

Definition	Event
Start time of continuous presence of the anesthesia care provider	Anesthesia begin
Handoff time of the patient to the recovery room or intensive care unit nurse	Anesthesia end
Time patient entered the out-of-OR location if a neuraxial or regional anesthetic was performed in this location prior to entering the OR	Enter block room
Time when the patient left the out-of-OR location, if applicable	Leave block room
Time when the patient stretcher entered the OR	Enter the OR
Time when the patient stretcher left the OR	Leave the OR
Time when the patient was turned over to the surgical team for prepping and draping	Anesthesia release
Time of insertion of the tracheal tube, laryngeal mask airway, or other airway device for patient ventilation	Intubation
Time that surgery began	Surgery begin
Time that surgery ended	Surgery end
Time when patient was turned from supine to prone, or vice versa	Position change
Time when a brief break or lunch relief started	Break/lunch start
Time when a brief break or lunch relief ended	Break/lunch end
Time when an arterial or central venous catheter was placed	Invasive line placement
Where surgery was performed	Case location
Time reserved in the OR scheduling system for the case	Scheduled case duration
Recorded in years	Patient age
Intravenous, including emergency category	ASA physical status
General, neuraxial, regional, converted to general, monitored anesthesia care	Type of anesthesia
True if the patient entered the OR prior to 8:00 AM	First-case start

ASA = American Society of Anesthesiologists; OR = operating room.

progressive drop in oxygen saturation measured by pulse oximetry from 100% to 90% in a patient undergoing robotic prostatectomy. Our approach was also conservative because there are other physiologic perturbations where the anesthesiologist would likely be notified that we did not include (*e.g.*, ST segment depression, hypercapnia not responding to an increase in minute ventilation, or runs of supraventricular tachycardia). In addition, we did not include "false alarm" conditions (*e.g.*, disconnection of an electrocardiogram electrode, kinking of the blood pressure tubing, or plugging of the capnograph sampling tubing) that may generate a call to the attending to help troubleshoot and/or resolve the problem.

For each minute of the day, we determined the total number of critical portions of cases that occurred simultaneously (fig. 1). For example, if at 8:40 AM there was a patient being extubated, a patient ready for induction of general anesthesia, and a patient with hypoxemia due to severe bronchospasm, there would be three critical portions of cases in the interval from 8:40:00 AM to 8:40:59 AM. Consequently, the total number of providers needed would equal the number of ORs with cases running plus three anesthesiologists.

Statistical Methods

Hypothesis 1. For each minute of each workday excluding Thursdays, the running minimum number of anesthesia providers during overlapping 5 min was calculated (*i.e.*, to determine the number of ORs with cases). Thursdays were excluded because the OR starts 1 h later on this day and we were assessing supervision as a function of time of day. Over the same overlapping intervals, the minimum number of simultaneous critical portions of cases was calculated (*i.e.*, to determine the number of anesthesiologists needed). For each workday, the number of ORs was calculated as the maximum of the running minimums of the number of simultaneous providers. The number of anesthesiologists needed daily was the maximum of the running minimums of simultaneous critical portions of cases. The ratio of the number of ORs to number of anesthesiologists needed was then calculated for each day. This was most commonly simply 24 ORs divided by the maximum number of anesthesiologists needed for at least 5 min. For hypothetical ratios from 1.0 to 3.0 (*i.e.*, one anesthesiologist supervising from one to three ORs), the percentage of workdays for which the daily ratio was smaller was calculated. The use of overlapping 5-min intervals deliberately resulted in underestimation of this ratio (*i.e.*, increasing the chance of rejecting Hypothesis 1). For the ratio of 2.0, the lower 95% confidence limit was calculated for the percentage of workdays for which at least one supervision lapse would have occurred. The 95% confidence interval (CI) was calculated using the method of Blyth-Still-Casella (StatXact-9, Cytel Software Corporation, Cambridge, MA).

Hypothesis 2. For each minute of each of the 202 workdays, excluding Thursdays, the total number of providers needed was calculated = provider in the operating room + anesthesiologist (if a critical portion of a case occurred) + and person on break (if applicable). Next, for each workday, the minute of the day with the largest total number of providers was calculated. That minute was then classified as "first case" if it occurred at 8:00 AM or earlier, otherwise "morning" if before 10:56 AM, otherwise "lunch" if before 1:31 PM, and otherwise "afternoon." We calculated the percentage of days for which a minute at or before 8:00 AM had the largest total number of providers for the day, along with the 95% lower confidence

Table 2. Tasks Considered as Critical Portions of the Anesthetic

Event	Start	End	Rational
Induction of GA	Enter the OR	Intubation or equivalent + 3 min	Participate in the preoperative briefing along with the surgeon, supervise induction of general anesthesia and securing of airway, check patient positioning
Postincision after regional or neuraxial block	Surgical incision	Surgical incision + 2 min	If block is inadequate, general anesthesia will be needed
Invasive line placement following induction of GA	Intubation	Until first physiologic data are recorded in the AIMS from the invasive line	Regulatory requirements related to billing for invasive lines
Turning patient between supine and prone	Position change time: 3 min	Position change time + 5 min (supine to prone) or 3 min (prone to supine)	Watch lines and airway to ensure that they do not become dislodged during the flip, ensure safe positioning following the flip. Prone positioning is more involved that returning patient to the supine position, so extra time was allocated
Neuraxial block supervision prior to entering the OR	Enter the OR– 11 min*	Enter the OR	Participate in the timeout and supervise the block
Neuraxial block after entering the OR	Enter the OR	Enter the OR + 11 min*	Participate in the timeout and supervise the block
Regional block for postoperative analgesia placed in block room	Enter the OR	Enter the OR: 24 min†	Participate in the timeout and supervise the block
Emergence from GA	Extubation time	Extubation time + 3 min	Assess readiness for extubation, assess adequate ventilation after extubation

* Mean time from entering the block room to documentation that the spinal or epidural had been placed was 11 min, SD = 9 min (n = 1,759). † Mean time from entering the block room to documentation that the regional block was placed was 23.8 min, SD = 21.8 min (n = 962).

