

MEMO ON SURGEON LIABILITY

Questioning your liability when working with CRNAs is common question for operating practitioners - "am I liable for the actions of another provider if they are not a physician?"

The answer is unequivocally "no". Operating practitioners (surgeons, physicians, dentists etc.) incur no additional liability when a CRNA provides anesthesia. In fact, surgeons incur the same liability regardless of who is providing anesthesia - an anesthesiologist or CRNA. The following document provides a great deal of evidence - the American Society of Anesthesiologists perhaps provides the most noteworthy legal brief, where they reach the same conclusion.

Surgeons incur liability for anesthesiologists or CRNAs (or any licensed professional) if, 1) they were to exert control (i.e. "you will perform 'x' action"), 2) facility bylaws detail such liability, or 3) if the surgeon and anesthesia provider had a employer-employee relationship, which moves away from professional liability and towards corporate liability.

CRNAs are highly trained anesthesia professionals with an established and impressive record of safety. CRNAs are recognized experts in anesthesia delivery and airway management, and each carries their own individual malpractice insurance (\$1M/\$3M aggregate). Bearing these facts in mind and using objectivity in assessing the evidence, conclusions arrive where common sense would bring us: that licensed professionals are responsible for their own areas of knowledge, experience, and expertise.

Please refer to the following documents for thorough understanding on the matter.

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3. Another Article on the Surgeon's Liability for Anesthesia Negligence. Gene Blummerich, Esq. (2008).
4. Surgeon Liability for Anesthesia Service - Common Misperceptions. Charles M. Key, Esq. (2015).
5. Surgeon Liability, American Association of Nurse Anesthetists, Practice Division, 2015
6. American Society of Anesthesiologists Legal Counsel: Surgeon Liability for Nurse Anesthetists: Fact or Fiction? Judith Jurin Semo, Esq. (2000).
7. 2014 Update on Proper Interpretations of CRNA Regulations and Laws. Karen Owens, Esq. (2014).
8. AZ Case Review Returns No Cases of CRNA Liability for Surgeons. Karen Owens, Esq. (2014).
9. Arizona Association of Nurse Anesthetists Clarification on ARS 32-1634.04 (2014).
10. Health Affairs Journal: No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians (2010).
11. Arizona Association Summary: Cochrane Collaboration Researchers Find No Differences in Care Provided by CRNAs and Anesthesiologists (2014).
12. Cochrane Collaboration Abstract and Plain Language Summary: Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients (2014).
13. American Association of Nurse Anesthetists. Quality of Care: Synopsis of Published Information Comparing CRNA and Anesthesiologist Patient Outcomes (2009).

Certified Registered Nurse Anesthetists (CRNAs) and Operating Practitioner Liability

One Page Summary

1. Physicians, surgeons, podiatrists & dentists who work with independent CRNAs are not legally responsible for the CRNAs actions^{1,2,3,4}
2. A surgeon has equal liability risk working with an anesthesiologist directly, in a team practice with anesthesiologists supervising CRNAs or when working with CRNAs independently. There is no risk difference. ^{1,2,3,4}
3. In a review of Arizona case law over the last 100 years there has never been a physician, podiatrist or dentist found liable for the actions of an independent CRNA. ^{1,2,3}
4. Obstetricians are not liable for epidural placement or complications when place by an independent CRNA. ^{1,2,3,4,5}
5. The American Society of Anesthesiologists legal counsel has also come to the same conclusion. ⁴
6. What may put physicians, podiatrists & dentists at legal risk is unreasonable and restrictive hospital bylaws which may infer liability when there is none.
7. In over 100 years there has never been a study suggesting care by independent CRNAs has any increased risk to patients throughout the perioperative period and multiple studies showing that CRNA care is equivalent to that of anesthesiologists. ^{6,7,8}

1 Arizona Association of Nurse Anesthetists. (2014) Advisory Opinion on Physician Liability.

2 Coppersmith, Gordon, Schermer, Owens & Nelson. (2014). Case Law Review On Physician Liability for CRNAs in Arizona

3 Coppersmith, Gordon, Schermer, Owens & Nelson. (2004 & 2014). CRNA Practice Issues, Legal Opinion

4 American Society of Anesthesiologist Newsletter. Judith Jurin Semo, Esq (2000). Surgeon Liability for Nurse Anesthetists: Fact or Fiction?

5 Arizona Board of Nursing Advisory Opinion. Retrieved 2014 20, Jan, from Arizona State Board of Nursing: <http://tinyurl.com/mszgwow>

6 Health Affairs (2010). No Harm Found When Nurse Anesthetists Work Without Supervision by Physicians. Retrieved from

<http://content.healthaffairs.org/content/29/8/1469.full?ijkey=ezh7UYKLtCYL&keytype=ref&siteid=healthaff>

7 Quality of Care in Anesthesia (2009) Synopsis of Published Information Comparing CRNAs and Anesthesiologist Patient Outcomes. Retrieved from <http://www.aana.com/resources2/professionalpractice/Documents/Quality%20of%20Care%20in%20Anesthesia%2012102009.pdf>

8 Cochrane Review (2014) Researchers Find No Differences in Care Provided by CRNAs and Anesthesiologists: Cochrane Collaboration.

Retrieved from <http://www.aana.com/newsandjournal/News/Pages/081314-Researchers-Find-No-Differences-in-Care-Provided-by-CRNAs-and-Anesthesiologists-Cochrane-Collaboration.aspx>



LEGAL BRIEFS

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ANOTHER ARTICLE ON THE SURGEON'S LIABILITY FOR ANESTHESIA NEGLIGENCE

Key words: Control, liability.

In the years I have served as General Counsel for the American Association of Nurse Anesthetists (AANA), no subject has received more of my attention than the question of a surgeon's liability for the negligence of a nurse anesthetist. It is pretty remarkable that I should have devoted so much attention to this subject when you consider how safe anesthesia has become. The incidence of a major anesthetic problem has become so rare that most surgeons will spend their entire careers without ever seeing one. So, why are surgeons so concerned? In the mid-1980s, an increase in the number of anesthesiologists led to increased competition between nurse anesthetists and anesthesiologists. Occasionally, some anesthesiologists would tell surgeons that it would be better to work with anesthesiologists than nurse anesthetists to avoid liability. One anesthesiologist wrote that no surgeon "should" be held liable when working with an anesthesiologist but "a surgeon or dentist *automatically* becomes responsible whenever a nurse administers anesthesia without medical direction by an anesthesiologist [emphasis added]." As a legal matter, I knew that the courts did not decide questions of liability based on what state agency happened to issue the provider's license. The courts impose liability only when a surgeon con-

trolled the procedure or participated in the negligence; not simply because the surgeon was working with, or supervising, a nurse anesthetist. Most importantly, I had read enough cases to know that liability was anything but automatic. Nonetheless, even if the warning was inaccurate and unjustified, as a marketing strategy, it worked all too well. Nurse anesthetists needed real answers to counter a threat to their practices.

I have tried to provide accurate information about this subject. To show that liability was not automatic, my columns have described case after case where surgeons were not held liable for the negligence of the nurse anesthetists they were working with or supervising. To show that the same principles were used to determine liability of surgeons for negligence of anesthesiologists and nurse anesthetists, I even provided lists of cases where surgeons got sued or were held liable for anesthesia mishaps when they worked with anesthesiologists. Instead of providing conclusions, I have given citations so that my accuracy and honesty would not be a factor. Anyone could look at the cases to see if I had accurately reported what the court decided.

Despite these efforts, the marketing campaign has continued, and surgeons continue to be concerned about liability when working with Certified Registered Nurse Anes-

thetists (CRNAs). Since the cases I have cited cannot be denied, they are dismissed as old or stale. Well, practicing law is not like selling fish. Fresher cases are not necessarily any better than old ones, unless the law is changing. And, the law in this area is not changing. Liability is based on control. That legal concept predates the discovery of anesthesia, the American Revolution, and the birth of Christopher Columbus. The law's tradition of basing liability on control can be found in laws adopted by Charlemagne in the 9th century and even those described in the Bible. Cases have different outcomes, not because the law changes, but because the principles of the law are applied to different factual patterns. The factual patterns may change from case to case, but the courts continue to apply the same principles. The same principles that determine the liability of surgeons for errors of nurse anesthetists also determine the liability of surgeons for the negligence of anesthesiologists. When these cases are read, you see the courts examining the facts: What control did the surgeon have over the anesthesia? Was the surgeon aware of the patient's condition? Would a reasonable surgeon faced with the same facts have done things differently? If the anesthesiologists were right and liability was automatic, why do the courts have to spend so much time struggling

with the facts? Moreover, are nurse anesthetists being punished for their success? Anesthesia is so safe that the number of anesthesia cases reaching appellate courts is small to begin with, and finding a steady stream of cases is difficult indeed.

What is dated are not the cases—they are based on solid legal principles—but the false conclusion that working with a nurse anesthetist rather than an anesthesiologist automatically determines a surgeon's liability. It was untrue 30 years ago, it was untrue 20 years ago, it is untrue today, and tomorrow it will still be untrue.

A surgeon's liability for anesthesia was not an issue when surgeons were "captain of the ship." The captain of the ship doctrine simply assumed that the surgeons controlled (and was liable for) everything that went on in the operating room (including anesthesiologists and nurse anesthetists) and did not permit any evidence to contradict the surgeon's ability to control what happened in the operating room. That assumption may never have been true, but it certainly became less and less true as operations became more complex. Eventually, courts refused to follow it as they became more and more aware that the success of surgery depended on a number of highly educated individuals, working cooperatively toward a successful conclusion. Unfortunately, by the time captain of the ship had died out, nurse anesthetists had been forced to defend themselves against charges that they were illegally practicing medicine by describing their collaborative practice setting as one where they were "supervised" or "directed" by a surgeon. Thus, the nurse anesthetists were not practicing medicine because they were engaging in a nursing function while the surgeon made whatever

medical decisions might be required. This approach had been incorporated into the licensing laws of several states. The fall of captain of the ship roughly coincided with a dramatic increase in the number of anesthesiologists. Anesthesiologists trying to find an advantage in the newly competitive world of anesthesia seized on this previously immaterial distinction as the cornerstone of a campaign to urge surgeons to use anesthesiologists because only in this way, the argument went, would surgeons avoid being caught up in lawsuits over anesthesia mishaps.

There were two fallacies to this argument that surgeons ignored in the emotional phobia over liability. One was legal: supervision did not lead to liability. Liability was based on control. A surgeon could supervise a nurse anesthetist without being in control. No legal doctrine equated supervision with control or liability.

Second, from a medical standpoint, anesthesia was becoming much safer and just as the law did not look at who issued the provider's license to determine liability, neither did anesthesia mishaps. Anesthesia mishaps, while rare, appeared to occur with the same frequency whether the administrator was an anesthesiologist, a nurse anesthetist, or a team of both providers.

So, at the very time surgeons were being told to avoid nurse anesthetists if they did not want to be automatically liable for anesthesia mishaps, what the courts were really looking at was evidence of the surgeon's control. The surgeon was liable for an anesthesia mishap only if the surgeon was in control of the process or procedure that led to the mishap and otherwise the surgeon was not.

Moreover, in their newly generated concern over the type of license

held by their anesthesia providers, surgeons missed another important legal lesson. To be held liable, the surgeon had to have a very specific type of control. The difference between an employee, for whose negligence there is liability, and an independent contractor for whose negligence there is no liability, is not just control, but control over the way the job is done. An employer has the right to control an employee not only as to *what* shall be done but also *how* it shall be done. On the other hand, when someone supervises an independent contractor, he or she can control the *result* (the "what") but not the details and means (the "how"). A surgeon would rarely have the knowledge to control the details and means by which anesthesia is administered. In fact, in some cases in which surgeons have been held liable for the negligence of an anesthetist, the surgeon has admitted to being in control but has confused control of the results with control of the details and means. For example, "Keep the patient relaxed, quiet, and don't let the patient move!" is control of the results. On the other hand, "Let's administer 200 mg of anectine because this patient is quite overweight," or "This looks like a difficult airway. Do an awake fiberoptic intubation!" are examples of control of the details and means. There is a huge difference between having ultimate control of the ways and means (and being liable) and having control over the ultimate result (for which there is no liability).

Where an employer is interested only in the results, and the contracting party independently determines the details of the method by which the desired results are obtained, an independent contractor relationship exists and the rule of *respondet superior* does not apply. *Drennan v Community Health Investment Corporation* (905 S.W.2d 811, Texas, 1995)

Liability depends on the facts of the case

The principles governing the liability of a surgeon working with a nurse anesthetist are the same as those governing the liability of a surgeon working with an anesthesiologist. Courts do not look at the status of the anesthesia administrator but at the degree of control the surgeon exercises over the manner in which the administrator—whether that administrator is a CRNA or an anesthesiologist—provided the anesthetic. Thus, a court may render different conclusions for cases that involve a surgeon working with a CRNA—or, for that matter, a surgeon working with an anesthesiologist—if the surgeon controlled the CRNA in one case but not in another. A surgeon is not *automatically* liable when working with a CRNA, nor is the surgeon immune from liability when working with an anesthesiologist. In order for a surgeon to be liable for the acts of the anesthesia administrator, the surgeon must be in control of the details and means used by the anesthetist and not merely be supervising or directing the administrator.

Surgeons have been held not liable for working with CRNAs

There are many cases in which courts have found that the surgeon was not in control of the CRNA and, therefore, not liable for the negligence of the CRNA (Table 1).

Even in cases in which the surgeon was held liable, there is often evidence of individual wrongdoing on the part of the surgeon. Although some states require that a CRNA may administer anesthesia only under the supervision or direction of a physician, mere supervision does not establish “control” nor create liability. As the Court stated in *Voss v Birdwell* (188

Table 1. Cases in which surgeons have been held not liable for working with CRNAs

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| <i>Cavero v Franklin Benevolence Society</i> (223 P. 2d 471, California, 1950) |
| <i>Fortson v McNamara</i> (508 So. 2d 35, Florida, 1987) |
| <i>Franklin v Gupta</i> (567 A. 2d 524, Md, 1990) |
| <i>Goodman v Phythyon</i> (803 S. W. 2d 697, Tennessee, 1990) |
| <i>Hughes v St. Paul Fire and Marine Insurance Company</i> (401 So.2d 448, Louisiana, 1981) |
| <i>Kemalyan v Henderson</i> (277 P. 2d 372, Washington, 1954) |
| <i>Pierre v Lavallie Kemp Charity Hospital</i> (515 So. 2d 614, La., 1987) |
| <i>Thomas v Raleigh General Hospital</i> (358 SE 2d 222, W. Va., 1987) |
| <i>Sesselman v Mullenberg Hospital</i> (306 A.2d 474, New Jersey, 1954) |
| <i>Starcher v Byrne</i> (687 So. 2d 737, Mississippi, 1997) |
| <i>Carlson v Javurek</i> (526 F. 2d 203, SD, 1975) |

Kan. 643 at 655, 364 P.2d 955 (1961):

In determining whether a person is the servant of another it is necessary that he not only be subject to the latter's control or right of control with regard to the work to be done and the manner of performing it, but that this work is to be performed on the business of the master or for his benefit. Actual control, of course, is not essential. It is the right to control which is determinative. On the other hand, the right to supervise, even as to the work and the manner of performance, is not sufficient; otherwise a supervisory employee would be liable for the negligent act of another employee though he would not be the supervisor or master of that employee in the sense the law means it. (Restatement, Agency 2d, § 220[1], [1958]; *Yorston v Pennell*, Appellant [1959], 397 Pa. 28, 39, 153 A.2d 255).

Other cases also have held that mere supervision or direction of a CRNA is insufficient evidence to hold a physician liable for the CRNA's negligence. See, for example, *Baird v Sickler*, 69 Ohio St.2d 652, (1982); *Foster v Englewood Hospital*, 19 Ill.App.3d 1055 (1974); *McCullough v Bethany Medical Center*, 235 Kan. 732 (1984); *Elizondo v Tavarez*, 596 S.W.2d 667 (Texas, 1980); *Parker v Vanderbilt*, 767 S.W. 2d 412 (Tenn., 1988); and *Whitfield v Whittaker Memorial Hospital*, 210 Va. 176 (1969).

Surgeons have been held liable for working with anesthesiologists

Working with anesthesiologists rather than CRNAs does not insulate surgeons from liability. As we have noted, the legal principles that determine liability are the same whether the surgeon works with an anesthesiologist or a CRNA, and the outcome depends on the facts of the case. As one would expect, there are numerous cases where surgeons have been sued when working only with anesthesiologists and surgeons have been held liable for anesthesia mishaps when working with anesthesiologists (Table 2).