AIMS = anesthesia information management system; GA = general anesthesia; OR = operating room.

limit. We tested whether the percentage exceeded half (*i.e.*, most) of the days. The calculations were performed twice, once with ties for the time of the day being assigned to the earlier time of day and once to the later time of day. For example, if the daily maximum of 35 anesthesia providers were needed on a day both at 7:58 AM and at 8:02 AM, then first the maximum would be attributed to the 7:58 AM "first case" and next attributed to the 8:02 AM "morning." The calculations were also repeated using anesthesiologists' critical portions instead of the total number of providers needed.

Table 3. Evidence-based Physiologic Events Considered as Critical Portions of Cases

Event	Definition	Reference
Hypoxemia	Spo_2<90% for 2 min	Ehrenfeld *et al.* 2010[29]
Tachycardia	Median HR >110 for 5 min	Reich *et al.* 2002[30]
Hypotension	Median systolic BP <70 over 10 min	Reich *et al.* 2005[31]
Hypertension	Median systolic BP >160 over 5 min and scheduled procedure length >2 h	Reich *et al.* 2002[30]

Patients younger than 18 yr were excluded in the published outcome studies for tachycardia, hypotension, and hypertension. Using the methodology described for Hypothesis 3, fewer than 20% of the minutes of critical portions (table 2 and 3) were accounted for by minutes with the above physiologic events (P < 0.0001, mean 14.7%, SE 0.5%). Excluding physiologic events occurring during critical portions (table 2) reduced the percentage to 13.8% (SE 0.4%).

BP = blood pressure; HR = heart rate; Spo_2 = oxygen saturation, measured by pulse oximetry.

Hypothesis 3. For all combinations of the 253 workdays and OR first cases of the day, the time from each OR entrance to anesthesia release was known from the anesthesia information management system data. The probability distribution of the n = 5,769 times to release were not normally distributed with or without inverse squared, inverse, inverse square root, logarithmic, square root, or squared transformations of the release time durations (all Lilliefors tests $P < 0.00001$, Systat 13, SYSTAT Software, Chicago, IL). Therefore, the mean was taken for each day. The 253 means followed a normal distribution (Lilliefors test $P = 0.42$). The means had neither statistically significant Pearson auto-correlation from 1 day to the next (Pearson r = −0.01, $P = 0.94$) nor from 1 week to the next (r = 0.11 $P = 0.08$). Therefore, the 95% two-sided CI for the mean release time was calculated using the Student t distribution, with the sample size being the 253 workdays. Similarly, the overall mean was compared

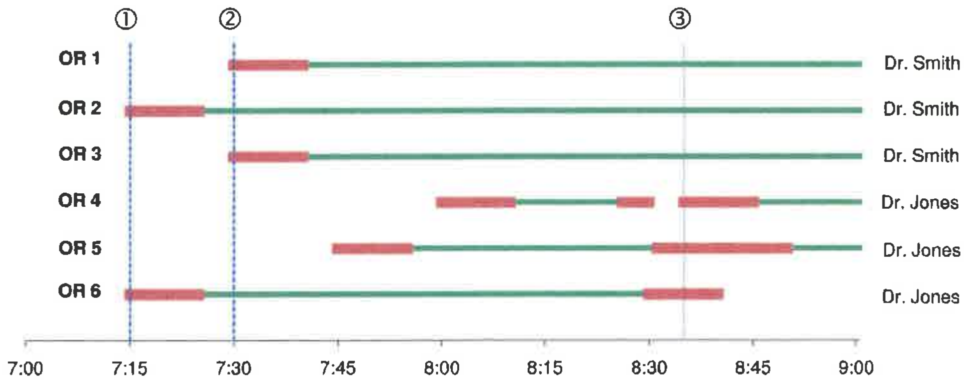

Fig. 1. Example of overlapping critical portions of cases. Critical portions of cases are noted by the *thick red lines*, and other portions by the *thin green lines*. During critical portions of cases, a supervising anesthesiologist would be expected to be present. A six operating room (OR) suite is staffed by two anesthesiologists, Drs. Smith and Jones. Dr. Smith is medically directing ORs 1 to 3 and Dr. Jones ORs 4 to 6. At time 1 (7:15), induction takes place in OR 2 and 6, staffed by the two anesthesiologists in their own rooms with no lapse in supervision. At time 2 (7:30), Dr. Smith has two cases to induce in OR 1 and 3, but Dr. Jones is available and performs the simultaneous induction in OR 3, preventing a lapse in supervision. At time 3 (8:35), Dr. Jones is helping treat a patient with hypoxemia and severe bronchospasm in OR 5, and Dr. Smith is cross-covering the extubation of the patient in OR 6. The patient in OR 4 has to wait for induction, as both anesthesiologists are busy. There has been a supervision lapse due to the occurrence of three simultaneous critical portions of cases.

with the anesthesia release time of 22 min determined at Yale-New Haven Hospital[21] using Student one group two-sided *t* test.

Results

Hypothesis 1: Staffing Lapses

The percentage of days during which there would have been at least one 5-min interval with too few anesthesiologists to supervise all critical portions of cases at varying ratios of ORs to anesthesiologists is shown in figure 2. Even at a ratio of 1:2, there would have been at least one such lapse in supervision for 35% of days (lower 95% confidence limit = 30%). At a ratio of 1:3, there would be supervision lapses on 99% of days (lower 95% confidence limit = 96%).

Extrapolating from figure 5b of the French simulation study[19] with 24 ORs, a staffing ratio of 1:2, and one additional floater anesthesiologist (*i.e.*, effective supervision ratio of 1:1.8), the expected incidence of supervision lapses is 12%. We observed a 12% incidence with a supervision ratio of 1:1.7.

The first hypothesis that supervision lapses would take place on one-third of days and that our results would be similar to the simulation study was confirmed.

Hypothesis 2: Time of Day with Largest Number of Providers Needed

The average peak activity (total providers needed) during cases occurred at the start of the workday for most days (fig. 3, table 4, $P < 0.0001$). This was especially true for critical portions of cases (*i.e.*, times that would influence anesthesiologist staffing; table 3). The second hypothesis was confirmed.