Clearly, surgeons should not pick their anesthesia providers on the basis of licensure. If proof is needed, consider *Herrington v Hiller*, 883 F.2d 411 (U.S. Ct. of App., 5th Cir., 1989). A 448-bed hospital with the only obstetrical unit in 60 miles refused to institute 24-hour anesthesia coverage because it would have meant the hospital would have had to let CRNAs place epidural catheters. The hospital refused, presumably,

Table 2. Cases involving anesthesia mishaps in which surgeons were sued when working with anesthesiologists

Chism v Campbell (250 Neb. 921; 553 N.W.2d 741, 1996)
Kerber v Sarles (542 N.Y.S.2d 94; 151 A.D.2d 1031, 1989)
Costell v Toledo Hospital (98 Ohio App. 3d 586; 649 N.E.2d 35, 1994)
Adams v Childrens Mercy Hospital (848 S.W.2d 535, 1993)
Brown v Bozorgi (234 Ill. App. 3d 972; 602 N.E.2d 48, 1992)
Ruby Jones v Neuroscience Associates, Inc. (250 Kan. 477; 827 P.2d 51, 1992)
Seneris v Haas (45 Cal. 2d 811; 291 P.2d 915, 1955)
Szabo v Bryn Mawr Hospital (432 Pa. Super. 409; 638 A.2d 1004, 1994)
Tiburzio-Kelly v Montgomery (452 Pa. Super. 158; 681 A.2d 757, 1996)
Bert v Meyer (663 N.Y.S.2d 99, 1997)
Robertson v Hospital Corporation of America (653 So.2d 1265, Court of Appeals of Louisiana, 1995)
Menzie v Windom Community Memorial Hospital (774 F.Supp. 91, USDC Conn., 1991)
Thompson v Presbyterian Hospital (652 P.2d 260, Okla., 1982)
Dunn v Maras (182 Ariz. 412; 897 P.2d 714, 1995)
Medvezc v Choi (569 F.2d 1221, U.S. Ct. of App., 3d Cir., 1977)
Carolan v Hill (553 N.W.2d 882, Iowa, 1996)
Vogler v Dominguez (624 N.E.2d 56, Ind., 1994)
Quintal v Laurel Grove Hospital (62 Cal.2d 154; 397 P.2d 161, 1965)
Schneider v Einstein Medical Center, 390 A.2d 1271 (Penn. 1978)
Kitto v Gilbert, 570 P.2d 544 (Colo. 1977)

to follow the recommendations of the American Society of Anesthesiologists in its 1983 Statement on Regional Anesthesia. The plaintiff went to the hospital to give birth at 3:00 AM. The attending physician ordered an immediate cesarean section. Because the hospital did not have 24-hour anesthesia coverage, there was a delay in the start of the procedure while an anesthesiologist was called and came to the hospital. The child was deprived of oxygen that the parents blamed on the delay, caused, in turn, by the hospital's anesthesia politics. The trial court would not let the parents tell the jury why it had taken so long to start the cesarean section. The US Court of Appeals disagreed and

ordered a new trial. The district court was wrong to keep evidence from the jury that the hospital had refused to provide 24-hour anesthesia coverage because of anesthesia politics.

Efforts to eliminate supervision from the HCFA* rules

As most of us know, the continued misrepresentation of the surgeon's liability for negligence of the anesthesiologist led the AANA to seek reformation of the regulatory framework. Constant attacks on CRNAs as illegally practicing medicine at the turn of the 20th century had led nurse anesthetist leaders to seek protection by having some licens-

ing laws provide that when a nurse anesthetist administered anesthesia under the supervision of a physician, the nurse anesthetist was practicing nursing, not medicine. When in the 1980s that concept was corrupted and the requirement of supervision was used as a tool to restrict CRNA practice, AANA leadership tried to educate surgeons on the law but increasingly felt backed into a corner. There were few options since surgeons simply ignored accurate information in favor of simplistic but inaccurate descriptions of their liability. Reluctantly, AANA leadership decided that if supervision was going to be used to restrict CRNA practice, then AANA would have to seek the elimination of supervision.

While the AANA's efforts were misunderstood as a plan to expand scope of practice, in reality, all the AANA wanted was to preserve existing CRNA practice. It was not the path AANA had wanted to take but every alternative to convince surgeons that liability was not an issue had been foreclosed. The obvious place to start was where the supervision issue mattered most—its effect on reimbursement in the federal Medicare rules. We know the outcome. Even more misinformation was thrown at nurse anesthetists and when the battle finally ended, both AANA and anesthesiologists were forced to accept a compromise neither side wanted. The requirement of supervision was retained but individual state governors could, if requirements were met, cause their state to "opt out" of the supervision requirements. Today, 14 states have opted out of the Medicare supervision requirement and some progress is being made to realize the AANA's goal—to secure for future nurse anesthetists the ability to continue to work collaboratively

* HCFA is the Health Care Financing Administration, which is now known as the Centers for Medicare & Medicaid Services or CMS.

as part of the surgical team, providing safe, quality anesthesia services to the American public.

American Jurisprudence Proof of Facts

Recently, I have become aware of an example of the headway we are making. There has been a major change in the *American Jurisprudence Proof of Facts* and its section on anesthesia. *American Jurisprudence Proof of Facts* is a legal compendium that is useful in finding cases but is not given the same respect among courts as decided cases themselves. Its article on anesthesia (8 *AmJur* POF 2d, p. 570), published back in 1976, cited several cases in which surgeons were not held liable for the negligence of nurse anesthetists. Nonetheless, the authors somehow concluded: "However, it is still true that in almost all cases either as a result of negligent failure to supervise, or from application of general principles of vicarious liability, surgeons are usually held liable for negligence of nurse-anesthetists." (8 *AmJur* POF 2d, p. 601) I always doubted the accuracy of the statement. For one thing, no authority for the statement was ever given. No one ever acknowledged counting the cases, either. In addition, it was clear from the article itself that there were many cases in which surgeons had been held not to be liable for the negligence of nurse anesthetists. Like many other irritating and unfair aspects of this subject, the statement

was often quoted by those attempting to restrict the practice of nurse anesthetists. It was sometimes even cited as if it were authority by the courts. (See, for example, *McCullough v Bethany Medical Center* (235 Kan. 732; 683 P. 2d 1258, 1984)).

In July 2006, American Jurisprudence released the 2006 Supplement for *Proof of Facts*, and the article on anesthesia was supplemented by the following statement: "This article has been superseded by the following articles: Anesthesia Malpractice, 6 *AmJur* Proof of Facts 3d 1." The new article no longer says that surgeons "are usually held liable for negligence of nurse anesthetists." In fact, the new article is a much better reflection of the reality of the anesthesia marketplace. The new article refers to the modernization of nursing practice statutes, the broadening scope of CRNA responsibilities, and points out that CRNAs administer a variety of anesthetics without supervision. The article even notes that "Because some CRNAs perform this procedure [spinals] frequently, they usually can perform the procedure efficiently and more safely than many anesthesiologists...often the CRNA must make critical decisions when supervised by a physician with no anesthesia training." (6 *AmJur* POF 3d § 3).

Traditionally, physicians and hospitals have been held vicariously liable for the nurse's negligence under the theories of agency or respondeat superior. However, since studies have shown the

absence of a significant difference in the quality of care delivered by nurse anesthetists and anesthesiologists, many states have now expanded by statute the scope of the CRNA's responsibilities. Today, courts recognize that the CRNA and the anesthesiologist do not perform mutually exclusive functions. In fact, it is often realized that the difference between practicing medicine and nursing cannot always be articulated with certainty. Like the anesthesiologist, the nurse [anesthetist] may be in a position to make life-or-death decisions for the patient. (6 *AmJur* POF 3d §27)

Conclusion

One would like to think that anesthesia personnel would be selected on some basis that relates to the quality of care they provide rather than some muddled impression of how the surgeon can reduce the exposure to liability. Unfortunately, concerns relating to the success of the surgery and the well-being of the patient have all too often been made secondary to what the surgeon wrongly believes will reduce malpractice claims. The truth is that surgeons cannot be guaranteed immunity from anesthesia mishaps no matter who they work with. Moreover, liability and immunity are not automatic in the case of either provider. Surgeons concerned with liability should find the safest provider, an inquiry that has never depended on the agency issuing the provider's license. As *Herrington v Hiller* shows, allowing politics to dictate the choice of anesthesia provider protects neither the patient nor the surgeon.



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Surgeon Liability for Anesthesia Services – Common Misperceptions

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Surgeon Liability for Anesthesia Services – Common Misperceptions

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We all know that we are responsible for our own actions, and that under the law of negligence, this can include things that we do (“acts”) and things that we fail to do (“omissions”). We also know that we can sometimes be responsible, under the law, for the acts or omissions of others. For example, an employer may be liable to third parties for the acts or omissions of its employees. In the case of professional employees, an employer’s liability arises simply because of the employer-employee relationship.

A surgeon who is not the employer of the anesthesia provider (CRNA or MD anesthesiologist (MDA)) is generally not liable for the acts or omissions of the CRNA/MDA.¹ This is true even where the surgeon is “supervising” a CRNA for purposes of state licensure or reimbursement. This is because “supervise” in that context does not mean directing the CRNA as to the manner and means by which the CRNA administers anesthesia. In fact, a surgeon would almost never undertake to direct a CRNA in the provision of anesthesia services (and generally should not do so), simply because the training and experience of a CRNA in anesthesia will normally exceed that of the surgeon.

The cases that have considered the question are uniform in their support.

Cases that have held that a surgeon was not liable for the acts or omissions of a CRNA:

- *Glassman v. Costello*, 267 Kan. 509, 523-524, 986 P.2d 1050, 1060-61 (1999) (surgeon not liable for CRNA’s negligence).
- *Starcher v. Byrne*, 687 So. 2d 737, 741-742 (Miss. 1997) (surgeon not liable for CRNA’s negligence).
- *Parker v. Vanderbilt*, 767 S.W 2d 412, 415-416 (Tenn. App. 1988) (rejecting “captain of the ship” doctrine and finding surgeon not liable for CRNA’s negligence.)
- *Fortson v. McNamara*, 508 So. 2d 35, 37 (Fl. App. 1987) (surgeon not liable for CRNA’s negligence).
- *Pierre v. Lallie Kemp Charity Hospital*, 515 So. 2d 614, 620-621 (La. App. 1987) (surgeon not liable for CRNA’s negligence).
- *Hughes v. St. Paul Fire and Marine Insurance Co.*, 401 So. 2d 448, 450 (La. App. 1981) (surgeon not liable for CRNA’s negligence).
- *Sesselmon v. Mulenberg Hospital*, 306 A. 2d 474, 475-477 (N.J. Super. Ct., App. Div. 1954) (surgeon not liable for CRNA’s negligence).

Cases in which a surgeon was sued for alleged anesthesia error when working with an anesthesiologist:

- *Sanchez v. Barba*, 2011 WL 1105807 (Conn. Super. 2011) (defense verdict upheld in case involving injury to patient due to placement of esophageal stethoscope).
- *Chism v. Campbell*, 250 Neb. 921, 553 N.W. 2d 741, 744-745 (1996) (summary judgment for surgeon and MDA).

¹ Accord, 1 American Law of Medical Malpractice 3d § 3:17 (West 2014). The cases above reflect the consistency of this general rule. Research has disclosed no case finding the surgeon vicariously liable for the acts or omissions of a CRNA or MDA.

- *Carolan v. Hill*, 553 N.W. 2d 882 (Iowa 1996) (ulnar nerve injury; defense verdict remanded in part).
- *Robertson v. Hospital Corporation of America*, 653 So. 2d 1265, 1266-1273 (La. App. 1995) (ulnar nerve damage; liability apportioned 72% to MDA, 20% to surgeon, 10% to hospital).
- *Szabo v. Bryn Mawr Hospital*, 432 Pa. Super. 409; 638 A. 2d 1004, 1006 (1994) (remanded for determination of surgeon's control over MDA).
- *Adams v. Childrens Mercy Hospital*, 848 S.W. 2d 535, 538 (Mo. App. 1993) (surgeon not liable for negligence of anesthesia resident under faculty supervision).
- *Brown v. Bozorgi*, 234 Ill. App. 3d 972; 602 N.E. 2d 48, 51 (1992) (surgeon not liable for MDA's negligence).
- *Franklin v. Gupta*, 567 A. 2d 524, 539 (Md. Ct. App. 1990) (rejecting the "captain of the ship" doctrine; surgeon not liable for MDA or CRNA negligence).
- *Thomas v. Raleigh General Hospital*, 358 S.E. 2d 222, 224-225 (W.Va. App. 1987) (surgeon not liable for MDA or CRNA negligence).
- *Schneider v. Einstein Medical Center*, 390 A. 2d 1271, 1277-1278 (Penn. Super. 1978) (surgeon liable for failure to cancel procedure when MDA not able to intubate patient).



About the Author

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Surgeon Liability

AANA Practice Division

The following discusses the legal relationship between surgeons and nurse anesthetists and some of the common misconceptions that arise in this area. Please bear in mind that this information does not constitute legal advice or a legal opinion.

The Nature of Surgeon Responsibility

While surgeons commonly order nurse anesthetists to give anesthetics, surgeons have no affirmative obligation to control the substantive course of the anesthetic process. To the contrary, a surgeon may rely upon the nurse anesthetist as the anesthesia expert. A nurse anesthetist uses independent judgment in determining the appropriate kind of anesthetic to be administered, as well as types of drugs and dosages. Merely requesting that a nurse anesthetist provide an anesthetic is not in itself an act of "control" that will necessarily make a surgeon liable for a nurse anesthetist's acts.

There are many cases which stand for the proposition that surgeons are not automatically liable for CRNA actions. In addition, surgeons do not escape liability when working with anesthesiologists. As discussed below, courts typically apply the same standard when judging whether surgeons are liable for the acts of an anesthesia provider, regardless of whether the provider is a nurse anesthetist or anesthesiologist.

Below are links to several articles by the AANA's general counsel concerning liability issues involving nurse anesthetists and surgeons. As these articles demonstrate, in determining whether a physician is liable for the negligence of a nurse anesthetist with whom the physician works, the status of the anesthesia administrator is not the relevant factor. Rather, courts examine whether the degree of control the physician exercised over the anesthesia administrator, regardless of whether the administrator is a nurse anesthetist or an anesthesiologist.

A physician is not automatically liable when working with a nurse anesthetist; nor is the physician immune from liability when working with an anesthesiologist. Courts have held surgeons liable for the negligence of anesthesiologists when the surgeons had control of the anesthesiologists' actions. In *Schneider v. Einstein Med. Ctr.*, 390 A.2d 1271 (Penn. 1978) and *Kitto v. Gilbert*, 570 P.2d 544 (Colo. 1977), the courts found the physicians liable for the negligence of anesthesiologists because the physicians were in control of the anesthesiologists' actions. The question, as in cases of a physician working with nurse anesthetists, is whether the physician was in control of the acts of the anesthesiologist. This is a factual inquiry and not a conclusion of law.

There are many cases in which courts have found that the surgeon was not in control of the nurse anesthetist and, therefore, not liable for the negligence of the nurse anesthetist. E.g., *Cavero v. Franklin Benevolence Soc'y*, 223 P.2d 471 (Cal. 1950); *Fortson v. McNamara*, 508 So.2d 35 (Fla. 1987); *Franklin v. Gupta*, 567 A.2d 524 (Md. 1990); *Hughes v. St. Paul Fire and*

Marine Ins. Co., 401 So.2d 448 (La. 1981); *Kemelyan v. Henderson*, 277 P.2d 372 (Wash. 1954); *Parker v. Vanderbilt*, 767 S.W.2d 412 (Tenn. 1988); *Pierre v. Lavallie Kemp Charity Hosp.*, 515 So.2d 614 (La. 1987); *Thomas v. Raleigh Gen'l Hosp.*, 358 S.E.2d 222 (W. Va. 1987); *Sesselmen v. Mullenberg Hosp.*, 306 A.2d 474 (N.J. 1954).

Moreover, numerous cases hold that mere supervision or direction of a nurse anesthetist is insufficient to hold a physician liable for a nurse anesthetist's negligence. See, e.g., *Sesselmen v. Mullenberg Hosp.*, 306 A.2d 474 (N.J. Super. Ct. App. Div. 1973) (error for trial court to instruct that obstetrical surgeon could be liable for nurse anesthetist's negligence where obstetrician never exercised control over nurse anesthetist and nurse anesthetist merely received obstetrician's instructions concerning the work to be performed); *Baird v. Sickler*, 69 Ohio St.2d 652 (1982); *Foster v. Englewood Hosp.*, 19 Ill. App. 3d. 1055 (1974); *Elizondo v. Tavaréz*, 596 S.W.2d 667 (Tex. 1980); *Whitfield v. Whittaker Mem. Hosp.*, 210 (Va. 176 (1969).

It is clear from the case law that in order for a physician to be liable for the acts of the anesthesia administrator, the physician must control the administrator's actions and not merely be supervising or directing the administrator.

In a January 1988 report of the Center for Health Economics Research (CHER), an independent Boston-area based research organization that analyzes and evaluates health-related policy issues, CHER concluded that "both legal doctrine and case history (as reviewed by the AANA and ASA) do not indicate a tendency on the part of the courts to hold surgeons liable more often when they work with nurse anesthetists than with anesthesiologists."

In light of the above, it is erroneous for anyone to state or imply that surgeons are at greater risk when they work with nurse anesthetists rather than anesthesiologists.

Summary

Courts apply the same standard to judge whether surgeons are liable for the acts of the anesthetist whether the anesthetist is a CRNA or an anesthesiologist.

If you have questions or comments about this topic, please contact the AANA's Professional Practice Division at practice@aana.com or (847) 655-8870.

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Surgeon Liability for Nurse Anesthetists: Fact or Fiction?*Judith Jurin Semo, Esq.*

Whenever a physician works with a nonphysician allied health practitioner, a legitimate concern exists as to the circumstances under which the physician may be held responsible for the actions of the nonphysician. In some cases, the nonphysician may be an assistant who directly assists the physician in providing services to the patient, accepting instruction as to each specific action to be taken. In other cases, the nonphysician provider may be trained in an area entirely different from the physician's specialty and may perform services needed for patient care, but they may be separate and distinct from the specific services the physician is providing.

Overview

Employers are responsible for the actions of their employees performed in the reasonable scope of their employment under the doctrine of respondeat superior, under which the master is responsible for the acts of the servant. Often in hospitals, ambulatory surgical centers and physician offices, however, personnel employed by different entities combine to provide services to patients, and several different parties can be sued in the event of injury. Generally, in cases involving adverse anesthesia incidents, at least three parties may be named defendants: the hospital or other facility at which the surgical procedure took place, the surgeon or other operating physician and the anesthesiologist and/or the nurse anesthetist involved.

Physicians (and hospitals) may be held accountable for the actions of persons who are not their employees based upon a variety of theories of vicarious liability, under which the law of agency is used to impose liability on a physician who possesses a right to control the actions of the nonemployee health care provider. The law of agency sets forth principles regarding the circumstances under which one person can be held accountable for the actions of another. Often, the nonemployee is said to become the borrowed servant of the physician. Courts differ on the precise rationale under which vicarious liability should be imposed. Some courts look to whether the physician had the right to control the nonemployee, while others courts will impose liability only if the physician actually took steps to control the person.

A more outdated theory of liability known as captain of the ship once was a basis for finding the surgeon responsible for every person working in the operating room, without regard to whether the surgeon did or did not try to exert control or even knew what the other personnel were doing. That theory has fallen into

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disfavor as courts recognize that today's operating rooms are more complicated facilities with more specialized personnel, some of whom are skilled in areas in which the surgeon has little training.

Physicians typically ask for a snapshot of the legal principles and want to know in a few words under what circumstances they can be held responsible. The truth is that the cases in this area do not lend themselves to easy characterization. This article will provide an overview of some of the theories and facts relied upon by the courts in evaluating liability of a physician (or hospital) for a nonemployee. Many times the cases involve a nonemployee nonphysician, including nurses and nurse anesthetists. In some instances, the facts concern a nonemployee physician, including anesthesiologists. Readers should recognize that courts in different states may follow different principles and that the procedural history of the case, including the different parties who may have settled before a case is decided, also may bear on the outcome.

Vicarious Liability

Determining vicarious liability is a fact-intensive process that depends upon the facts of the incident giving rise to the lawsuit. The theories that the parties present to the court also affect the outcome. The cases fall along a spectrum: A surgeon may be held legally responsible for the actions of a nurse anesthetist if the surgeon takes steps to intervene in the provision of anesthesia or if the surgeon accepts responsibility for the actions of the nurse anesthetist. A hospital may be held accountable for the actions of nonemployee nurse anesthetists if the hospital's own policies are not followed. Some courts reason that a surgeon can be held accountable if the surgeon had the right to control the actions of the nonemployee without regard to what steps the surgeon actually did or did not take to control the actions of the nonemployee. In determining whether the surgeon had the right to control the nonemployee, courts look at a variety of factors, including the facts of the case, expert testimony regarding the standard of practice and any hospital policies regarding the conditions under which a nonphysician may practice. Finally, at the far end of the spectrum, the more extreme view is represented by the "captain of the ship doctrine that many courts now decline to follow.

Physicians typically ask for a snapshot of the legal principles and want to know in a few words under what circumstances they can be held responsible. The truth is that the cases in this area do not lend themselves to easy characterization.

Significantly, courts generally do not consider the scope of practice of the nurse anesthetist or other nonphysician practitioners in reaching their decisions. Instead, the courts look at doctrines of the law of agency discussed above as well as the hospital or department of anesthesiology policies or protocols regarding practice by nurse anesthetists.

That is not to say that the licensing provisions governing the nonphysician's practice are not relevant. For example, the Supreme Court of Georgia* reviewed the licensing statute governing nurse anesthetist practice in order to assess the liability of an anesthesiology practice and a hospital where anesthesia was administered by a student nurse anesthetist under the supervision of a physician's assistant. The court found that the anesthesiology practice which employed the physician's assistant had breached its duty in allowing an uncertified student nurse anesthetist to administer anesthesia while not under the direction and responsibility of an anesthesiologist as required by Georgia law. Similarly, the

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hospital was found liable for violating its legal duty by using a surgical consent form stating that anesthesia would be administered under the direct supervision of an anesthesiologist and by knowingly permitting the anesthesiology practice to violate its statutory duty.

So what guidance can be drawn from the cases?

Right to Control

In a 1994 decision of the North Carolina Supreme Court, the court found the surgeon responsible for the actions of the nurse anesthetist with whom he had worked because the surgeon was capable of exercising control over the nurse anesthetist, knew the principles of anesthesia administration and had exercised control on at least one occasion during the procedure. In reaching this decision, the court relied in part on the hospital's anesthesia manual, which provided that anesthesia care would be provided by nurse anesthetists working under the responsibility and supervision of the surgeon doing the case. The conclusion that the surgeon had the right to control the nurse anesthetist was supported by the fact that the hospital did not employ or contract with an anesthesiologist.

Interestingly, the court departed from the decisions of other courts and decided that the surgeon could be held liable for the negligence of a skilled assistant if the surgeon in fact possessed the right to control that assistant at the time of the assistant's negligent act.

Actual Control

A Maryland appellate court decision illustrates how courts have moved away from the captain of the ship doctrine and instead have looked at whether the surgeon exercised actual control over the negligent nonemployee assistant before imposing liability. In this case, an anesthesiologist had evaluated the patient as a high-risk patient for anesthesia and had prescribed the anesthesia plan but had not specified the anesthetic agents to be used and was not present when the hospital-employed nurse anesthetist induced the patient. The plaintiff's expert testified at trial to several violations of the standard of care by the anesthesiologist and by the nurse anesthetist. The court declined to impose liability on the surgeon, finding that there was no evidence that the surgeon had in any way supervised or controlled, had attempted to control or had the right to control the conduct of the anesthesiologist and nurse anesthetist.

The controlling factor in determining whether a surgeon is to be held accountable for a nurse anesthetist's actions is whether, based on the facts of the case, the surgeon actually exercised control or had the right to exercise control over the nurse anesthetist during the surgical procedure.

In another case where a patient was injured in the course of the administration of anesthesia by a nurse anesthetist who was supervised by his employer-anesthesiologist, the court determined that the operating surgeon could not be held accountable for the administration of anesthesia. The court stated that the surgeon would not be held responsible in the absence of actual control.

The lack of control over the way in which a nurse anesthetist provides services has served as a rationale for finding that a hospital was not vicariously liable for the actions of a nurse anesthetist. In a 1995 decision, a Texas appellate court relied on uncontroverted testimony that the nurse anesthetist was an independent contractor who determined with the surgeon,

outside the parameters and control of the hospital, the details of providing anesthesia to the injured patient. (The liability of the surgeon and the nurse anesthetist, both of whom had settled with the plaintiff, was not at issue.)

Violation of Hospital Policies

Where hospital policies relating to the administration of anesthesia are not followed, the hospital is subject to liability for the anesthesia-related injury. In an appellate court decision in Texas, the hospital was held vicariously liable for the injury caused to a patient when a nurse anesthetist administered anesthesia for an emergency cesarean delivery. The hospital's anesthesia department policies required that an anesthesiologist perform the preanesthesia evaluation, discuss the anesthesia plan with the patient and supervise a nurse anesthetist by being physically present or immediately available in the operating suite. The obstetrician testified that he did not supervise the nurse anesthetist and that he understood that the anesthesiologists were immediately available if help was needed.

The Supreme Court of Alabama reached a similar result in a case in which a patient died following the administration of anesthesia by a nurse anesthetist who had not notified his anesthesiologist-employer before administering anesthesia. The question before the court was the potential liability of the hospital for the actions of the nurse anesthetist. The court reasoned that the hospital maintained detailed guidelines and manuals concerning the duties of nurse anesthetists and that the disputed facts concerning the degree of control retained by the hospital over the nurse anesthetist was an issue of fact for the jury to decide.

Specialized Training

- Several courts that have considered the potential vicarious liability of surgeons for the actions of nurse anesthetists have noted the specialized training of nurse anesthetists in ruling that the surgeons were not responsible for the nurse anesthetists' actions. An appellate court in Florida stated that the nurse anesthetist was not under the immediate personal supervision of the surgeon and that she performed her duties independently. The court noted that the nurse anesthetist was certified by the state as a nurse anesthetist and was authorized to practice under a protocol approved by the medical staff. The court concluded that the nurse anesthetist could not be characterized as a mere nurse, and therefore, the surgeon was not responsible for her actions.

A Tennessee court also declined to impose liability on the surgeons when the hospital-employed nurse anesthetist and a student nurse anesthetist administered anesthesia. The court stated that the question was whether the surgeons exercised control over the manner in which the nurse anesthetist acted. The court took note of the hospital protocols that authorized the nurse anesthetist to administer anesthesia to patients in the absence of the anesthesiologist. The court noted that a nurse anesthetist is a highly trained specialist acquiring skills in the course of his or her training that a surgeon does not possess. The surgeons did not select the drugs used to anesthetize the patient or direct the procedures used by the nurse anesthetists. The court concluded that the nurse anesthetist was not the borrowed servant of the surgeons and the surgeons were not liable for the actions of the nurse anesthetist and student nurse anesthetist.

State Law Issues and Points Raised by the Plaintiff

A 1999 decision of the Supreme Court of Kansas illustrates how

state law and the specific allegations asserted by the plaintiff can affect the outcome of the case. The case involved a patient who died following the administration of anesthesia by a nurse anesthetist. Under Kansas law, the defendant obstetrician could not be held vicariously liable for the nurse anesthetist's actions because both of them were covered by the state compensation fund. The plaintiff contended that the obstetrician had been negligent in failing to direct and monitor the nurse anesthetist in the administration of anesthesia. The court found that it was proper to allow the jury as the trier of fact to decide the nature and extent of the obstetrician's duty of direction. Accordingly, the court affirmed the finding that the obstetrician had a duty to direct the administration of anesthesia by the nurse anesthetist. The lower court had based its finding on the nursing statute that provided that a nurse anesthetist functions in an interdependent role as a member of a physician-directed health care team.

Conclusion

- The controlling factor in determining whether a surgeon is to be held accountable for a nurse anesthetist's actions is whether, based on the facts of the case, the surgeon actually exercised control or had the right to exercise control over the nurse anesthetist during the surgical procedure. If not, the surgeon is likely not to be held accountable for the actions of the nurse anesthetist or adverse patient outcomes resulting from the administration of anesthesia. Under this control or right to control test, the scope of practice of the nurse anesthetist under state law is less important. Whatever state law provides, if a hospital requires some level of physician oversight of anesthesia services, or if the surgeon intervenes in the administration of anesthesia, the surgeon may be found liable for a nurse anesthetist's actions.

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May 27, 2014

Via Electronic and U.S. Mail

Mr. Mike MacKinnon
Arizona Association of Nurse Anesthetists
400 E. Meadow Lane
Pinetop, Arizona 85935

Re: CRNA Practice in Surgical Procedures

Dear Mike:

You have asked us to update our memorandum of March 2004 about the proper interpretations of terms in the state statutes and federal Medicare regulations of certified registered nurse anesthetists ("CRNAs") and to briefly discuss the question of surgeon liability when the surgeon directs the CRNA's provision of anesthesia in the OR. This memorandum addresses these questions based on current law and regulation.

In 2012, the Arizona legislature substantially updated the law regarding CRNA practice. It provided more guidance regarding the scope of practice for CRNAs, including the scope of their authorization to administer anesthetics. This new law was passed at least in part in response to a state auditor decision that prior law did not permit CRNAs to administer anesthetics.

There have been no major changes in the scope of practice laws at the federal level. With respect to supervision, the law has not changed. Despite the federal "opt-out" provision, in Arizona, we conclude that CRNAs must practice at the direction of and in the presence of a physician, but not under the supervision of a physician.

1. Arizona Statutory Provision.

The state law addressing the scope of professional practice for CRNAs is A.R.S. § 32-1634.04 ("new statute"), which appears in the Arizona Nurse Practice Act. The new statute provides:

32-1634.04. Certified registered nurse anesthetist; scope of practice

A. A certified registered nurse anesthetist may administer anesthetics under the direction of and in the presence of a physician or surgeon in connection with the preoperative, intraoperative or postoperative care of a patient or as part of a procedure performed by a physician or surgeon in the following settings:

1. A health care institution.
 2. An office of a health care professional who is licensed pursuant to chapter 7, 11, 13 or 17 of this title.
 3. An ambulance.
- B. In connection with the preoperative, intraoperative or postoperative care of a patient or as part of the procedure in the settings prescribed in subsection A of this section, a certified registered nurse anesthetist as part of the care or procedure may:
1. Issue a medication order for drugs or medications to be administered by a licensed, certified or registered health care provider.
 2. Assess the health status of an individual as that status relates to the relative risks associated with anesthetic management of an individual.
 3. Obtain informed consent.
 4. Order and evaluate laboratory and diagnostic test results and perform point of care testing that the certified registered nurse anesthetist is qualified to perform.
 5. Order and evaluate radiographic imaging studies that the certified registered nurse anesthetist is qualified to order and interpret.
 6. Identify, develop, implement and evaluate an anesthetic plan of care for a patient to promote, maintain and restore health.
 7. Take action necessary in response to an emergency situation.
 8. Perform therapeutic procedures that the certified registered nurse anesthetist is qualified to perform.
- C. A certified registered nurse anesthetist's authority to administer anesthetics or to issue a medication order as prescribed by this section does not constitute prescribing authority.

The new statute represents the first major new legal guidance for CRNAs since 1928. *See State v. Borah*, 51 Ariz. 318, 76 P.2d 757 (Ariz. 1938) (state supreme court decided that nurses could administer anesthetics under the direction of dentists).

A. CRNA Practice in the New Statute With Respect to Directing Practitioners.

The new statute continues to allow CRNAs to administer anesthetics “under the direction of and in the presence of a licensed physician or surgeon...” However, the new statute now also specifies permitted procedures, locations and directing practitioners. Specifically:

- Permitted procedures: The CRNA may administer anesthesia “in connection with the preoperative, intraoperative or postoperative care of a patient or as part of a procedure performed by a physician or surgeon” This provision makes clear that CRNAs are not limited to the operating room, but may assist in pre- and post-operative settings as well as in procedures performed in locations other than the operating room.

- Permitted locations: As noted above, a CRNA may perform services as part of a procedure performed by a physician or surgeon, whether or not such procedure takes place in the operating room. Further, the new statute says that:
 - A CRNA may work in a *health care institution, an office of a licensed health care professional* and an *ambulance*. “Health care institution” is a broad term that includes “every place, institution, building or agency, whether organized for profit or not, that provides facilities with medical services, nursing services, health screening services, other health-related services, supervisory care services, personal care services or directed care services and includes home health agencies ... outdoor behavioral health care programs and hospice service agencies.” A.R.S. § 36-401(20).
 - A CRNA practices “in the presence of” a directing practitioner when the directing practitioner is “*within the same room or an adjoining room or within the same surgical or obstetrical suite.*” A.R.S. § 32-1601(17).
- Permitted directing practitioners: The new law specifies that the “health care professionals” who may direct CRNA work are podiatrists, dentists, medical doctors and osteopaths. CRNAs may *not* accept direction from naturopaths, other advanced practice nurses, pharmacists, physician assistants, homeopathic physicians or respiratory therapists.

The new statute does not define the phrase “under the direction of,” and our research has revealed no case law interpreting this term. However, we conclude that under the plain language of the new statute, CRNAs are not required to practice under a physician’s supervision. The legislature could have used the term “supervision” had it intended supervision, but did not. We believe that on its face, the phrase “under the direction of” is a less restrictive standard than “supervision.”

B. CRNA Scope of Practice Under the New Statute.

Notably, the new law provides substantial guidance with respect to a CRNA’s scope of practice even beyond procedure, location and direction. At A.R.S. § 32-1634.04(B), the new statute sets forth a list of permitted CRNA functions in connection with procedures, including the ability (when qualified) to:

- Issue a medication order for drugs or medications to be administered to a patient
- Assess the health status of the patient relating to anesthetic management
- Obtain informed consent
- Order and evaluate lab and diagnostic tests and perform point of service testing
- Order and evaluate imaging studies
- Identify, develop, implement and evaluate an anesthetic plan of care
- Respond to emergencies

- Perform therapeutic procedures.

It is also important to note that CRNAs may not “prescribe” drugs or medications. The new statute makes clear that the authority to order drugs or medications to be administered does not constitute prescribing authority. A.R.S. § 32-1634.04(C).

C. CRNA Qualifications Under the New Statute.

Finally, the new statute specifies the qualifications necessary for a nurse to obtain a certificate from the Arizona Board of Nursing (“Board”) in order to practice as a CRNA. A.R.S. § 32-1634.03. The CRNA must complete an anesthesia program accredited by the Council on Accreditation of Nurse Anesthesia (or another national accrediting body recognized by the Board), must submit an application to the Board and must pay a fee. The new statute authorizes the Board to issue a temporary certificate prior to the submission of an application. Of course, hospitals or other facilities may impose additional qualifications.