Hypothesis 3: Anesthesia Release Time

The mean number of minutes of critical portions of first-case starts was 22.2 min (95% CI 21.8–22.8 min, SD 2.8 min). This observation matched observational findings reported previously from Yale-New Haven Hospital[21] ($P = 0.29$). Thus, the third hypothesis that the mean number of critical minutes for first-case starts would match the anesthesia release time measured by observers[21] was confirmed.

Effect of Providing Higher Supervision Ratios or Staggered First-case Starts on Supervision Lapses

Because the three hypotheses were satisfied, as a sensitivity analysis, we examined the effect on supervision lapses of either lowering the supervision ratio from 1:2 at the start of the day to 1:3 after first cases had begun or supervising at a 1:3 ratio throughout the day with staggered first-case start times. The former strategy would be possible only if there were anesthesiologists with nonclinical assignments (*e.g.*, academic institutions), whereas the latter approach could be instituted anywhere. When critical portions of cases occurring at or before 8:00 AM and breaks were excluded, at least one supervision lapse would occur on 14% of days at the 1:3 supervision ratio (95% lower confidence limit = 10%). However, when breaks were included, supervision lapses increased to 62% of days (95% lower confidence limit = 56%; fig. 4). The breaks affecting the maximum supervision ratio were principally lunch reliefs (see fig. 2 and table 4). These findings indicate that at a 1:3 supervision ratio, additional providers (*e.g.*, certified registered nurse anesthetists) would be needed to provide breaks. In contrast, if supervision were maintained at 1:2 throughout the day, there would be supervision lapses on only 0% and 2% of days, excluding and including breaks, respectively. Thus, additional providers would not be necessary at a 1:2 supervision ratio. Overall, the

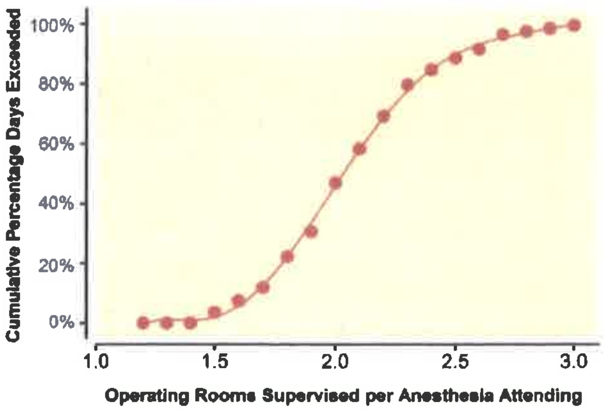

Fig. 2. Risk of supervision lapses based on number of rooms supervised by each anesthesiologist. A supervision lapse is defined as a critical portion of a case (see tables 1 and 2) where there are insufficient anesthesiologists available. For each of the 202 weekdays (excluding Thursday, when the operating room [OR] starts late) in the study interval, the minimum number of providers busy during the five previous 1-min intervals was calculated for each minute of the case. The maximum of this series equals the number of ORs that were running simultaneously at any point in the day (typically 24, but occasionally smaller if any OR were closed for the day). Similarly, the minimum number of critical portions during consecutive overlapping 5-min intervals was determined. The maximum of this series equals the number of anesthesiologists required to supervise all critical portions of cases. The ratio of maximum rooms divided by maximum anesthesiologists was then computed for each day. The value on the y-axis corresponds to the cumulative probability among the 202 days where the ratio listed on the x-axis would be exceeded for at least one interval during the day. For example, suppose each anesthesiologist is supervising two rooms, then on 35% of days, there would be at least one interval when a supervision lapse would occur.

financial benefit of decreasing the supervision ratio from 1:2 to 1:3 is offset by the need for additional nonanesthesiologist providers.

Discussion

In this study, we confirmed results of the French simulation study,[19] showing that even at a supervision ratio of one anesthesiologist for every two anesthesia providers, all simultaneous critical portions of cases could not be supervised on one-third of days without occasionally waiting for the anesthesiologist. We also confirmed that the largest number of providers is needed at the start of the day, and that is also when there was the highest incidence of critical portions of cases. The mean anesthesia release time (22 min) we measured was close to that measured at Yale-New Haven Hospital.[21] That time represents the average expected delay in starting the second case when an anesthesiologist has two patients who are ready for induction simultaneously and there is not another anesthesiologist who is available to cross-cover.

Our findings and the simulation results[19] are in contrast to the study of Wright *et al.*,[23] which found that cases with a start time after 3 PM had the highest proportion of adverse events. We obtained different results because our focus was on the time of the day with the largest total number of critical portions among all ORs. Wright *et al.* [23] considered when each individual case had the highest risk.

Administrators who want to reduce their anesthesia group's costs[24] by encouraging them to decrease their anesthesiologist supervision ratios need to consider the effect of our findings on the timeliness of first-case starts, which is often a major institutional focus.[11,12] At a ratio of one anesthesiologist to three anesthesia providers, it will not be possible to start all ORs simultaneously and have sufficient anesthesiologists to supervise all critical portions of cases on most days. Either the administrators will need to accept the fact that the additional OR often will be delayed from its scheduled start time, or agree to rearrange the OR schedule so that first cases supervised simultaneously by each anesthesiologist will have staggered start times.[20] The former approach can lead to discontent, because such delays are publicly visible.[25] The use of staggered starts has a built-in expectation that some ORs will start later than other ORs. For some organizations this may be advantageous (*e.g.*, surgeons running multiple ORs or who simply prefer to start somewhat later than the "official" start time may embrace this change). Provided the ORs selected for the staggered start times[20] are those with the most expected underutilized OR time, this has no economic disadvantage.[12,13,26,27]

Another potential approach to the problem of supervision lapses during first cases of the day is for the anesthesia group to make additional anesthesiologists available at the start of the day. Then, once the ORs have been started, some of these individuals are released to perform other duties important to the department (*e.g.*, research, informatics, and management and administrative duties). The importance of Hypothesis 2 is in knowing that lunch breaks are not the bottleneck; rather, it is the first case starts that must be considered economically.[12,24] However, the importance of our sensitivity analysis is in showing that this approach then necessitates adding additional nonanesthesiologists for breaks, which may nullify the economic benefit.

The fact that some organizations do not routinely provide breaks is not a limitation of our study to such practices, because our results of the importance of the start of the workday with respect to the peak incidence of staffing lapses would then be even *stronger*. Similarly, the fact that we studied a tertiary hospital with many long cases rather than an outpatient surgery center with short cases is not a limitation because, from the simulation study,[19] our results would be even stronger for short cases. Instead, the principal limitations of our study relate to the definitions of critical portions of anesthetics. Although we relied on process times recorded in an anesthesia information management system, such times

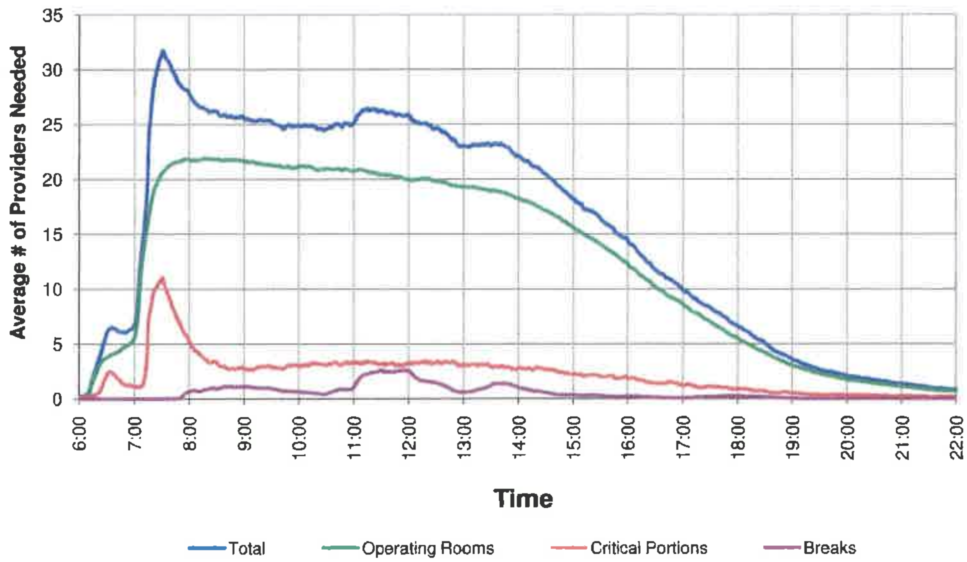

Fig. 3. Average daily workload by hours of the day. During each hour of the workday between 6:00 AM and 11:00 PM, the average numbers of staff required (providers, anesthesiologists, and break personnel) were determined. Operating rooms (*green line*) equals the number of providers, and critical portions (*red line*) are as defined in tables 1 and 2, indicating the number of supervising anesthesiologists required. Breaks (*purple line*) represent staff relieving providers for lunch and bathroom breaks. The total number of providers needed (*blue line*) is the sum of the other three quantities. The peak activity occurred at 7:30 AM, as did the number of critical portions of cases. Some operating rooms have scheduled start times of 6:30 AM and others at 7:30 AM, based on surgical specialty; this has no bearing on the results.

recorded by nurses in an operating room information system could be used equivalently, as shown by Sandberg *et al.*[28]

During our analysis, we assumed, as did Paoletti and Marty,[19] that any anesthesiologist can go into any OR when a critical portion of the case occurs and provide supervision equivalent to the anesthesiologist who is otherwise occupied and cannot be interrupted. If complex patients are involved or an extended discussion about management has taken place, such substitution may provide suboptimal patient care. To the extent that all anesthesiologists are not equivalent and thus not able to supervise every critical portion of cases (*e.g.*, a patient to receive a regional block that the available anesthesiologist does not feel qualified to perform), the percentage of days with a lapse in supervision

Table 4. Percentages of n = 202 Days for which the Time of Day Had the Largest Total Number of Providers and/or Critical Portions for Any Minute of the Day

Time of Day	First Case*	Morning†	Lunch‡	Afternoon§
% Days with ties assigned to the earliest minute of day with the maximum total number of providers for the day	78% (n = 157) $P < 0.0001$ 95% CI >73%	11% (n = 23)	10% (n = 20)	1% (n = 2)
% Days with ties assigned to the latest minute of day with the maximum total number of providers for the day	69% (n = 140) $P < 0.0001$ 95% CI >64%	11% (n = 23)	18% (n = 36)	1% (n = 3)
% Days with ties assigned to the earliest minute of day with the maximum critical portions for the day	99% (n = 199) $P < 0.0001$ 95% CI >96%	0% (n = 1)	1% (n = 2)	0% (n = 0)
% Days with ties assigned to the latest minute of day with the maximum critical portions for the day	96% (n = 193) $P < 0.0001$ 95% CI >93%	2% (n = 5)	2% (n = 4)	0% (n = 0)

The *P* value tests whether the proportion is greater than half.

* First case = in the operating room after 6:30 AM through 8:00 PM. † Morning = in the operating room after 8:00 AM through 10:55 AM. ‡ Lunch = in the operating room after 10:55 AM through 1:30 PM. § Afternoon = in the operating room after 1:30 PM.

CI = confidence interval.

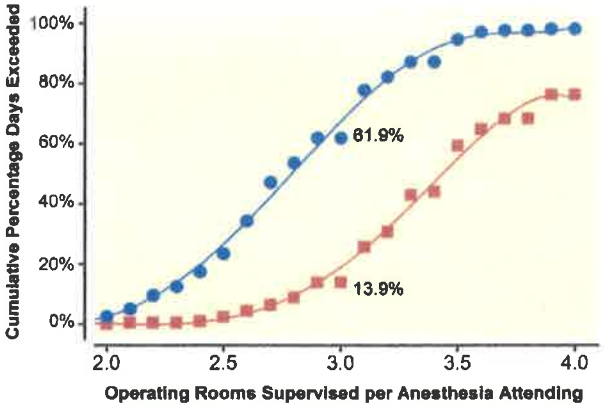

Fig. 4. Risk of supervision lapses excluding critical portions of cases on or before 8 AM. This graph was constructed as described in the legend for figure 2, with the exception that critical portions of cases occurring on or before 8 AM were excluded. Excluding supervision lapses during first-case starts represents a strategy of either staggering the start times of first cases or providing additional anesthesiologists at the start of the day. The *blue circles* and *regression line* represent the cumulative percentage of days with at least one supervision lapse when lunch reliefs and breaks after 8 AM were excluded. The *red squares* and *regression line* represent the cumulative percentage of days with at least one supervision lapse when lunch reliefs and breaks after 8 AM were included. The large increase in staffing lapses at a supervision ratio of 1:3 (13.9%–61.9%) indicates that additional staff would need to be present if lunch relief is to be provided. At a supervision ratio of 1:2, minimal additional staff would be needed, because the increase in days with staffing lapses is small (0% to 2%). Thus, the potential financial benefit of reducing the anesthesiologist staffing ratio will be offset by the need to provide additional providers for lunch relief.

with a 1:2 supervision ratio would be even larger than the observed 35%.