2. Medicare Regulations.

As we noted in our 2004 memorandum, current Medicare regulations continue to require “supervision,” with a state “opt out” provision. Specifically:

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) Standard: Organization and staffing. The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by--

- (1) A qualified anesthesiologist;
- (2) A doctor of medicine or osteopathy (other than an anesthesiologist);
- (3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;
- (4) *A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is **under the supervision** of the **operating practitioner** or of an anesthesiologist who is immediately available if needed; or*
- (5) An anesthesiologist’s assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) Standard: Delivery of services. Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies

must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

(c) Standard: State exemption.

(1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

(Emphasis supplied.)

Arizona has not opted out of the Medicare supervision requirement. However, the longtime existence of our state statute (requiring direction and the presence of a directing practitioner) makes this irrelevant. We believe the new statute has the same effect as the opt-out provision in the Medicare regulation. As a result, in Arizona CRNAs operate without physician "supervision" and instead operate "under the direction" of a physician or surgeon.

3. Surgeon Liability.

The use of a CRNA should not affect the liability of the surgeon in the OR suite who is providing the care for which the anesthetic is needed. Under state law, the surgeon would only direct the nurse anesthetist to provide anesthesia – in essence the same direction that the surgeon would provide to a physician anesthesiologist. The state statute does not require the surgeon to "supervise" the provision of the anesthetic. Under this analysis, which we believe is well supported by the statutory language, the surgeon should face the same liability issues whether the anesthesia provider is a CRNA or an anesthesiologist. Indeed, as in 2004, we continue to be unable to find any reported Arizona cases that specifically address surgeon liability for CRNA practice.

Mr. Mike MacKinnon

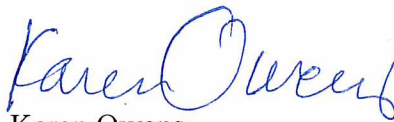
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4. Conclusion.

It does not appear that the state or federal regulatory frameworks impose substantial barriers to the use of CRNAs. Of course, credentialing standards need to be developed and applied, just as they are for other practitioners. Finally, it is important to remember that decisions about which categories of practitioners will practice in hospitals must be unilateral ones made by the hospitals and their boards, to avoid conflict of interest and competitive concerns. Physician input certainly may be welcomed by hospitals in their review of such matters, but ultimately the decision needs to be made by the hospital, not the medical staff.

Sincerely,



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October 20, 2014

Via Electronic and U.S. Mail

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Re: Research into Liability for CRNA Practice

Dear Mike:

As you requested, here are the results of research into court actions and jury verdicts regarding CRNA practice in Arizona. I apologize, once again, for how long this has taken. I think you will find the results interesting.

First, in review of the Arizona jury verdict database in Westlaw, a major collector of such material, we found no cases in which CRNA's have been sued. We did find a 2005 case in which a patient sued the supervising surgeon, the anesthesiologist, and the anesthesia practice that employed the anesthesiologist. The anesthesiologist and his employer admitted negligence by the nursing staff, but we were unable to determine whether "nursing staff" included CRNAs. Ultimately, the jury returned a defense verdict, meaning that the anesthesiologist and "nursing staff" won.

We also found an article on the AANA website regarding liability of surgeons for supervision of CRNAs: The article discussed a research study from 1988 – so quite old – which found that courts were no more likely to hold surgeons accountable in malpractice actions when they worked with CRNAs compared to when they worked with anesthesiologists.
<http://www.aana.com/resources2/professionalpractice/pages/surgeon-liability.aspx>

Another AANA website find was an article by the AANA general counsel on this issue. This article includes tables of reported cases involving CRNAs or anesthesiologists. None of these cases reported in the tables were from Arizona.
<http://www.aana.com/resources2/professionalpractice/Documents/SL%20Another%20Article%20on%20Surgeon's%20Liability.pdf>

We did not find any information within the allotted hours outside AANA publications. However, we did find one article in which your California counterpart responded when the California Medical Association and California Association of Anesthesiologists sued the state for

Mr. Michael McKinnon

October 20, 2014

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opting out of the Medicare CRNA supervision requirement. According to the article, at http://journals.lww.com/ajnonline/Fulltext/2010/05000/Physicians_Want_Supervision_of_Nurse_Anesthetists.7.aspx:

[Yet] the evidence is overwhelming that nurse anesthetists provide expert, high-quality, safe anesthesia care regardless of whether a physician is supervising," said Mitchell H. Tobin, senior director of State Government Affairs at the American Association of Nurse Anesthetists. "Tellingly, there hasn't been a single published report of adverse patient care related to opting out of the requirements in any of the 15 states [including California] that have done so" since November 2001, when the rule allowing state governors to opt out went into effect.

■ It seems to me it is good news that we found very little out there, and nothing, either in the way of jury verdicts or literature, to support the notion that surgeons are at greater risk in working with CRNAs than working with anesthesiologists.

Again, I apologize for taking so long on this project. I wish you the very best in your and your organization's endeavors!

Sincerely,



Karen Owens

Arizona Association of Nurse Anesthetists

CRNA 'Supervision' Requirement in Arizona



The Question of "Supervision":

■ Nurse Anesthetists practicing in Arizona are not required by state law to have physician supervision.

ARS 32-1634.04. states:

A CERTIFIED REGISTERED NURSE ANESTHETIST MAY ADMINISTER ANESTHETICS UNDER THE DIRECTION OF AND IN THE PRESENCE OF A PHYSICIAN OR SURGEON IN CONNECTION WITH THE PREOPERATIVE, INTRAOPERATIVE OR POSTOPERATIVE CARE OF A PATIENT

The legal opinion of Coppersmith, Gordon, Schermer, Owens & Nelson law firm obtained in 2004 and updated in 2014 states that the term "under the direction of" in the statute is not as restrictive as "supervision". Their opinion states:

The key to Arizona law is that CRNAs may administer anesthetics "under the direction of and in the presence of a licensed physician or surgeon..." The statute defines "in the presence of" as meaning that the individual providing direction is in the surgical suite.

The statute does not define the phrase "under the direction of," and our research has revealed no case law interpreting this term. However, the plain language of the statute makes clear that CRNAs are not required to practice under physician supervision. The legislature could have used the term "supervision" had it intended supervision, but did not. We believe that on its face, the phrase "under the direction of" is a less restrictive standard than "supervision"

Beyond this, guidance from the Arizona Board of Nursing makes clear that CRNAs may provide analgesia (such as epidurals for obstetric patients) without physician direction or presence. This is made clear in the AZBON Advisory opinion entitled "ADVISORY OPINION ANALGESIA BY CATHETER TECHNIQUES"

The Question of “Surgeon liability”:

A physician or surgeon is not automatically liable when working with a nurse anesthetist; nor are they immune from liability when working with an anesthesiologist. The legal opinion obtained by the AZANA is clear in this regard:

The use of a CRNA should not affect the liability of the surgeon in the OR suite who is providing the care for which the anesthetic is needed. Under state law, the surgeon would only direct the nurse anesthetist to provide anesthesia – in essence the same direction that the surgeon would provide to a physician anesthesiologist. The state statute does not require the surgeon to “supervise” the provision of the anesthetic. Under this analysis, which we believe is well supported by the statutory language, the surgeon should face the same liability issues whether the anesthesia provider is a CRNA or an anesthesiologist.

While surgeons commonly order nurse anesthetists to give anesthetics, surgeons have no affirmative obligation to control the substantive course of the anesthetic process. To the contrary, a surgeon may rely upon the nurse anesthetist as the anesthesia expert. A nurse anesthetist uses independent judgment in determining the appropriate kind of anesthetic to be administered, as well as types of drugs and dosages. Per ARS32 it is within the scope of practice of a CRNA to create and implement an anesthetic plan. Merely requesting that a nurse anesthetist provide an anesthetic is not in itself an act of "control" that will necessarily make a surgeon liable for a nurse anesthetist's acts.

There are many cases, which stand for the proposition that surgeons or physicians are not automatically liable for CRNA actions. In addition, surgeons or physicians do not escape liability when working with anesthesiologists. As discussed below, courts typically apply the same standard when judging whether surgeons are liable for the acts of an anesthesia provider, regardless of whether the provider is a nurse anesthetist or anesthesiologist.

Courts have held surgeons liable for the negligence of anesthesiologists when the surgeons had control of the anesthesiologists' actions. In *Schneider v. Einstein Med. Ctr.*, 390 A.2d 1271 (Penn. 1978) and *Kitto v. Gilbert*, 570 P.2d 544 (Colo. 1977), the courts found the physicians liable for the negligence of anesthesiologists because the physicians were in control of the anesthesiologists' actions. The question, as in cases of a physician working with nurse anesthetists, is whether the physician was in control of the acts of the anesthesiologist. This is a factual inquiry and not a conclusion of law.

There are many cases in which courts have found that the surgeon was not in control of the nurse anesthetist and, therefore, not liable for the negligence of the nurse anesthetist. E.g., *Cavero v. Franklin Benevolence Soc'y*, 223 P.2d 471 (Cal. 1950); *Fortson v. McNamara*, 508 So.2d 35 (Fla. 1987); *Franklin v. Gupta*, 567 A.2d 524 (Md. 1990); *Hughes v. St. Paul Fire and Marine Ins. Co.*, 401 So.2d

448 (La. 1981); *Kemelyan v. Henderson*, 277 P.2d 372 (Wash. 1954); *Parker v. Vanderbilt*, 767 S.W.2d 412 (Tenn. 1988); *Pierre v. Lavallie Kemp Charity Hosp.*, 515 So.2d 614 (La. 1987); *Thomas v. Raleigh Gen'l Hosp.*, 358 S.E.2d 222 (W. Va. 1987); *Sesselmen v. Mulenberg Hosp.*, 306 A.2d 474 (N.J. 1954).

Moreover, numerous cases hold that mere supervision or direction of a nurse anesthetist is insufficient to hold a physician liable for a nurse anesthetist's negligence. See, e.g., *Sesselmen v. Mulenberg Hosp.*, 306 A.2d 474 (N.J. Super. Ct. App. Div. 1973) (error for trial court to instruct that obstetrical surgeon could be liable for nurse anesthetist's negligence where obstetrician never exercised control over nurse anesthetist and nurse anesthetist merely received obstetrician's instructions concerning the work to be performed); *Baird v. Sickler*, 69 Ohio St.2d 652 (1982); *Foster v. Englewood Hosp.*, 19 Ill. App. 3d. 1055 (1974); *Elizondo v. Tavarez*, 596 S.W.2d 667 (Tex. 1980); *Whitfield v. Whittaker Mem. Hosp.*, 210 (Va. 176 (1969).

It is clear from the case law that in order for a physician to be liable for the acts of the anesthesia administrator, the physician must control the administrator's actions and not merely be supervising or directing the administrator.

In a January 1988 report of the Center for Health Economics Research (CHER), an independent Boston-area based research organization that analyzes and evaluates health-related policy issues, CHER concluded that "both legal doctrine and case history (as reviewed by the AANA and ASA) do not indicate a tendency on the part of the courts to hold surgeons liable more often when they work with nurse anesthetists than with anesthesiologists."

In light of the above, it is erroneous for anyone to state or imply that surgeons are at greater risk when they work with nurse anesthetists rather than anesthesiologists.

Conclusions:

Based on the statute and legal opinion there is no supervision requirement in the state of Arizona for Nurse Anesthetists. There is also no requirement to have an Anesthesiologist when a CRNA is practicing anesthesia in any form. The statute is clear that CRNAs practice anesthesia "under the direction of and in the presence of" the operating practitioner which can be met simply by the operating practitioner ordering "anesthesia by CRNA". There is no requirement for the operating practitioner to sign the CRNAs chart or dictate the anesthetic. It is important to differentiate analgesia from anesthesia (explained above) as there is no requirement for physician direction or presence during analgesia. However regardless of the statute or case law it is important that the CRNA acts within the credentialing and bylaws of the facility which can be more restrictive than current law.

All available case law and the legal opinion on the statute clearly show there is no implied or increased liability of the surgeon for actions of a CRNA. In fact there is no increased liability for the surgeon regardless who performs the anesthesia, CRNA or Anesthesiologist.

Mike MacKinnon MSN CRNA

President AZANA

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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 states¹³ 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 aggre-

gated 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

| Characteristic | Opt-out states | | | Non-opt-out states | | |
|-------------------------|--------------------------|-------------------------|---------------------|--------------------------|--------------------------|----------------------|
| | 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. ^aBase 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

| Anesthesia provider | Mortality | | | Complications | | |
|---------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| | Non-opt-out states | Opt-out states | | Non-opt-out states | Opt-out states | |
| | | Before opting out | After opting out | | 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. ^aOdds 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 de-

scribe 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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Researchers Find No Differences in Care Provided by CRNAs and Anesthesiologists: Cochrane Collaboration

Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review titled “Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients” prepared by The Cochrane Collaboration.

Headquartered in England, the esteemed Cochrane Collaboration is an independent, international network of healthcare practitioners, researchers, patient advocates and others who analyze healthcare research to produce credible, accessible health information. This high-quality, relevant and up-to-date information supports healthcare professionals, legislators/regulators, and patients in making better-informed healthcare choices.

The objective of the anesthesia study (Issue 7 of *The Cochrane Library*, 2014) was to assess the safety and effectiveness of different anesthesia providers for patients undergoing surgical procedures under general, regional or epidural anesthesia. The inquiry was motivated by “an increasing demand for surgery, pressure on healthcare providers to reduce costs, and a predicted shortfall in the number of medically qualified anaesthetists (anesthesiologists),” the report stated.

“We hoped that this may lead to an increase in confidence in the skills of NPAs (nonphysician anesthetists) within the anaesthetic community and may potentially lead to greater flexibility in team roles, both within and between countries, depending on patient need,” the researchers noted in their paper as part of their rationale for “Why it is important to do this review.”

In the United States, Certified Registered Nurse Anesthetists (CRNAs) are the hands-on providers of more than 34 million anesthetics to patients each year. As advanced practice registered nurses, CRNAs attain 7-8 years of education, training, and critical care nursing experience resulting in a master’s or doctoral degree. They deliver anesthesia to patients in the same types of facilities, for the same types of procedures, and using the same techniques and standards of care as physician anesthesiologists.

“The Cochrane Collaboration is revered as one of the most thorough, unbiased research entities in the world,” said Dennis Bless, CRNA, MS, president of the 47,000-member American Association of Nurse Anesthetists (AANA). “Based on the collaboration’s findings, we believe the U.S. healthcare industry and state and federal policymakers can continue to have confidence that greater utilization of CRNAs to the fullest extent of their scope of practice and skills promotes patient access to safe, cost-effective anesthesia care, especially now when it is desperately needed.”

The question explored by the collaboration has been the subject of numerous research studies over the years. More than 8,000 unique research papers were identified for the literature review, with a total of six meeting all of the requirements for inclusion in the final, extensive analysis.

The researchers concluded that, “No definitive statement can be made about the possible superiority of one type of anesthesia care over another.” It was noted that the complexity of perioperative care, the low intrinsic rate of complications related directly to anesthesia, and the limitations of the data used in the non-randomized studies reviewed make it impossible to provide a definitive answer to the review question.

In 2010, an extensive literature review also lead researchers from the Lewin Group to conclude that there are no differences in the safety of CRNAs compared with anesthesiologists. Their findings were published in *Nursing Economic\$* as part of a study titled “Cost Effectiveness Analysis of Anesthesia Providers.”

The Cochrane Collaboration relies on more than 31,000 volunteers in 120 countries to conduct systematic reviews of randomized, controlled trials of healthcare interventions, and occasionally non-randomized studies as well. The collaboration has had an official relationship with the World Health Organization (WHO) since 2011.

Physician Anaesthetists Versus Non-Physician Providers of Anesthesia for Surgical Patients, Lewis SR, Nicholson A, Smith AF, Alderson P. (2014). Cochrane Database of Systematic Reviews 2014, Issue 7. Art. No.: CD010357. DOI: 10.1002/14651858.CD010357.pub2.

Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients (Review)

Lewis SR, Nicholson A, Smith AF, Alderson P



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WILEY

[Intervention Review]

Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients

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ABSTRACT

Background

With increasing demand for surgery, pressure on healthcare providers to reduce costs, and a predicted shortfall in the number of medically qualified anaesthetists it is important to consider whether non-physician anaesthetists (NPAs), who do not have a medical qualification, are able to provide equivalent anaesthetic services to medically qualified anaesthesia providers.

Objectives

To assess the safety and effectiveness of different anaesthetic providers for patients undergoing surgical procedures under general, regional or epidural anaesthesia. We planned to consider results from studies across countries worldwide (including developed and developing countries).

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE and CINAHL on 13 February 2014. Our search terms were relevant to the review question and not limited by study design or outcomes. We also carried out searches of clinical trials registers, forward and backward citation tracking and grey literature searching.

Selection criteria

We considered all randomized controlled trials (RCTs), non-randomized studies (NRS), non-randomized cluster trials and observational study designs which had a comparison group. We included studies which compared an anaesthetic administered by a NPA working independently with an anaesthetic administered by either a physician anaesthetist working independently or by a NPA working in a team supervised or directed by a physician anaesthetist.