There are aspects of our analysis related to our definitions of critical portions of cases (tables 1 and 2) that could result in some readers viewing our conclusions as too conservative. Several of our colleagues offered feedback that they do not think that it is necessary for the supervising anesthesiologist to be physically present for induction or emergence in straightforward cases with experienced certified registered nurse anesthetists, as long as they are immediately available. The extent to which anesthesiologist presence is required during and soon after the anesthesia release time varies highly among countries because of varying regulatory requirements and within countries among institutions (*e.g.*, depending on local requirements for participation in the preoperative briefing). Because the intraoperative briefing including the surgeon and all anesthesia providers reduces mortality,[18] likely its inclusion will be increasingly prevalent.

In summary, we showed that the start of the OR day is the period of time when the anesthesiologist supervision requirement is greatest. Even with lunch breaks included, this result is so robust that changes in the anesthesiologist supervision ratio can be described to administrators simply in terms of the effect on first-case starts. This finding is useful because the psychology of first-case starts is already understood (*e.g.*, how they are interpreted economically).[11] Decreasing the supervision ratio by anesthesiologists from 1:2 to 1:3 will have a great effect on the timeliness of the start of the first cases of the day due to the high incidence of simultaneous critical portions of cases peaking at that time. As the economics of first-case starts are also fully developed, the decision to stagger first- case starts appropriately[11–13,26,27] *versus* having more anesthesiologists can be modeled for each facility.[11,12,24] Unless one of these options is chosen, the consequence will be a marked increase in the incidence of supervision lapses.

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By Brian Dulisse and Jerry Cromwell

No Harm Found When Nurse Anesthetists Work Without Supervision By Physicians

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ABSTRACT In 2001 the Centers for Medicare and Medicaid Services (CMS) allowed states to opt out of the requirement for reimbursement that a surgeon or anesthesiologist oversee the provision of anesthesia by certified registered nurse anesthetists. By 2005, fourteen states had exercised this option. An analysis of Medicare data for 1999–2005 finds no evidence that opting out of the oversight requirement resulted in increased inpatient deaths or complications. Based on our findings, we recommend that CMS allow certified registered nurse anesthetists in every state to work without the supervision of a surgeon or anesthesiologist.

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Surgical anesthesia in the United States is administered by both anesthesiologists and certified registered nurse anesthetists (CRNAs). For almost 150 years, these nurses were the dominant providers of anesthesia services, but by 1986 the rapid influx of physicians into the specialty resulted in a greater number of anesthesiologists who practiced alone or in a team arrangement with nurse anesthetists.[1,2] Even so, 37,000 certified registered nurse anesthetists provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals.[3]

Background On The Issue

Until recently, the Centers for Medicare and Medicaid Services (CMS) reimbursement rules for anesthesia providers prohibited payments to certified registered nurse anesthetists who administered anesthesia in the absence of physician supervision. This supervision could be provided by either an anesthesiologist or the surgeon,[4] although surgeons now largely defer to anesthetists at the operating table during the administration of anesthesia and immediately after surgery.

In December 1997, CMS published a proposed rule to, in the words of the final version, "let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners [seeing Medicare patients] in each category."[5] The agency later reported basing its decision on a "lack of evidence to support...[the] requirement for [surgeon or anesthesiologist] supervision of Certified Registered Nurse Anesthetists."[6]

It should be noted that except for the extra training that anesthesiologists receive in medical school and residency in specialties other than the direct provision of anesthesia, both certified registered nurse anesthetists and anesthesiologists undergo similar classroom and clinical training in anesthesia care.[7]

Anesthesiologists opposed the proposed rule, arguing that they provide anesthesia care superior to that of certified registered nurse anesthetists,[2,8] even though adverse events related to anesthesia are rare regardless of the provider.[5,9–11] The final CMS rule of November 2001 maintained physician supervision of nurse anesthetists "unless the governor of a State, in consultation with the State's Boards of Medicine & Nursing, exercises the option of exemption from this requirement" through a written request signed by the governor.[6]

As of 1998, eighteen states permitted certified registered nurse anesthetists to practice independently of any physician,[12] although for reimbursement purposes, Medicare still required physician supervision at least by the surgeon if not by an anesthesiologist.[6] By 2005, fourteen governors in mostly rural states[13] had submitted written requests to Medicare and opted out of the supervised anesthesia requirement. Solo practice by certified registered nurse anesthetists is especially important in rural areas, where anesthesiologists are in short supply.

This article explores whether the change in CMS policy toward anesthesia supervision had a negative impact on patient outcomes. We begin by examining the absolute level and time trends of adverse patient outcomes within the states that opted out and those that did not.

It is important to note, however, that differences in these gross measures do not constitute prima facie evidence of a response to the policy change. The act of opting out of the supervision requirement does not necessarily imply any changes in the actual practice of anesthesia within any hospital in a state. The opt-out exemption does not mandate that hospitals allow certified registered nurse anesthetists to provide anesthesia without supervision by a surgeon or an anesthesiologist. It means only that Medicare would not require such supervision as a condition of reimbursement.

Nonetheless, if patient outcomes are unchanged after a state has opted out, as we show to be the case, then the requirement that governors petition CMS to exempt certified registered nurse anesthetists from physician supervision is unnecessary and should be rescinded.

Study Data And Methods

For the opt-out policy to affect outcomes, two conditions must be fulfilled. First, the opt-out policy must result in a shift in anesthesia arrangements. If the policy change does not affect anesthesia arrangements, then it alone could not affect patient outcomes.