Data collection and analysis

Three review authors independently assessed trial quality and extracted data, contacting study authors for additional information where required. In addition to the standard methodological procedures, we based our risk of bias assessment for NRS on the specific NRS risk of bias tool presented at the UK Cochrane Contributors' Meeting in March 2012. We considered case-mix and type of surgical procedure, patient co-morbidity, type of anaesthetic given, and hospital characteristics as possible confounders in the studies, and judged how well the authors had adjusted for these confounders.

Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients (Review)

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Main results

We included six NRS with 1,563,820 participants. Five were large retrospective cohort studies using routinely collected hospital or administrative data from the United States (US). The sixth was a smaller cohort study based on emergency medical care in Haiti. Two were restricted to obstetric patients whilst the others included a range of surgical procedures. It was not possible to combine data as there was a degree of heterogeneity between the included studies.

Two studies failed to find a difference in the risk of death in women undergoing caesarean section when given anaesthesia by NPAs compared with physician anaesthetists, both working independently. One study reported there was no difference in mortality between independently working provider groups. One compared mortality risks between US states that had, or had not, 'opted-out' of federal insurance requirements for physician anaesthetists to supervise or direct NPAs. This study reported a lower mortality risk for NPAs working independently compared with physician anaesthetists working independently in both 'opt-out' and 'non-opt out' states.

One study reported a lower mortality risk for NPAs working independently compared with supervised or directed NPAs. One reported a higher mortality risk for NPAs working independently than in a supervised or directed NPA group but no statistical testing was presented. One reported a lower mortality risk in the NPA group working independently compared with the supervised or directed NPA group in both 'opt-out' and 'non-opt out' states before the 'opt-out' rule was introduced, but a higher mortality risk in 'opt-out' states after the 'opt-out' rule was introduced. One reported only one death and was unable to detect a risk in mortality. One reported that the risk of mortality and failure to rescue was higher for NPAs who were categorized as undirected than for directed NPAs.

Three studies reported the risk of anaesthesia-related complications for NPAs working independently compared to physician anaesthetists working independently. Two failed to find a difference in the risk of complications in women undergoing caesarean section. One failed to find a difference in risk of complications between groups in 'non-opt out' states. This study reported a lower risk of complications for NPAs working independently than for physician anaesthetists working independently in 'opt-out' states before the 'opt-out' rule was introduced, but a higher risk after, although these differences were not tested statistically.

Two studies reported that the risk of complications was generally lower for NPAs working independently than in the NPA supervised or team group but no statistical testing was reported. One reported no evidence of increased risk of postoperative complications in an undirected NPA group versus a directed NPA group.

The risk of bias and assessment of confounders was particularly important for this review. We were concerned about the use of routine data for research and the likely accuracy of such databases to determine the intervention and control groups, thus judging four studies at medium risk of inaccuracy, one at low and one, for which there was insufficient detail, at an unclear risk. Whilst we expected that mortality would have been accurately reported in record systems, we thought reporting may not be as accurate for complications, which relied on the use of codes. Studies were therefore judged as at high risk or an unclear risk of bias for the reporting of complications data. Four of the six studies received funding, which could have influenced the reporting and interpretation of study results. Studies considered confounders of case-mix, co-morbidity and hospital characteristics with varying degrees of detail and again we were concerned about the accuracy of the coding of data in records and the variables considered during assessment. Five of the studies used multivariate logistic regression models to account for these confounders. We judged three as being at low risk, one at medium risk and one at high risk of incomplete adjustment in analysis.

Authors' conclusions

No definitive statement can be made about the possible superiority of one type of anaesthesia care over another. The complexity of perioperative care, the low intrinsic rate of complications relating directly to anaesthesia, and the potential confounding effects within the studies reviewed, all of which were non-randomized, make it impossible to provide a definitive answer to the review question.

PLAIN LANGUAGE SUMMARY

Physician anaesthetists versus nurse anaesthetists for surgical patients

Background

There is an increasing demand for surgery, pressure on healthcare providers to reduce costs, and a predicted shortfall in the number of medically qualified anaesthetists. This review aimed to consider whether anaesthesia can be provided equally effectively and safely by nurse anaesthetists (without medical qualifications) as by medically qualified anaesthetists with specialist training.

Study characteristics

Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients (Review)
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The evidence was current up to 13 February 2013. We found six relevant studies, five of which were large observational studies from the US with a comparison group and with study durations from two to 11 years, and one was a much smaller 12 week study from Haiti. There were over 1.5 million participants in the studies. Information for these studies was taken from American insurance databases (Medicare) and from hospital records. The small study was based on emergency medical care after the 2008 hurricanes in Haiti.

Key results

Most studies stated that there was no difference in the number of people who died when given anaesthetic by either a nurse anaesthetist or a medically qualified anaesthetist. One study stated that there was a lower rate of death for nurse anaesthetists compared to medically qualified anaesthetists. One study stated that the risk of death was lower for nurse anaesthetists compared to those being supervised by an anaesthetist or working within an anaesthetic team, whilst another stated the risk of death was higher compared to a supervised or team approach. Other studies gave varied results. Similarly, there were variations between studies for the rates of complications for patients depending on their anaesthetic provider.

Quality of the evidence

Much of the data came from large databases, which may have contained inaccuracies in reporting. There may also be important differences between patients that might account for variation in study results, for example, whether patients who were more ill were treated by a medically qualified anaesthetist, or whether nurse anaesthetists worked in hospitals that had fewer resources. Several of the studies had allowed for these potential differences in their analysis, however it was unclear to us whether this had been done sufficiently well to allow us to be confident about the results. There was also potential confounding from the funding sources for some of these studies.

Conclusion

As none of the data were of sufficiently high quality and the studies presented inconsistent findings, we concluded that it was not possible to say whether there were any differences in care between medically qualified anaesthetists and nurse anaesthetists from the available evidence.

Quality of Care in Anesthesia

Synopsis of Published Information Comparing
Certified Registered Nurse Anesthetist and
Anesthesiologist Patient Outcomes

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Introduction

Nurse anesthetists have been providing quality anesthesia care in the United States for nearly 150 years. In administering more than 30 million anesthetics annually, CRNAs have compiled an enviable safety record. No studies to date that have addressed anesthesia care outcomes have found that there is a significant difference in patient outcomes based on whether the anesthesia provider is a CRNA or an anesthesiologist.

The practice of anesthesia has become safer in recent years due to improvements in pharmacological agents and the introduction of sophisticated technology. Recent studies have shown a dramatic reduction in anesthesia mortality rate to approximately one per 250,000 anesthetics.

The fact that there is no significant difference regarding the quality of care rendered by anesthesiologists and CRNAs is not surprising. “[A]n understanding of the nature of anesthesia would lead one to expect this. The vast majority of anesthesia-related accidents have nothing to do with the level of education of the provider.” [Blumenreich, GA, Wolf, BL. “Restrictions on CRNAs imposed by physician-controlled insurance companies.” *AANA Journal*. 1986;54:6:538-539, at page 539.]

The most common anesthesia accidents are lack of oxygen supplied to the patient (hypoxia), intubation into the esophagus rather than the trachea, and disconnection of oxygen supply to the patient. All of these accidents result from lack of attention to monitoring the patient, not lack of education. In fact, the Harvard Medical School standards in anesthesia are directed toward monitoring, which reiterates the basic point — most anesthesia incidents relate to lack of attention to monitoring the patient, not lack of education.

As Blumenreich has stated:

Anesthesia seems to be an area where, beyond a certain level, outcome is only minimally affected by medical knowledge but is greatly affected by factors such as attention, concentration, organization and the ability to function as part of a team; factors towards which all professions strive but which no profession may claim a monopoly. *See id.* at page 539.

Section One

Summary of Pertinent Quality of Care Studies and Data

1. Needleman/Minnick OB Anesthesia Study in *Health Services Research*

[Needleman, J, Minnick, AF. “Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes.” *Health Services Research*. November 2008. DOI: 10.1111/j.1475-6773.2008.00919x.]

In the November 2008 online issue of *Health Services Research*, researchers Jack Needleman, PhD, MS, and Ann F. Minnick, PhD, RN, FAAN, published the results of a national study titled “Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes.” Using a geographically broad sample of hospitals in seven states, Needleman/Minnick sought to determine the ability of anesthesia provider models and hospital resources to explain maternal outcome variations. According to the researchers, “Given that almost 4 million U.S. women give birth annually, determining improvement strategies is important (National Center for Health Statistics 2005).” [page 3]

The results of the Needleman/Minnick study revealed that obstetrical (OB) anesthesia is equally safe in hospitals that use only Certified Registered Nurse Anesthetists (CRNAs) or a combination of CRNAs and physician anesthesiologists, compared with hospitals that use only anesthesiologists. These results confirmed the results of a 2007 study using Washington state data that revealed no difference in OB anesthesia complication or mortality rates between hospitals that use only CRNAs compared with hospitals that use only anesthesiologists (Simonson, et al.; see pp. 5-7 in this booklet.)

A. Rationale for Undertaking Study

According to the researchers, high cesarean delivery rates and extensive use of epidural pain relief make anesthesia an important component of obstetrical care. This study was undertaken:

- To identify any systematic differences in outcomes between hospitals using CRNA-only, anesthesiologist-only, and CRNA/anesthesiologist staffing models.
- To determine the ability of anesthesia provider models and hospital resources to explain maternal outcome variations.

B. Background

The study involved more than 1.14 million OB patients from 369 hospitals in seven states, including California, Florida, Kentucky, New York,

Texas, Washington, and Wisconsin. Participating hospitals met the following conditions: reported at least one live birth in the 2002 American Hospital Association Annual Survey, provided at least one year of discharge data to state agencies, and responded to a 2004 survey on organization and resources of obstetrical services. Approximately 10 percent of all births in U.S. hospitals from 1999-2001 occurred in these facilities.

Data was assembled from the information given by the hospitals to their state agencies and from the 2004 survey on obstetric services.

Four outcomes were coded from the discharge data: death, anesthesia complications, nonanesthesia maternal complications, and obstetrical trauma. Hospitals were classified into one of five anesthesia models: anesthesiologist-only; CRNA-only; both anesthesiologists and CRNAs practicing at the hospital, with an anesthesiologist required to be present at the initiation of all planned cesarean sections; both anesthesiologists and CRNAs practicing at the hospital, with an anesthesiologist not required to be present at the initiation of all planned cesarean sections; and hospitals in which the anesthesia model differed between labor/delivery and general operating areas.

Variables such as the organization of OB services and OB anesthesia, patient characteristics, and hospital characteristics were taken into consideration.

The researchers conducted a logistic regression of each outcome measure on a full model that included the anesthesia model, other hospital characteristics, and patient characteristics. In addition, because anesthesia and other complications were more prevalent in patients undergoing cesarean deliveries, a logistic regression was also conducted on a full model for each outcome measure restricted to cesarean patients.

Significant Findings and Patterns. Several important findings and patterns emerged from the Needleman/Minnick study:

- The death rate was very low (0.007 percent), and anesthesia complications occurred in less than 1 percent of the sample.
- The most common anesthesia model was anesthesiologist-only (39 percent); the second-most common was CRNA-only (23 percent).
- Death rates were highest in hospitals with anesthesiologist-only models, although the differences were not statistically significant.
- Anesthesia complication rates were lower in the CRNA-only hospitals (0.23 percent) than in the anesthesiologist-only hospitals (0.27 percent). Rates in the other hospitals varied from 0.24 per-

cent to 0.37 percent, with the differences not being statistically significant from the anesthesiologist-only hospitals.

- Multivariate analysis found no systematic differences between hospitals with anesthesiologist-only models and hospitals with models using CRNAs. There was no consistent pattern associating other hospital or patient characteristics with outcomes.

C. Conclusions

Needleman/Minnick concluded the following:

- Hospitals that use only CRNAs, or a combination of CRNAs and anesthesiologists, do not have systematically poorer maternal outcomes compared with hospitals using anesthesiologist-only models.
- At least in the area of obstetrical services, there may be no gain in anesthesia safety from restricting which licensed providers can provide anesthesia services. The use of CRNAs may make it possible to provide obstetric anesthesia coverage where anesthesiologists are not available because of cost or other factors pertaining to regulation and payment.

2. Simonson OB Anesthesia Study in Nursing Research

[Simonson, DC, Ahern, MM, Hendryx, MS. "Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery." *Nursing Research*. 2007; 56:9-17]

In the January/February 2007 issue of *Nursing Research*, a team of researchers led by Daniel Simonson, CRNA, MHPA, published the results of a retrospective analysis titled "Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery." Using data from the state of Washington, the researchers set out to identify differences in the rates of anesthetic complications for cesarean section in hospitals where the obstetrical (OB) anesthesia was provided solely by CRNAs compared with hospitals where the OB anesthesia was provided solely by anesthesiologists.

The study results showed that there is no difference in complication rates or mortality rates between hospitals that use only CRNAs compared with hospitals that use only anesthesiologists.

A. Rationale for Undertaking Study

According to the researchers, the study was undertaken:

- To determine whether there are any differences between hospitals that employ only CRNAs to perform OB anesthesia and hospitals that employ only anesthesiologists to perform OB anesthesia.
- Because research data is needed to assist hospitals and anes-

thetia groups in making cost-effective staffing choices.

B. Background

For purposes of the study, Washington state hospital admission data for 1993-2004 were obtained from the Comprehensive Abstract and Reporting System database and merged with data from a survey of anesthesia or medical staff at hospitals where OB anesthesia was staffed by CRNAs only and hospitals where OB anesthesia was staffed by anesthesiologists only. A total of 134,806 patient records were analyzed, including those of 33,236 patients who were cared for by CRNAs only and 101,570 who were cared for by anesthesiologists only.

Regression analysis was used to adjust for independent variables such as hospital characteristics (geographic location, size, and teaching status), patient demographics (age, primary payer, and type of admission), and patient comorbidities.

In the study sample, there were 965 OB anesthesia complications and 17 deaths. According to the researchers, 76 percent of the complications were of a less serious nature per the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and only one of the deaths had an ICD-9-CM code associated with an anesthetic complication. The CRNA-only hospitals had a complication rate of 0.58 percent, while the anesthesiologist-only hospitals had a rate of 0.76 percent.

Significant Findings and Patterns. Several important findings and patterns emerged from the Simonson study:

- Hospitals with CRNA-only staffing had a lower rate of anesthetic complications than those with anesthesiologist-only staffing (0.58 percent vs. 0.76 percent, $p = .0006$). However, after regression analysis, this difference was not significant.
- The CRNA-only hospitals had a greater percentage of Medicaid, rural, teaching, urgent admission, and very young (under 17 years old) patients; the anesthesiologist-only hospitals had a greater percentage of emergency admissions and older mothers (over 35 years old).
- A substantially higher percentage of sicker patients were transferred to CRNA-only hospitals, a factor which could, potentially, affect the number of anesthetic complications in a facility. However, this did not prove to be the case.

C. Conclusions

Simonson et al. concluded the following:

- That OB anesthesia complications are no different between the

CRNA-only and anesthesiologist-only staffing models. “As a result, hospitals and anesthesiology groups may safely examine other variables, such as provider availability and costs, when staffing for obstetrical anesthesia.” [page 1]

- That further study is needed to validate the use of ICD-9-CM codes for anesthesia complications as an indicator of quality.

3. Pine Study in the AANA Journal

[Pine, M, Holt, KD, Lou, YB. “Surgical Mortality and Type of Anesthesia Provider.” *AANA Journal*. 2003; 71:109-116.]

In the April 2003 *AANA Journal*, Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate healthcare outcomes, and a team of researchers published the results of a groundbreaking study titled “Surgical Mortality and Type of Anesthesia Provider.” The study analyzed the effect of different types of anesthesia providers — specifically Certified Registered Nurse Anesthetists (CRNAs) and physician anesthesiologists — on the death rates of Medicare patients undergoing surgery.

The results revealed that patients are just as safe receiving their anesthesia care from CRNAs or anesthesiologists working individually, or from CRNAs and anesthesiologists working together.

A. Rationale for Undertaking Study

According to the researchers, the study was undertaken:

- To attempt to answer lingering questions about surgical patients’ safety related to types of anesthesia providers, even though estimates of anesthesia-related deaths today are as low as 1 in 200,000 to 300,000 cases. [*To Err is Human: Building a Safer Health System*. Kohn, LT, Corrigan, JM, Donaldson, MS. Washington, DC: National Academy Press. 1999.]
- To provide state governors with valid scientific data to help them decide whether their respective states should opt out of the federal physician supervision requirement for nurse anesthetists. [*Federal Register*. Vol. 66, No. 219, pp. 56762-56769.] Without such data, governors must rely on older studies (see analyses of Bechtoldt and Forrest studies, pp. 10-13 in this booklet) or seriously flawed studies (see analysis of Silber/Pennsylvania study, pp. 25-32 in this booklet).

B. Background

The researchers studied 404,194 Medicare cases that took place from 1995-1997 in 22 states. Only cases with clear documentation of type of

anesthesia provider were studied, and adjustments were made for differences in case mix, clinical risk factors, hospital characteristics, and geographic location. The types of surgical procedures included carotid endarterectomies, cholecystectomies, herniorrhaphies, mastectomies, hysterectomies, laminectomies, prostatectomies, and knee replacements.

Groundbreaking Results. The Pine study yielded the following important findings:

- *Mortality rates were similar* for CRNAs and anesthesiologists working individually.
- There was *no statistically significant difference* in the mortality rate for CRNAs and anesthesiologists working together versus CRNAs or anesthesiologists working individually.
- There was *no statistically significant difference* in the mortality rate for hospitals *without* anesthesiologists versus hospitals where anesthesiologists provided or directed anesthesia care.

C. Conclusions

Pine et al. concluded the following:

- That while their findings differed from those of Silber et al. (see analysis of Silber/Pennsylvania study, pp. 25-32 in this booklet), they were consistent with earlier research and with current data which estimate that anesthesia-related deaths today are as low as 1 in 200,000 to 300,000 cases. [*To Err is Human: Building a Safer Health System*. Kohn, LT, Corrigan, JM, Donaldson, MS. Washington, DC: National Academy Press. 1999.]
- That based on the surgical procedures included in the study, *inpatient surgical mortality is not affected by whether the anesthesia provider is a CRNA or an anesthesiologist.*

Pine Versus Silber. The Silber/Pennsylvania study (see analysis on pp. 25-32 in this booklet), which was published nearly three years before the Pine study, contained glaring methodological deficiencies that Pine et al. endeavored to avoid. Specifically, approximately two-thirds of the cases which Silber et al. classified as *not involving an anesthesiologist* in the patient care either A) actually *did* have an anesthesiologist involved in some, but not all, of a patient's procedures, or B) *had no bill* for the anesthesia care (making it impossible to confirm whether an anesthesiologist was or was not involved).

Further, cases in which anesthesiologists worked alone were not distinguished from those in which CRNAs and anesthesiologists worked together. Finally, only cases in one state — Pennsylvania — were included in the Silber study.

This failure by Silber et al. to more accurately quantify the cases in which anesthesiologists were involved led the researchers to conclude that there was an increase of 2.5 deaths per 1,000 patients when an anesthesiologist was not involved in the case. This inflated ratio was alarmingly out of sync with the Institute of Medicine's (IOM's) published report that anesthesia mortality rates today are approximately 1 death per 200,000 to 300,000 anesthetics administered, a ratio also routinely cited by the American Society of Anesthesiologists (ASA). [*To Err is Human: Building a Safer Health System*. Kohn, LT, Corrigan, JM, Donaldson, MS. Washington, DC: National Academy Press. 1999.] Had Silber et al. identified a more accurate (i.e., larger) number of cases as involving anesthesiologists, the ratio obviously would have been much different.

Pine et al. sought to avoid the limitations that marred the Silber study by taking the following steps:

- Studying cases from 22 states, instead of just a single state.
- Using only cases that clearly identified the type(s) of anesthesia provider involved in the patient care.
- Distinguishing between care provided by CRNAs and anesthesiologists working together and care provided by anesthesiologists or CRNAs working individually.

The results of the efforts by Pine et al. to attribute anesthesia care to the correct provider(s) was twofold: 1) The researchers attained data that is more consistent with current overall anesthesia-related mortality rates cited by the IOM, the ASA, and the American Association of Nurse Anesthetists, and 2) they found no statistically significant difference in mortality rates when anesthesia is given by a CRNA working individually, an anesthesiologist working individually, or CRNAs and anesthesiologists working together.

Pine Rebuttal to ASA Comments on Pine Study. In May 2003, the "ASA Preliminary Comment on Pine Study" was released. In a gross misinterpretation of the Pine study results, the ASA claimed that Pine et al. found 38 deaths per 10,000 cases in hospitals where anesthesiologists administered or directed all anesthetics, and 45 deaths per 10,000 cases when an anesthesiologist was not involved. From this, ASA suggested that "the Pine study data support what most recent studies have found — that anesthesiologists improve anesthesia outcomes." [ASA Preliminary Comment on Pine Study. Lobbying day handout. May 2003.]

That same month, Dr. Pine wrote "Response to 'ASA Preliminary Comment.'" He stated that for the ASA to suggest that his study's data

supports “the conclusion ‘that anesthesiologists improve anesthesia outcomes’ ” is evidence of “either a woeful ignorance of the basics of data analysis or a cynical contempt for the intelligence of the intended audience.” Defending his study, Dr. Pine wrote that his data actually found 34 deaths per 10,000 cases when CRNAs administered anesthesia while working together with anesthesiologists, and 45 deaths per 10,000 cases *when anesthesiologists worked without a CRNA*. He pointed out that this difference of 11 deaths per 10,000 cases was “even more impressive than the 7 deaths per 10,000 cases” difference cited by the ASA (see paragraph above), and that based on this data, “the AANA could claim that anesthesiologists should not be permitted to administer anesthesia unless a CRNA is present to prevent the excess mortality associated with physicians attempting to engage in the practice of nursing. However, unlike the ASA, the AANA has enough respect for its audience to avoid making such unwarranted claims.”

Dr. Pine reiterated his study’s findings that after risk adjustment there is no statistically significant difference between CRNAs working individually, anesthesiologists working individually, or CRNAs and anesthesiologists working together. He added that his study’s data support the conclusion that even when there are two anesthesia providers working together, substituting an anesthesiologist for a CRNA does nothing to lower the mortality rate. [Pine, M. Response to “ASA Preliminary Comment.” www.aana.com. May 2003.]

4. Bechtoldt Study

[Bechtoldt, Jr, AA. “Committee On Anesthesia Study. Anesthetic-Related Deaths: 1969-1976.” *North Carolina Medical Journal*. 1981;42:253-259.]

A. Background

A 10-member Anesthesia Study Committee (ASC) of the North Carolina Medical Society reviewed approximately 900 perioperative deaths in that state over the eight-year period from 1969 to 1976. The ASC determined that 90 perioperative deaths were, to a certain extent, related to the administration of an anesthetic. The ASC did not study types of anesthesia-related outcomes other than death. Based on an ASC survey of hospitals, the ASC estimated that more than two million anesthetics were administered in North Carolina from 1969 to 1976.

The ASC defined “anesthetic-related” deaths as those in which the ASC determined that anesthesia was found to be a) the sole cause of death or b) the major contributing factor.

In categorizing cases, the ASC used information from death certifi-

cates and questionnaires completed by anesthesia providers of record. Based on that data, the ASC estimated that there had been one anesthetic-related death per 24,000 anesthetics administered.

The ASC used six different criteria to review the cases, including the following:

- type of anesthetic involved
- location where anesthesia was administered within the facility
- type of practitioner(s) involved in anesthesia administration
- surgical procedure or operation
- patient risk classification

B. Comparison of Outcome According to Provider Type

The ASC classified those who had administered anesthesia as follows:

- certified registered nurse anesthetist (CRNA) working alone
- anesthesiologist working alone
- CRNA and anesthesiologist working together
- surgeon or dentist
- unknown (in some of the cases, the type of practitioner administering the anesthetic was not identifiable based upon the information available to the ASC)

Bechtoldt reported that the ASC:

...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for about half of the anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthetics administered. [page 257] [emphasis added]

Bechtoldt stated that the ASC’s study included patients representing all risk categories. The study did not, however, address whether particular types of anesthesia providers (i.e., anesthesiologists or CRNAs) tended to encounter patients having particular risk factors. Because CRNAs working alone provided approximately half of the nearly two million anesthetics administered in the state during the period of the study, it is reasonable to believe CRNAs provided care to patients covering the full spectrum of physical status and anesthetic risk.

5. Forrest Study

[Forrest, WH. “Outcome — The Effect of the Provider.” In: Hirsh, R, Forrest, WH, et al., eds. *Health Care Delivery in Anesthesia*. Philadelphia: George F. Stickley Company. Chapter 15. 1980:137-142.]

Forrest reviewed data that had been collected as part of an intensive hospital study of institutional differences that the Stanford Center for Health Care Research conducted. Forrest analyzed mortality and severe morbidity outcome data from 16 randomly selected hospitals, controlling for case-mix variations. The data concerned 8,593 patients undergoing 15 surgical procedures over a 10-month period (May 1973 through February 1974). Using that data, Forrest compared outcomes based upon type of anesthesia provider.

For study purposes, the hospitals were classified as having either:

1. primarily physician (anesthesiologist) providers (9 hospitals), or
2. primarily nurse anesthetist providers (7 hospitals).

Each of the 8,593 patients were “weighted” to reflect the progression or stage of disease at the time of surgery, and “the probability of developing postoperative morbidity and mortality, given the stage of the patient’s disease.” Forrest initially compared actual patient outcome to the outcome that would have been predicted based upon the patient’s preoperative health status and the surgery performed. Compared with outcomes predicted, the actual results showed no significant difference in outcome between facilities having primarily nurse anesthetists or those having primarily physician anesthesiologists.

Forrest then looked at the data using three scales that differed based on definitions of “morbidity” applied to each scale. Slight differences between the two groups (i.e., primarily nurse anesthetist, or primarily anesthesiologist) were found, but the favored group varied according to the analysis criteria employed. That is, depending on criteria, sometimes the anesthesiologist-dominated group showed better outcomes, and sometimes the nurse anesthetist-dominated group fared better. After applying statistical tests to the results, Forrest stated:

Thus, using conservative statistical methods, we concluded that there were no significant differences in outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures. [page 141] [emphasis added]

The Forrest study was presented at a 1977 symposium sponsored by the Association of University Anesthetists; the symposium dealt with the broader subject of “Epidemiology and Demography of Anesthesia.” Official comments concluding this anesthesiologist-dominated proceeding (Chapter 25 of *Health Care Delivery in Anesthesia*, cited above) showed that the findings of Dr. Forrest, as well as others researching provider aspects of outcomes, caught some of the symposium

participants off guard. As one commenter stated:

It was surprising that the stage of training of the anesthesiologist or administration of an anesthetic by a nurse anesthetist or anesthesiologist seemed to affect risk very little. . . . [page 220]

Still another physician commenter, who was chair of a university-based anesthesia department, articulated a reaction possibly shared by many of his colleagues in academia:

Dr. Forrest’s very carefully done study showed no difference in outcome whether the provider was a nurse anesthetist or an anesthesiologist. . . . If we had to accept the data that there are no differences in outcome between anesthetics administered by anesthesiologists compared to nurse anesthetists, the consequences would be truly extraordinary. It would mean that we would have to question our very careers; we would have to question the value of anesthesia residency training programs; we would have to question organization in hospitals; we would have to question and reexamine projections for manpower needs in the future; we would have to question medical economics as they are projected right now. With some of the data presented to us [during the full symposium] we were very comfortable because they matched expectations. . . . Now in the study comparing nurse anesthetists and anesthesiologists, we do not have this comfort. [pages 223-224]

6. Minnesota Department of Health Study

In 1994, the Minnesota Department of Health (DOH), as mandated by the state Legislature, studied the provision of anesthesia services by CRNAs and anesthesiologists. The department reached four conclusions, including the following:

There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider. [page 23, DOH study.] [emphasis added]

7. Centers for Disease Control

In 1990, the federal Centers for Disease Control (CDC) considered undertaking a multimillion-dollar study regarding anesthesia outcomes. Following a review of anesthesia data from a pilot study issued by the CDC and the Battelle Human Affairs Research Centers, however, the CDC concluded that morbidity and mortality in anesthesia was too low to warrant a broader study. The pilot study, published on December 1, 1988, was titled, “Investigation Of Mortality and Severe Morbidity Associated With Anesthesia: Pilot Study.” The pilot study stated that:

To obtain regional estimates of rates of mortality and severe morbidity totally associated with anesthesia with a precision of about 35% a nationwide study consisting of 290 hospitals should be selected. This size study would cost approximately 15 million dollars spread over a 5-year period.

8. National Academy of Sciences Study

This study was mandated by the U.S. Congress and performed by the National Academy of Sciences, National Research Council. The report to Congress stated: "There was no association of complications of anesthesia with the qualifications of the anesthetist or with the type of anesthesia." [House Committee Print No. 36, Health Care for American Veterans, page 156, dated June 7, 1977.]

9. Nurse Anesthetist Professional Liability Premiums

Based on a comparison of 1988 data from St. Paul Fire and Marine Insurance Company, at the time the country's largest provider of liability insurance for CRNAs (but no longer providing liability coverage for healthcare professionals), and 2004 data from CNA Insurance Company, currently the largest insurer of CRNAs, insurance premiums for nurse anesthetists have decreased nationally a total of 39 percent in that time span. (This pertains to claims-made coverage, typically for self-employed CRNAs.) The premium drop is detailed in the appendix titled, "Nurse Anesthetist Professional Liability Premiums: Premium Changes from 1988 to 2004," found at the back of this booklet. The appendix details premium information for CRNAs, both on a state-by-state basis and nationally.

The decrease in CRNA malpractice insurance premium rates demonstrates the superb anesthesia care that CRNAs provide. The rate drop is particularly impressive considering inflation, an increasingly combative legal system, and generally higher jury awards.

Section Two

Anesthesiologist Distortions Concerning Quality of Care

The following section discusses articles (by Abenstein and Warner; Silber et al.; Wiklund and Rosenbaum; and Vila et al.) that anesthesiologists have primarily cited to support their view that CRNAs should be anesthesiologist supervised, and that utilization of anesthesiologists improves anesthesia outcomes. As the following will demonstrate, however, none of the articles cites any credible scientific evidence that validates the anesthesiologists' position. In fact, two of the four articles do not even discuss the role of CRNAs in anesthesia care.

1. Abenstein and Warner Article in *Anesthesia & Analgesia*

[Abenstein, JP, Warner, MA. "Anesthesia providers, patient outcomes and costs." *Anesthesia & Analgesia*. 1996;82:1273-1283.]

A. *Abenstein and Warner Distortions Concerning Minnesota Department of Health Study*

The Minnesota Department of Health (DOH) study discussed earlier led to development of the Abenstein and Warner article. In its 1994 study of the provision of anesthesia services by CRNAs and anesthesiologists, the DOH reached four "key findings,"¹ including the following:

There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient

¹ "Limitations on the study made it impossible to fully evaluate the cost of service provided under each type of employment arrangement. However, there are some findings worth noting. Anesthesia providers are paid equivalent amounts per case under Medicare, and will likely under Medicaid, as well, when new guidelines are implemented. Reimbursement is declining to all anesthesia providers for federally funded programs and other third party payers are also beginning to negotiate lower reimbursement rates."

"There are no studies, either national in scope or Minnesota-specific, which conclusively show a difference in patient outcomes based on type of anesthesia provider."

"National and state health care reform are effecting [sic] the entire health care market in Minnesota. Although this study is the result of concerns over the changing market for anesthesia services, the primary forces driving these changes are effecting [sic] all of health care. For more than a decade, rising health care costs have been a major concern for state and federal programs. As both Medicare, and later Medicaid, began to review their payment methodologies to reduce costs, payers and providers were prompted to seek new ways to control costs and, at the same time, maintain or improve the quality of services. Reduced payments by payers have brought about greater competition in many areas, including anesthesia services, and a growth in managed care concepts (i.e., negotiated fees, the formation of provider networks). This has been particularly true in Minnesota."

"As a result of the reduced reimbursement to anesthesia providers and the increased focus on cost containment, Minnesota hospitals have had to examine their budgets and attempt to cut costs. Hospitals began to look for new service delivery models that would encourage the cooperation of providers in their delivery of services, maintain high quality, and be cost effective. Consequently, several hospitals made the decision to terminate their CRNAs from their hospital staff and to contract for services. The providers are thus responsible for the billing and overhead costs, not the hospital, and for providing quality service to the patient. This decision, based on economics and the changing market, provide cost savings to these hospitals. The impact of health care market dynamics will continue as the market demands shift and develop both locally and nationally."

"In summary, anesthesia services continue to be provided primarily in a 'care team' approach using both anesthesiologists and CRNAs, with current risk levels remaining very low. The market and demand for both CRNAs and anesthesiologists is changing and we can expect continued flux in this market for several years." [pages 23-24 of the Minnesota DOH study]

outcomes based on type of anesthesia provider. [page 23, DOH study] [emphasis added]

The Minnesota Society of Anesthesiologists (MSA) had urged the DOH to reach different conclusions, and the department refused to do so. Disappointed that their views about quality weren't reflected in the department's report, anesthesiologists decided to seek a different forum to air their opinions. Two Minnesota anesthesiologists — doctors Abenstein and Warner — essentially repackaged the MSA's report that the MSA had submitted to the DOH, and published it as an article in June 1996 in *Anesthesia and Analgesia*. Abenstein and Warner acknowledge in their article that it "is an abridged version of a document submitted by the Minnesota Society of Anesthesiologists to the Minnesota Commissioner of Health." [page 1273]

The Abenstein and Warner article purported to analyze quality of care in anesthesia, quoted the Minnesota Department of Health report at length at the end of the article, but failed to mention the key conclusion about quality quoted above. It is clear that Abenstein and Warner failed to mention the conclusion because it did not fit their thesis that CRNAs should be anesthesiologist supervised.