Second, there must be some systematic difference in the outcomes associated with the different anesthetist arrangements. If the outcomes across the different arrangements are the same, then even if the policy change affected anesthesia arrangements, it would not affect overall patient outcomes in opt-out states.

We therefore examined whether there was a material change in the provision of anesthesia services away from anesthesiologists in favor of certified registered nurse anesthetists and, separately, whether there is evidence of different outcomes associated with the two types of anesthetists. In examining outcomes, we first determined whether case-mix complexity differed between opt-out and non-opt-out states and by anesthetist training.

DATA SOURCE To address the research questions, we used the 5 percent Medicare Inpatient (Part A) and Carrier (Part B) Medicare limited data set files for 1999–2005. The files include all Part A claims from facilities and Part B claims from physicians and suppliers for a 5 percent sample of beneficiaries.

Given the distribution of states opting out of physician supervision at different times, we used seven calendar years of Medicare 5 percent data. This gives three full years of post-opt-out data for six of fourteen opt-out states and at least two full years of data for eleven opt-out states. Any deleterious effects of shifts to more anesthesia by unsupervised nurse anesthetists should be seen soon after a state opts out because more anesthesia complications would occur during the patient's inpatient hospital stay.

We abstracted Part A claims for each study year for all admissions in all Medicare surgical diagnosis-related groups (DRGs), which were 98,000–114,000 claims per year. Procedures taking place in ambulatory surgery centers were excluded because of uncertainty in measuring mortality or complications in those cases.

Because the 5 percent limited data sets do not contain the patient's measurement on the physical status scale of the American Society of Anesthesiologists, we merged onto the claims the anesthesia base units for the most complex anesthesia procedure (*International Classification of Diseases*, Ninth Revision, or ICD-9) code for each admission. For example, the base unit for a thyroid biopsy is 3; for cardiac catheterization, 8; and for tracheobronchial reconstruction, 18.[14]

We used the two Part B procedure modifier fields to identify three anesthesia provider arrangements: anesthesiologists practicing solo, certified registered nurse anesthetists practicing solo, and team anesthesia in which anesthesiologists supervise or direct nurse anesthetists. If a modifier on either a nurse anesthetist or an anesthesiologist claim indicated supervision or direction of the nurse anesthetist, then the anesthesia category was defined as team anesthesia.

Any nonteam hospitalization with a certified registered nurse anesthetist claim but no anesthesiologist claim was coded as certified registered nurse anesthetist solo. Finally, any procedure with an anesthesiologist claim not already characterized as team or certified registered nurse anesthetist solo was considered anesthesiologist solo.

Because all date fields in the data are aggregated to the quarter level, it was not possible to accurately link inpatient Part B anesthesia claims to specific hospitalizations for patients who had multiple hospitalizations in the same quarter. Therefore, we excluded patients with more than one hospitalization in a quarter.

The resulting seven-year pooled file contained 741,518 surgical discharges. Roughly one-third did not have any anesthetist claim. The majority of cases without anesthesia bills were for procedures that often do not require an anesthetist, such as percutaneous transluminal coronary angioplasty, pacemaker lead inserts, sigmoidoscopies, bronchoscopies, diagnostic catheterizations, and endoscopic surgeries.

Hospitalizations without a Part B anesthesia claim were excluded unless a surgical procedure took place in a Medicare "pass-through" hospital. In these hospitals, claims for services by nurse anesthetists are rolled into ("passed through") the Part A hospital claims. Therefore, observations from these hospitals were assigned to the certified registered nurse anesthetist solo category.

Hospitalization claims were also deleted if a Part B inpatient anesthetist claim was present in the previous quarter for the same beneficiary with no admission claim in that quarter. We assumed in those cases that the anesthetist filed his or her claim earlier than the hospital's claim for the same admission.

This left us with 481,440 hospitalizations for analysis, of which 412,696 were in non-opt-out states and 68,744 were in opt-out states. Of the latter, 41,868 hospitalizations occurred before the state had opted out.

ANALYTIC METHODS We analyzed two outcomes measures: inpatient mortality and complications. Mortality is reported on the Medicare discharge abstract. To measure possible anesthesia complications, we identified seven relevant patient safety indicators developed by the Agency for Healthcare Research and Quality:[15] complications of anesthesia (patient safety indicator 1); death in low-mortality diagnoses (indicator 2); failure to rescue from a complication of an underlying illness or medical care (indicator 4); iatrogenic pneumothorax, or collapsed lung (indicator 6); postoperative physiologic and metabolic derangements, or physical or chemical imbalances in the body (indicator 10); postoperative respiratory failure (indicator 11); and transfusion reaction (indicator 16). (Descriptions of each complication are provided in the online Appendix.)[16]

Each of these complications occurred only infrequently. Therefore, we used a single no/yes indicator (0 for no, 1 for yes) to show if any one of them occurred on a single admission.

State-level analyses cannot completely answer the question of whether allowing certified registered nurse anesthetists to provide anesthesia without supervision exposes patients to meaningful additional risks. By focusing on individual hospitalizations, however, it is possible to use Medicare claims to isolate any impact of opting out by anesthesia provider type.

It is possible that hospital managers systematically refer more difficult procedures to anesthesiologists and less difficult ones to nurse anesthetists. We therefore controlled for patient characteristics and procedure complexity.

We compared inpatient mortality rates between opt-out and non-opt-out states, stratifying by year and anesthesia arrangement. Anesthesiologists practicing alone were involved in more complex surgical procedures than certified registered nurse anesthetists practicing alone. Therefore, we adjusted anesthesiologist solo mortality rates by applying to the anesthesiologist solo group the nurse anesthetist case-mix for surgeries that the two providers had in common.

Frequency weighting was done at the diagnosis-related group level for each state, separately. T-tests were used to measure the differences in the adjusted mortality rates between opt-out and non-opt-out states within each stratum.

We also estimated logistic regressions using indicators for state opt-out status before and after opt-out and for anesthesia provider, to determine the effects of these variables on the probability of mortality and complications. Also included were the patient's age, sex, and race, along with year indicators and the procedure's anesthesia base units, to measure its complexity. The model was applied to surgical admissions pooled across all seven years in all opt-out and non-opt-out states.