As Christine Zambricki states in an article from the October 1996 *AANA Journal*:

We are curious as to how the authors' [Abenstein and Warner] omission of three of the [Minnesota DOH's] four concluding findings could be overlooked in *Anesthesia and Analgesia's* extensive peer and editorial review. This is especially surprising because the finding that directly contradicts Abenstein and Warner's principal thesis was considered crucial enough to the report to be restated in the report's executive summary. If, as the Minnesota Department of Health's report contends, there are no studies that 'conclusively show a difference in patient outcomes based on type of anesthesia provider,' it becomes difficult, if not impossible, to support the authors' thesis that an increase in the number of practicing anesthesiologists is the primary reason for the decrease in anesthesia-related mortality.

[Zambricki, CS. "Anesthesia providers, patient outcomes, and costs": the AANA responds to the Abenstein and Warner article in the June 1996 *Anesthesia and Analgesia*." *AANA Journal*. 1996;64:413-416, at page 415.]

The Abenstein and Warner article is a partisan advocacy piece — it is not a credible scientific evaluation. Remarkably, despite his subsequent decision to publish the Abenstein and Warner article, the editor of *Anesthesia and Analgesia* (Dr. Ronald Miller), stated that:

There were many reasons not to publish this paper. First, as recognized by Abenstein and Warner, '[it] lacks the scientific credibility of a review or original article and is related to policy making more than science'...Abenstein and Warner often are not only subjective, but clearly biased toward one method of anesthesia care delivery.... [Miller, Ronald D., "Perspective from the Editor-in-Chief: Anesthesia Providers, Patient Outcomes, and Costs." *Anesthesia and Analgesia*. June 1996, 82:1117-18.]

B. Abenstein and Warner Distortions Relating to Increased Number of Anesthesiologists and Anesthesia Safety

Abenstein and Warner conclude that improved patient outcomes associated with the administration of anesthetic agents have resulted almost exclusively from the growth of the number of practicing anesthesiologists. In contrast, as noted above, the Minnesota Department of Health concluded that studies to date do not show a difference in patient outcome based on whether the anesthesia provider is an anesthesiologist or CRNA, rejecting the position argued by Abenstein and Warner.

Gross variations between observed reductions in anesthesia-related mortality compiled by Abenstein and Warner and the growth in membership reported by the American Society of Anesthesiologists suggests that there is little, if any, correlation between the reduction in mortality and an increase in anesthesiologists. Increases in the numbers of practicing nurse anesthetists show the same long-term growth as anesthesiologists, and variations in the rate of growth of CRNAs seem to coincide with the variations in the decline of mortality compiled by Abenstein and Warner.

The exponential decline in anesthesia-related mortality has resulted from the almost complete elimination of administrators lacking anesthesia education; improvements in technology and anesthetic agents; a marked increase in the proportion of patients who received anesthesia care from highly educated anesthesia specialists, including anesthesiologists and CRNAs; and an increased understanding of the causes of adverse events associated with anesthesia.

In two different letters to the editor of *Anesthesia & Analgesia*, physicians elaborated on the flaws in Abenstein and Warner's analysis:

1. "It is interesting that there exist no data within the last 20 years concerning patient outcome as a function of anesthesia provider. Much has changed in anesthetic practice in 20 years, not only from the standpoint of medical and technical factors, but also in terms of the distribution of providers, the types of patients and surgeries encountered by these providers, and the organizational nature of

these practices. . . . In summary, although the data, information, and analyses provided by the authors are interesting and provocative, I strongly disagree with their nearly unqualified statement that 'the anesthesia care team and hybrid practices appear to be the safest methods of delivering anesthesia care. This safety may be due, in part, to the rapid availability of physicians, especially during medical crises.' The question of how best to organize anesthesia care (or any other type of medical care) for achieving maximum patient safety has not yet been thoroughly examined. It is inappropriate to make claims such as those made by the authors based on such a paucity of data and analysis." [David M. Gaba, MD, Department of Anesthesia, Stanford University School of Medicine, Veterans Affairs Palo Alto Health Care System, Palo Alto, California; *Anesthesia & Analgesia*. December 1996, 82:1347-1348, Letters to the Editor.]

2. "...I question the validity of the conclusion reached by the authors [Abenstein and Warner] regarding the anesthesia care team in which they state, 'When the data are critically examined, the evidence is very supportive that the anesthesiologist-led anesthesia care team is the safest and most cost effective method of delivering anesthesia care. At this time, public policy decisions should encourage the development of anesthesia care teams where none exist, particularly in the rural areas, and assure the continued utilization of this patient care model'. . . .Unchallenged acceptance of the conclusion that evidence supports a specific method of anesthesia care delivery to be the 'safest and most cost effective' is misleading to patients, colleagues, and those responsible for shaping health care delivery policy. . . . the participation of certified registered nurse anesthetists (CRNAs) in delivery of anesthesia care would have ceased many years ago if there was evidence that this participation resulted in a less favorable outcome compared with anesthesia personally administered by an anesthesiologist." [Robert K. Stoelting, MD, Department of Anesthesia, Indiana University School of Medicine, Indianapolis; *Anesthesia & Analgesia*. December 1996, 82:1347, Letters to the Editor.]

C. *Abenstein and Warner Distortions Relating to the Bechtoldt and Forrest Studies*

The report submitted to the Minnesota Department of Health by the Minnesota Society of Anesthesiologists, and the Abenstein and Warner article, rewrote the findings of the Bechtoldt and Forrest studies that we summarized previously. Abenstein and Warner claim that the studies show that there were differences in the outcomes of care based on

type of provider, ***notwithstanding that the actual researchers came to the opposite conclusion.***

The Minnesota Department of Health report, in addressing the Bechtoldt study, stated:

Observed differences [in the incidence of anesthetic-related deaths] suggest that anesthesiologists and the CRNA-anesthesiologist care team were somewhat associated with lower rates of anesthesia-related deaths than CRNA's [sic] working alone. However, given the absence of controls, the findings cannot be used to determine (1) whether the differences are greater than would be expected by chance, or (2) the extent that the type of anesthesia provider is responsible for the differences versus other factors. The author concluded that the incidence of patient death among these groups is 'rather similar.' [page 12, Minnesota DOH study]

Concerning the Forrest study, the Minnesota Department of Health stated:

Outcomes considered were deaths, complications, and intermediate outcomes. Ratios of the actual number of adverse outcomes (or deaths, morbidity, or weighted outcome scales) to the number predicted from selected patient and hospital characteristics (i.e., indirectly standardized outcomes ratios) for the two groups were compared and tested. The study concluded that, although there were some unadjusted outcome differences between the two groups, after controlling for patient and hospitals characteristics, there were no statistically significant differences in outcomes between the two groups of hospitals defined on the basis of primary type of anesthesia provider. [page 11, Minnesota DOH study]

A December 1996 *AANA Journal* article by Denise Martin-Sheridan and Paul Wing, as well as the Zambricki article cited earlier, details the Abenstein and Warner article's numerous distortions and errors. Martin-Sheridan and Wing conclude that:

In general, the authors [Abenstein and Warner] reconfigure statistics and findings in the literature concerning outcomes of anesthesia care based on provider. If the best available research studies did not support their position, we feel it was inappropriate and misleading to reconfigure data upon which recommendations for policy decisions were made.

[Martin-Sheridan, D, Wing, P. "Anesthesia providers, patient outcomes, and costs: a critique." *AANA Journal*. 1996; 64(6):528-534, at page 533.]

2. Silber Study in *Medical Care*

[Silber, JH, Williams, SV, Krakauer, H, Schwartz, JS. "Hospital and Patient Characteristics Associated With Death After Surgery. A Study of Adverse Occurrence and Failure to Rescue." *Medical Care*. 1992;30:615.]

The Silber study examined the death rate, adverse occurrence rate, and failure rate of 5,972 Medicare patients undergoing two fairly low-risk procedures —elective cholecystectomy and transurethral prostatectomy. The study did not discuss any anesthesia provider except physician anesthesiologists; the study did not even mention CRNAs. The study, therefore, had nothing to do with CRNAs and did not compare the outcomes of care of nurse anesthetists to those of anesthesiologists. The study did not address any aspect of CRNA practice; it certainly did not explore the issue of whether CRNAs should be physician supervised.

The Silber study was a pilot study, i.e., a study to demonstrate the feasibility of performing a more definitive study concerning patients developing medical complications following surgery. It would be inappropriate to formulate public policy based on the Silber study; the study does not address CRNAs, and cannot be considered conclusive even about the issues that it does address. The Silber study states, at page 625:

This pilot project examined ideas that, to our knowledge, have not been examined previously, and more work is needed before the full significance of the results can be determined. It is especially appropriate, therefore, that the limitations of the project be recognized.

At most, the study's conclusions support the proposition that certain facilities would benefit from having a board-certified anesthesiologist in the Intensive Care Unit. This might result in the "rescue" of some patients who have undergone elective cholecystectomies and transurethral prostatectomies and developed life-threatening postoperative complications. The Silber study's conclusions have nothing to do with nurse anesthetists or the nature of who may supervise, direct, or collaborate with nurse anesthetists. At most, the study concluded that anesthesiologists may play a clinically valuable role in caring for postoperative complications. The study, however, did not involve examination of the outcomes of anesthesia in the operating room.

In his analysis of the Silber study, Dr. Michael Pine (physician and expert in quality and health care) stated that:

Thus, the presence of board-certified anesthesiologists does

not appear to lower the rate of complications, either alone or in combination with other factors such as high technology. It is not anesthesia care but the failure to rescue patients once complications occur which contributes to the death rate. On the other hand, unmeasured factors such as a higher percentage of other board-certified physicians in the hospital, also may account for the better outcomes. The conclusion to be drawn from this study is that, although the presence of board-certified anesthesiologists may not make a difference in the operating room, it may make a difference in the failure to rescue patients from death or adverse occurrences after postoperative complications have arisen. This conclusion is in keeping with the expanded role that anesthesiologists have identified for themselves in post-operative care....

Dr. Pine went on to conclude, in pertinent part, regarding the Silber study that:

1. This study encompassed the entire period of operative and postoperative care and was not specific to anesthesia staffing.
2. The rate of deaths possibly attributable to anesthesia care is a negligible fraction of the death rate found in this study.
3. The factors that significantly affect mortality and are most amenable to clinical interventions arise during postoperative management, not during the administration of anesthesia.
4. The type of anesthesia provider does not appear to be a significant factor in the occurrence of potentially lethal complications. If anything, this study suggests that surgical skill is more important.
5. The presence of board-certified specialists does appear to make an important difference in post-surgical care."

Pennsylvania anesthesiologists have unsuccessfully attempted to use the Silber study as a justification for a restrictive regulation they have urged the state's board of medicine to adopt. While the board proposed the regulation, it has not adopted it. Reportedly, the board decided at a March 1998 meeting to withdraw the proposal. The proposed regulation would have required physicians who delegate duties to CRNAs to have qualifications that only anesthesiologists typically possess. The practical effect would have been to require CRNAs to be anesthesiologist supervised in every practice setting.

Significantly, the Independent Regulatory Review Commission (IRRC), a Pennsylvania oversight commission that reviews health care pro-

posals, carefully evaluated the Silber study, and issued a report rejecting the study as any basis for requiring anesthesiologist supervision of CRNAs. The IRRRC stated that:

Based on our review of the 1992 *Medical Care* article, we have concluded, as its authors clearly state, it is a preliminary study and that caution should be taken in making any definitive conclusions. More importantly, the authors did not consider the scenario of an operating physician delegating the administration of anesthesia to a CRNA, or what expertise the operating physician should have in order to safely delegate anesthesia to a CRNA. Therefore, we do not believe this study should be used as justification for the significant change in practice for the administration of anesthesia.

The IRRRC further stated that:

There have been two studies, both completed over 20 years ago, that compared the outcomes of anesthesia services provided by a nurse anesthetist and an anesthesiologist. Neither of these studies concluded that there was any statistically significant difference in outcomes between the two providers. This conclusion was also reached by the Minnesota Department of Health, which recently completed a study on the provision of anesthesia services. In fact, most studies on anesthesia care have shown that adverse outcomes and deaths resulting from anesthesia has decreased significantly in the last several decades as [a] result of improved drugs and monitoring technology.

3. *New England Journal of Medicine* Articles (by Wiklund and Rosenbaum)

[Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part one). *New England Journal of Medicine*. 1997;337(16):1132-1141. Wiklund, RA, Rosenbaum, SH. "Medical Progress: Anesthesiology" (part two). *New England Journal of Medicine*. 1997;337(17):1215-1219.]

These articles attempt to summarize key developments in the broad field of anesthesiology during the past 30 years. The articles focus on "preparation of patients for surgery, recent developments in anesthetic agents and techniques, multimodal pain management, and postoperative complications related to anesthesia."

The articles, however, do not attempt to compare patient outcomes by type of anesthesia provider. In fact, the articles do not discuss the

involvement or contributions of CRNAs. The articles, therefore, have no relevance to the issue of CRNA versus anesthesiologist quality, and certainly have no bearing on the question of whether CRNAs should be physician supervised.

The articles have some merit as an overview of anesthesiology developments during the past 30 years. For example, the authors discuss advances in applied research that have led to new technology, products, and techniques. In certain areas, however, the authors leave the path of an unbiased review of the specialty to make unsubstantiated or misleading comments about the unilateral contributions of anesthesiologists to the advancements achieved.

For example, part one of the article states in its opening paragraph that anesthesia-related deaths have decreased dramatically since the late 1960s, coinciding with a decision by the National Institutes of Health to "support training in clinical anesthesiology." While it makes logical sense that proper training should enhance outcomes in all disciplines, the reader is left to assume that it was this seminal event – physician training in anesthesiology – which has led directly to the decreased mortality rates mentioned.

In fact, many factors, some of which are discussed in the articles, have influenced the trend to improved anesthesia-related outcomes. The articles make little attempt to provide statistical support regarding the causes of outcome trends and do not compare outcomes based upon type of anesthesia provider, type of case, surgical setting, or patient physical status.

The authors make the blanket statement that:

Increasingly, anesthesiologists direct the preoperative assessment and preparation of patients for surgery with the aim of ensuring safe and efficient care while controlling costs by reducing unnecessary testing and preventable cancellations on the day of surgery. [page 1132]

While the value of preoperative patient assessment is indisputable, the authors reference only one article to substantiate their claim that anesthesiologist management of this process is particularly beneficial. In that case study [Fischer, SP. "Development and Effectiveness of an Anesthesia Preoperative Evaluation Clinic in a Teaching Hospital." *Anesthesiology*. 1996;85(1):196-206], cost-savings are reported through the use of an organized preoperative assessment clinic staffed by anesthesiologists and nurse practitioners, a service not previously available at this large, university-based medical center. Consequently,

both nurses and physicians contributed to the clinic's cost effectiveness. Any inferences to be drawn from the Fischer article are limited, because the article is based on a case study of a single anesthesia preoperative evaluation clinic. Moreover, the Fischer study did not compare CRNA preoperative evaluation effectiveness with that of anesthesiologists.

The Fischer article points out the benefits of developing protocols for reasonable preoperative testing and evaluation, but breaks no new ground in this area. If anything, the findings indicate that cost effective care in the preoperative period results from multidisciplinary guideline development and acceptance, as opposed to guidelines developed and managed solely by anesthesiologists.

Wiklund and Rosenbaum fail to support their premise that anesthesiologists, as a group, are "increasingly" staffing preoperative clinics and developing their own standardized protocols for assessing patients. In fact, their analysis of the Fischer article suggests there is a trend toward protocols developed by various specialties that can be utilized by all providers caring for the patient in the preoperative period.

Examples referenced in the article include guidelines jointly developed by the American College of Cardiology and the American Heart Association regarding the preoperative cardiovascular evaluation of patients undergoing noncardiac surgery. According to the authors, these guidelines have actually replaced those previously developed and standardized by anesthesiologists.

Further misleading editorial comments appear in part two of the article. Addressing the subject of new techniques of patient monitoring, the authors state:

Prompted by the Harvard Medical School report on standards of monitoring during anesthesia, the American Society of Anesthesiologists has become a leader in the adoption of standards of care and guidelines for practice. As a result, pulse oximetry and capnography (the analysis of carbon dioxide in exhaled air) are now used routinely to monitor general anesthesia in virtually all surgical patients in the United States. [page 1217]

Once again, the authors blend legitimate technological advancement with credit to a single professional group. In fact, the Harvard monitoring standards referenced here were first adopted and promoted by the American Association of Nurse Anesthetists. While it is true that the American Society of Anesthesiologists has since endorsed the standards as well, it is absurd to claim that oximetry and capnography have

become anesthesia standards of care solely "as a result" of the ASA's endorsement.

4. Silber Study in *Anesthesiology*

[Silber, JH, Kennedy, SK, Even-Shoshan, O, Chen, W, Koziol, LF, Showan, AM, Longnecker, DE. "Anesthesiologist Direction and Patient Outcomes." *Anesthesiology*. 2000; 93:152-63.]

In September 1998, anesthesiologists began publicizing a scientific abstract titled "Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?" The abstract was published in *Anesthesiology* [1998; 89:A1184], the journal of the American Society of Anesthesiologists (ASA), and reported the findings of a study, conducted in Pennsylvania, which compared the outcomes of surgical patients whose anesthesia was directed by anesthesiologists with patients whose anesthesia was directed by other physicians, such as surgeons. The study came to be known as the "Pennsylvania study."