Results

WHO PROVIDES ANESTHESIA We examined whether a state's decision to opt out of the supervision requirement resulted in different anesthesia arrangements. In our sample, the certified registered nurse anesthetist solo group provided anesthesia in 21 percent of surgeries in opt-out states and about 10 percent in non-opt-out states (Exhibit 1). Solo provision of anesthesia by nurse anesthetists increased over time in opt-out and non-opt-out states.

Although the absolute increase was roughly five percentage points in both opt-out and non-opt-out states, the proportional increase was larger in non-opt-out states (71 percent) than in opt-out states (28 percent). The growth of the solo share by certified registered nurse anesthetists in opt-out states came at the expense of

EXHIBIT 1

Percentages Of Surgical Anesthetics By Anesthesia Provider, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	17.6	40.7	41.7	7.0	47.3	45.8
2000	18.4	42.5	39.1	8.3	46.7	45.0
2001	20.2	42.0	37.8	9.2	45.3	45.5
2002	22.2	41.7	36.1	9.9	44.7	45.4
2003	22.9	42.5	34.7	10.3	43.7	46.0
2004	23.4	42.0	34.6	11.3	42.3	46.5
2005	22.5	42.8	34.7	12.0	41.5	46.5
1999–2005	21.0	42.0	37.0	9.7	44.5	45.8

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** Not all totals equal 100 percent because of rounding. CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together.

team anesthesia, while in the non-opt-out states it came at the expense of anesthesiologist solo anesthesia.

DIFFERENCES BY PATIENT TYPE OR PROCEDURE Before comparing trends in outcomes, we examined whether the case-mix of certified registered nurse anesthetists and anesthesiologists differed by type of patient or procedure. Exhibit 2 shows patient characteristics as of 2005, stratified by anesthesia provider and state opt-out status. The figures have not been adjusted for the different diagnosis-related group surgical cases that are typical of the two types of anesthesia providers. With the exception of base units, the differences in patient characteristics between the certified registered nurse anesthetist solo and anesthesiologist solo groups, although statistically significant, were clinically minor and would not explain large differences in patient outcomes within opt-out and non-opt-out states.

With the exception of the prevalence of African American patients, the differences within provider groups across opt-out status were also minimal.

In opt-out and non-opt-out states, the mean number of base units in the anesthesiologist solo group was about a full point higher than in the certified registered nurse anesthetist solo group ($p < 0.05$, or unlikely to be due to chance). This indicates that solo anesthesiologists were performing more complex or difficult procedures than the nurse anesthetist solo group. One might have expected higher relative complexity by nurse anesthetists practicing solo in opt-out states, given their higher proportion of cases.

However, many opt-out states are rural, and surgery and anesthesia in those states may be less complex overall than in more urban states. This is because patients with more difficult surgical procedures are referred to major urban hospitals with experienced surgical teams and technologies.

OUTCOMES FOR PATIENTS Given that the solo practice of nurse anesthetists did increase in opt-out states, we next determined whether there were any differences in patient outcomes by

EXHIBIT 2

Characteristics Of Anesthesia Patients In States That Did And Did Not Opt Out Of Physician Supervision, 2005

	Opt-out states			Non-opt-out states		
Characteristic	CRNA solo (*n* = 2,310)	MDA solo (*n* = 4,605)	Team (*n* = 3,736)	CRNA solo (*n* = 7,554)	MDA solo (*n* = 26,354)	Team (*n* = 29,511)
Age 75+	51%	48%	45%	44%	47%	44%
Male	41%	45%	44%	43%	45%	44%
African American	1%	2%	2%	8%	7%	11%
Base units[a]	7.2	8.3	7.6	7.2	8.4	7.6

SOURCE Authors' analysis of Medicare Parts A and B claims, 2005 limited data set. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. All comparisons of CRNA solo with MDA solo are significant at the 95 percent confidence level. [a]Base units indicate the severity of the case; see text.

anesthesia arrangement. We started with mortality rates within each hospital for procedures that the two provider types had in common in opt-out and non-opt-out states.

In non-opt-out states, mortality rates for the three anesthesia arrangements followed a general downward trend throughout the seven-year period, from 3.1–3.5 percent to 2.2–2.8 percent (Exhibit 3). A general downward trend is also apparent in opt-out states. Of particular interest is the mortality trend for the certified registered nurse anesthetist solo group in opt-out states. The rate increased from 1999 to 2001—prior to the introduction of the opt-out provision—and decreased from 2001 to 2005. December 2001 was when the first state, Iowa, opted out of the supervision requirement.

MULTIVARIATE ANALYSES Exhibit 4 shows the results of the multivariate analyses for inpatient mortality and complications. It presents the odds ratios for each of the three provider groups in three different opt-out status conditions: non-opt-out states, opt-out states prior to opting out, and opt-out states after opting out. In addition to the provider group and opt-out status indicators, the model controlled for patients' age categories, sex, and race; anesthesia procedure base units; indicators for the ten highest-mortality diagnosis-related groups; and an annual time trend.

The reference group for the odds ratios for both mortality and complications was the anesthesiologist solo group in non-opt-out states. All eight comparison cells for mortality had odds ratios less than 1.0, which indicates that mortality occurred with lower probability in all other combinations of provider and opt-out status than it did with solo anesthesiologists in non-opt-out states (the differences are all significant at the 0.05 level). In opt-out states, there were no statistically significant mortality differences between the periods before and after opting out.

Unlike mortality, complication rates did not differ between anesthesiologist and certified registered nurse anesthetist solo groups in non-opt-out states (Exhibit 4).[17] Yet, as with mortality, nurse anesthetists practicing solo in opt-out states had a lower incidence of complications (odds ratios were 0.798 before opting out and 0.813 after) relative to solo anesthesiologists in non-opt-out states. These differences were statistically significant for both time periods.

In opt-out states, complication rates for the nurse anesthetist solo group were essentially identical to those for the anesthesiologist solo group. The difference between complication rates for nurse anesthetist solo and team anesthesia was also not statistically different in opt-out states.

Discussion

Linking the change in CMS reimbursement policy to changes in patient outcomes requires both that the proportion of surgical procedures for which certified registered nurse anesthetists alone provided anesthesia changed as a consequence of the policy change, and that the type of anesthesia provider affects the likelihood of in-hospital mortality or other adverse event. Our analysis does not support either of the two.

Instead, we found that from 1999 to 2005, the proportion of surgeries in which anesthesia was provided by nurse anesthetists with no anesthesiologist involvement increased by five percentage points in both opt-out and non-opt-out states. However, the rate of increase was nearly three times as great in non-opt-out states as in opt-out states because nurse anesthetist solo rates initially were lower in the former than in

EXHIBIT 3

Surgical Inpatient Mortality Rates (Per 100 Patients) By Anesthetist Arrangement, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

Year	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	1.76	3.45	2.92	3.10	3.50	3.19
2000	2.50	3.67	1.79	3.16	3.21	2.58
2001	3.01	2.80	1.94	3.54	3.68	3.19
2002	2.26	2.72	2.15	3.09	3.44	2.95
2003	2.49	2.39	2.01	3.21	3.58	2.86
2004	1.86	3.82	2.03	2.84	3.20	3.08
2005	2.03	1.32	1.45	2.34	2.76	2.20

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. MDA solo and team mortality rates are based on CRNA case-mix. Inpatient mortality is attributable to anesthesia and all other causes.

EXHIBIT 4

Likelihood Of Death And Complications From Anesthesia, For Different Combinations Of Anesthesia Provider Groups And States' Opt-Out Status: Odds Ratios

	Mortality			Complications		
		Opt-out states			Opt-out states	
Anesthesia provider	Non-opt-out states	Before opting out	After opting out	Non-opt-out states	Before opting out	After opting out
MDA solo	1.00	0.797[a]	0.788[a]	1.00	0.824[a]	0.818[a]
CRNA solo	0.899[a]	0.651[a]	0.689[a]	0.992	0.798[a]	0.813[a]
Team	0.959[a]	0.708[a]	0.565[a]	1.067[a]	0.927	0.903

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. **NOTES** MDA solo is anesthesiologist without certified registered nurse anesthetist (CRNAs). CRNA solo is CRNA without anesthesiologist. Team is anesthesiologist and CRNA working together. The model includes year, base units, diagnosis-related groups, and the patient's age, race, sex. Complications include patient safety indicators 1, 2, 4, 6, 10, 11, and 16 of the Agency for Healthcare Research and Quality; see text. [a]Odds ratio is significantly different from 1 for MDA solo ($p = 0.05$).

the latter. This implies that the increase in the certified registered nurse anesthetist solo share in opt-out states cannot be ascribed wholly, if at all, to the change in the CMS supervision policy.

Whatever forces are driving the growing share of nurse anesthetist solo cases, they appear to be different in the fourteen opt-out states than in the non-opt-out states. In opt-out states, the seven-percentage-point decline in team anesthesia resulted in more solo practice by both types of anesthetists. Anesthesiologists practicing solo explained about one-third of the decline in team anesthesia, and nurse anesthetists practicing solo accounted for the other two-thirds. Elsewhere in the country, team anesthesia rates were constant.

Despite the shift to more anesthetics performed by nurse anesthetists, no increase in adverse outcomes was found in either opt-out or non-opt-out states. In fact, declining mortality was the norm. Moreover, the mortality rate for the nurse anesthetist solo group was lower than for the anesthesiologist solo group in opt-out states both before and after opting out, although the difference was statistically significant only before the state opted out.

These results do not support the hypothesis that allowing states to opt out of the supervision requirement resulted in increased surgical risks to patients. Nor do the results support the claim that patients will be exposed to increased risk as a consequence of more nurse anesthetists' practicing without physician supervision.

We did find that case-mix complexity was different for the two types of providers. Anesthesia base units for procedures in which anesthesiologists practiced solo were a full point higher than for procedures in which certified registered nurse anesthetists worked alone.

Although base units might not completely describe the complexity of either surgical or anesthetic procedures, base units were associated with a statistically greater mortality risk in our multivariate model. We estimate that each one-point increase in procedure base units is associated with a 7 percent higher mortality risk.

To this extent, base units can capture a sizable part of the complexity and risk of the procedures. Moreover, we believe that using additional measures of complexity would not qualitatively change our results.

There were clearly differences between the opt-out and non-opt-out states that were not a consequence of their opt-out status. With the exception of the proportion of African American patients, it does not appear that these differences were primarily caused by patient characteristics such as sex and age.

Yet opt-out states had lower mortality and complication rates than non-opt-out states, even prior to opting out. This suggests that some unobserved difference existed between opt-out and non-opt-out states, perhaps related to the fact that opt-out states were more rural and tended to be located in the West and Midwest.

In any case, the policy conclusions supported by this study remain valid. In opt-out states, mortality and complication rates for the certified registered nurse anesthetist solo group did not vary greatly between the period before opting out and the period after. That means that our data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision.

Policy Recommendations

Our analysis of seven years of Medicare inpatient anesthesia claims suggests that the change in CMS policy allowing states to opt out of the physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients. In particular, the absolute increase in the provision of anesthesia by unsupervised nurse anesthetists in opt-out states was virtually identical to the increase in non-opt-out states, and the proportional increase was smaller in opt-out states.

This lends no support to the belief that a meaningful shift in provider shares occurred as a consequence of the policy change. Similarly, our analysis found no evidence to suggest that there is an increase in patient risk associated with anesthesia provided by unsupervised certified registered nurse anesthetists.

Both a change in the proportion of anesthesia provided by the different groups—nurse anesthetists alone, anesthesiologists alone, and nurse anesthetists and anesthesiologists working in teams—and a difference in the outcomes of the different groups are necessary to conclude that the change in CMS policy led to changes in patient safety. Because our data provide no evidence to support either of these conditions, we conclude that patient safety was not compromised by the opt-out policy.

We recommend that CMS return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesiologist supervision without requiring state governments to formally petition for an exemption. This would free surgeons from the legal responsibility for anesthesia services provided by other professionals. It would also lead to more-cost-effective care as the solo practice of certified registered nurse anesthetists increases. ■

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