Nearly two years later, the Pennsylvania study was published in the July 2000 issue of *Anesthesiology* with the title, "Anesthesiologist Direction and Patient Outcomes." Reportedly, both the *Journal of the American Medical Association* and the *New England Journal of Medicine* declined to publish the Pennsylvania study, forcing the ASA to publish the study in its own journal if it wanted the study to be published at all. Given the ASA's political agenda and the composition of *Anesthesiology's* editorial board, which is exclusively comprised of more than 40 anesthesiologists, serious questions of objectivity can be raised.

Then, on January 18, 2001, the Health Care Financing Administration (HCFA, which became the Centers for Medicare & Medicaid Services, or CMS, in June 2001) published a 14-page anesthesia rule in the *Federal Register* [Vol. 66, No. 12, pp. 4674-87] that affirmed, in no uncertain terms, AANA's contention that the Pennsylvania study is not relevant to the issue of physician supervision of nurse anesthetists. (The January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions. The January 18 rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue, however, have in no way been repudiated by CMS and still remain part of the public record.)

On its surface, the study suggests that patient outcomes are better when nurse anesthetists are directed by anesthesiologists. However, a

closer examination clearly reveals that the study

- is not about anesthesia care provided by nurse anesthetists
- actually examines post-operative physician care.

A. Background

The study was conducted using data obtained from Health Care Financing Administration (HCFA) claims records. The study group consisted of 217,440 Medicare patients distributed across 245 hospitals in Pennsylvania who underwent general surgical or orthopedic procedures between 1991-94. Dr. Silber headed a research team that included three anesthesiologists.

B. Study Does Not “Compare Anesthesiologists Versus Nurse Anesthetists”

According to Dr. Longnecker, one of the anesthesiologist researchers: “The study ... does not explore the role of (nurse anesthetists) in anesthesia practice, nor does it compare anesthesiologists versus nurse anesthetists. Rather, it explores whether anesthesiologists provide value to the delivery of anesthesia care.” [Source: Memorandum from Dr. Longnecker to Certified Registered Nurse Anesthetists in University of Pennsylvania Health System’s Department of Anesthesia, October 5, 1998.]

Why, then, was such a misleading title (“Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?”) chosen for the abstract? The answer: *for political reasons*. Consider these facts:

- The abstract was published in the midst of the controversy between anesthesiologists and nurse anesthetists over HCFA’s proposal to remove the physician supervision requirement for nurse anesthetists in Medicare cases.
- The study was funded in part by a grant from the American Board of Anesthesiology, which is affiliated with the ASA. ASA vehemently opposes HCFA’s proposal.

Why was the name of the abstract changed prior to publication of the paper in the July 2000 issue of *Anesthesiology*? Most likely for the following reasons:

- As Dr. Longnecker stated in his memorandum, the study was not intended to examine the question posed by the abstract’s title.
- The study clearly could not and did not answer the question posed by the abstract’s title.
- Pressure from AANA in the form of statements to the media and commentary published on the Internet forced the researchers and ASA to rename the paper for publication.

C. Problems with the Data

Careful examination of the “findings” reported in the paper reveal numerous problems.

Glaring Admissions. In the next to last paragraph of the paper, the researchers conclude that, “Future work will also be needed to determine whether the mortality differences in this report were caused by differences in the quality of direction among providers, the presence or absence of direction itself, or a combination of these effects.” Boiled down, *this clearly is an admission by the researchers that the study does not, in fact, prove anything about the effect—positive or negative—of anesthesiologist involvement in a patient’s overall care, let alone the patient’s anesthesia care!*

This statement appears in a section titled “Discussion,” which is devoted primarily to explaining away the limitations of the billing data used (HCFA’s claims records comprise a retrospective database intended for billing purposes, not quality measurement) and the myriad adjustments for variables which the data required the researchers to make. According to the researchers, among other adjustments were those made for severity of illness and the effect of hospital characteristics.

The researchers, however, admit the following:

- “The accuracy of our definitions for anesthesiologist direction (or no direction) is only as reliable as the bills (or lack of bills) submitted by the caregivers.”
- “We cannot rule out the possibility that unobserved factors leading to undirected cases were associated with poor hospital support for the undirected anesthetist and patient.”
- “...if anesthesiologists had a tendency not to submit bills for patients who died within 30 days of admission, our results could be skewed in favor of directed cases.”

These admissions by the researchers seriously limit the application of the data. They are also proof that ASA’s use of data from this study, in advertising campaigns and lobbying efforts to discredit nurse anesthetists and frighten seniors, has been opportunistic, misleading, and ethically reprehensible at best.

Time Frame. Nurse anesthetists do not diagnose or treat nonanesthesia postoperative complications—they administer anesthesia. According to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), anesthesia mishaps usually occur *within 48 hours of surgery*. The study, however, evaluated death, complication,

and failure to rescue rates *within 30 days of admission*, encompassing not only the time period of the actual surgical procedures, but also a substantial period of postoperative care as well. Therefore, it is impossible to know from the data how many or what percentages of deaths, complications, and failures to rescue occurred within that 48-hour window and were directly attributable to anesthesia care. However, if one considered the study's sample size (217,440) in relation to the widely accepted anesthesia mortality rate of one death in approximately 240,000 anesthetics given, which is recognized by ASA, AANA and cited in the Institute of Medicine report, *To Err is Human: Building a Safer Health System* [Kohn, LT, Corrigan, JM, Donaldson MS. Washington, DC: National Academy Press. 1999], logic would dictate that less than a single individual in the entire database is likely to have died as the direct result of an anesthesia mishap!

What that leaves is this: *Based on the 30-day time frame, it is clear that the study actually evaluates postoperative physician care, not anesthesia care.*

Death Rates. The Pennsylvania study cites death rates that were many times more than the anesthesia-related death rates commonly reported in recent years, again leading one to conclude that the increase was almost certainly due to nonanesthesia factors.

In a June 2000 press release about the Pennsylvania study, the ASA stated "that patient safety has greatly improved from one [death] in 10,000 anesthetics to one in 250,000 anesthetics." (This amounts to four deaths in one million.) In the same press release, the ASA stated that, "Dr. Silber's findings show that for every 10,000 patients who had surgery, there were 25 more deaths if an anesthesiologist did not direct the anesthesia care." Through a complex series of calculations, the difference translates to 8,000 deaths in one million. Thus, the *difference* in mortality rates that the ASA cited is **2,000 times** the mortality rate ever attributed (including by the ASA) in the last decade to the administration of anesthesia. To attribute a difference of this magnitude solely to the supervision of CRNAs is ridiculous. In actuality, the large differences in mortality and failure-to-rescue are due to differences unrelated to the administration of anesthesia and outside the scope of practice of CRNAs, whether unsupervised, supervised by anesthesiologists, or supervised by other physicians.

Further, it has been noted by Dr. Michael Pine, a board-certified cardiologist widely recognized for his expertise in analyzing clinical data to evaluate healthcare outcomes, that after adjusting the death rates for case mix and severity, *the patients whose nurse anesthetists were su-*

pervised by nonanesthesiologist physicians were about 15% more severely ill than the patients whose nurse anesthetists were supervised by anesthesiologists. The paper provides no information to explain why the anesthesiologist-supervised cases involved less severely ill patients.

Dr. Pine's analysis of the study also reveals the following:

1. 7,665 patients (3.5%) died within 30 days of surgery.
2. Although the study found 258 more deaths of patients who may not have had an anesthesiologist involved in their case, the researchers' adjustments for differences among patients and institutions reduced the number by 78% (to 58 deaths).
3. The 58 "excess" deaths could be due to numerous, equally plausible factors, for example:
 - A. Faulty design of the study
 - B. Inaccurate or incomplete billing data (e.g., most of the 23,010 "undirected" cases used had no bill for anesthesia care)
 - C. Unrecognized differences among patients (e.g., medical information on patients' bills was insufficient to permit complete adjustment for their initial risks)
 - D. Unrecognized differences in institutional support (e.g., information about hospital characteristics was inadequate to permit full assessment)
 - E. Medical care unrelated to anesthesia administration (e.g., post-operative medical care provided by anesthesiologists or by other medical specialists who are more likely to be at hospitals in communities where anesthesiologists are plentiful)

The end result is a statistically insignificant difference in negative outcomes between anesthesiologist-directed and nonanesthesiologist-directed cases.

Complication Rates. After adjusting for case mix and severity, *the study found no statistically significant difference in complication rates when nurse anesthetists were supervised by anesthesiologists or other physicians.* Dr. Pine noted that poor anesthesia care is far more likely to result in significant increases in complication rates than in significant increases in death rates. Therefore, Dr. Pine concluded that *this finding strongly suggests that medical direction by anesthesiologists did not improve anesthesia outcomes.*

Failure to Rescue. For the most part, failure to rescue occurs when a physician is unable to save a patient who develops nonanesthesia complications following surgery. Therefore, it is not a relevant measure

of the quality of anesthesia care provided by nurse anesthetists. It is a relevant measure of postoperative physician care, however.

Patients Involved in More than One Procedure. For reasons not explained in the abstract, patients involved in more than one procedure were assigned to the nonanesthesiologist physician group if for any of the procedures the nurse anesthetist was supervised by a physician other than an anesthesiologist. It is impossible to measure the impact of this decision by the researchers on the death, complication, and failure to rescue rates presented in the abstract.

To emphasize the importance of this, consider the following hypothetical scenario: A patient is admitted for hip replacement surgery. A nurse anesthetist, supervised by the surgeon, provides the anesthesia. The surgery is completed successfully. Three days later the patient suffers a heart attack while still in the hospital and is rushed into surgery. This time the nurse anesthetist is supervised by an anesthesiologist. An hour after surgery, and for reasons unrelated to the anesthesia care, the patient dies in recovery. According to the researchers, a case such as this would have been assigned to the nonanesthesiologist group!

Patients Who Were Not Billed for Anesthesia Services. As noted in the discussion on death rates, most of the “undirected” cases had no bill for anesthesia care. The actual figure is 14,137 patients, or 61% of the 23,010 patients defined as undirected. The researchers’ flimsy rationale for lumping all nonbilled cases in the undirected category is as follows: “The ‘no-bill’ cases were defined as undirected because *there was no evidence of anesthesiologist direction, despite a strong financial incentive for an anesthesiologist to bill Medicare if a billable service had been performed*” (emphasis added). Of course, one might ask how many of those cases were not billed because an anesthesiologist had a bad patient outcome.

Referenced Studies. The researchers claim that their research “results were consistent with other large studies of anesthesia outcomes.” Interestingly, the two studies cited were by Bechtoldt (refer to page 10 of this booklet) and Forrest (refer to page 11 of this booklet). As indicated below, neither of these studies agrees with the conclusions reached by Dr. Silber and his team of researchers on the Pennsylvania study:

- Bechtoldt reported that the Anesthesia Study Committee (ASC) of the North Carolina Medical Society “...found that the incidence among the three major groups (the CRNA, the anesthesiologist, and the combination of the CRNA and anesthesiologist) to be rather similar. Although the CRNA working alone accounted for

about half of the anesthetic-related deaths, the CRNA working alone also accounted for about half of the anesthetics administered.”

- After applying statistical tests to the results of research conducted by the Stanford Center for Health Care Research, Forrest stated: “Thus, using conservative statistical methods, we concluded that there were no significant differences in the outcomes between the two groups of hospitals defined by type of anesthesia provider. Different methods of defining outcome changed the direction of differences for two weighted morbidity measures.”

Further supporting the argument that other studies do not agree with the purported findings of Silber and his fellow researchers is the following objective, third-party opinion offered by HCFA/CMS in the *Federal Register* on January 18, 2001: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the practice of any licensed professional.” [p. 4685-4686]

D. HCFA/CMS Affirms that Study Not About CRNA Practice

In the anesthesia rule published in the January 18, 2001, Federal Register by HCFA/CMS, the administration dismissed all claims by ASA and the Pennsylvania study research team that the study examined CRNA practice and was relevant to the supervision issue. HCFA/CMS stated the following:

- “We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law.” [p. 4677]
- “One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision.” [p. 4677]
- “Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs.” [p. 4677]

Although the January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision requirement after meeting certain conditions, the January rule's extensive comments supportive of nurse anesthetists and dismissing the relevancy of the Pennsylvania study to the supervision issue have in no way been repudiated by CMS and still remain part of the public record.

E. Conclusions

The following conclusions can be drawn from a careful examination of the study "Anesthesiologist Direction and Patient Outcomes":

- The study described has nothing to do with the quality of care provided by nurse anesthetists.
- The study examines postoperative physician care, not anesthesia care.
- The researchers so much as admit that the study does not prove anything with regard to the effect of anesthesiologist involvement in patient care.
- The timing of the publication in the ASA's own journal was politically motivated.
- HCFA/CMS finds no credence in ASA and Dr. Silber's assertions regarding the results of the Pennsylvania study.

5. Vila Study in *Archives of Surgery*

[Vila, H, Soto, R, Cantor, AB, Mackey, D. "Comparative Outcomes Analysis of Procedures Performed in Physician Offices and Ambulatory Surgery Centers." *Archives of Surgery*. 2003; 138:991-995.]

In the September 2003 issue of *Archives of Surgery* (an American Medical Association publication), a paper titled "Comparative Outcomes Analysis of Procedures Performed in Physician Offices and Ambulatory Surgery Centers" raised questions about patient safety in physician offices. The study was based in Florida.

The researchers, Hector Vila, Jr., MD; Roy Soto, MD; Alan B. Cantor, PhD; and David Mackey, MD, are among the first to compare office surgery outcomes with outcomes in ambulatory surgery centers (ASCs).

Because the methodology used for the study was flawed in many ways, *the only supportable conclusion one can reach from the results is that more comprehensive studies similar in nature need to be undertaken*. However, despite this particular study's flaws, and the fact that the results are of questionable value, research of this nature does have merit.

It is important to note that Vila et al.'s paper:

- Does not specifically mention CRNAs.
 - Does not compare the work of anesthesia providers (specifically, physician anesthesiologists and CRNAs).
- Has not been as widely misrepresented by the American Society of Anesthesiologists (ASA) or its state societies in an effort to denigrate CRNAs as the Silber/Pennsylvania study has been misrepresented (see analysis of Silber/Pennsylvania study, pp. 25-32 in this booklet).
- Makes the unsupportable assertion that office surgery may not be as safe when an anesthesiologist is not present.

A. Rationale for Undertaking Study

According to the researchers, the study was undertaken to determine whether patient safety is similar in Florida ASCs and offices.

B. Background

The researchers reviewed: "All adverse incident reports to the Florida Board of Medicine for procedure dates April 1, 2000, to April 1, 2002.... The numbers of office procedures performed during a 4-month period were used to estimate the total number of procedures. Ambulatory surgery death summaries, adverse incident data, and volumes of procedures for 2000 were procured from the Florida Agency for Health Care Administration."

Vila et al. concluded from their review of the two-year period that the risk of adverse incidents and deaths was approximately 10 times greater in the office setting than in ASCs, and that if all office procedures had been performed in ASCs, approximately 43 injuries and six deaths per year could have been prevented.

Vila et al. also concluded, without any solid evidence for support, that the presence of anesthesiologists in ASCs "may be a factor in more favorable outcomes."

C. AANA Comments on Vila Study

The AANA agrees that reasonable regulation of surgery and anesthesia in physicians' offices is warranted. The Association has long been proactive in educating anesthesia providers about and advocating for patient safety in the office setting. In 1999, the AANA developed and disseminated the *first* national Standards for Office Based Anesthesia Practice. The AANA also believes that surgery and anesthesia safety is based on appropriate patient-selection criteria, staffing, equipment, systems, and procedures, and not on the particular type of facility involved.

It is important that appropriate data on deaths and other adverse incidents related to office surgery be collected. Despite the Vila study's numerous methodological problems, the researchers' finding of significantly greater rates of mortality and adverse events in physicians' offices suggests that further study is needed.

Problems with the Study. Two areas of great concern with the Vila study are the following:

- The researchers' analysis largely consists of speculation unsupported by hard data, and
- The Vila study has major methodological flaws.

Vila et al. state that "anesthesiologists are present in nearly all ASCs and were present in the study reported by Hoefflin et al. in which there were no deaths in more than 23,000 office procedures [Hoefflin, SM, Bornstein, JB, Gordon, M. "General anesthesia in an office-based plastic surgical facility: a report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications." *Plast Reconstr Surg*. 2001;107:243-257]. This suggests that their presence may be a factor in more favorable outcomes."

The assertion that office surgery may be safer when an anesthesiologist is present is indefensible, for all of the reasons cited below.

- Anesthesiologist researchers have long made these kinds of assertions with little or no data to support their claims. For instance: Should Vila et al. be taken at their word that "anesthesiologists are present in *nearly all* (emphasis added) ASCs" simply because they say so? Where is the data to support this claim?
- "Presence" does not indicate "involvement." Do CRNAs actually administer (provide the hands-on care) in "nearly all" of Florida's ASCs, and are these facilities safer because this is so? Were CRNAs the main hands-on providers of anesthesia in the Hoefflin study? This pertinent information is not included in the Vila paper.
- According to the researchers themselves, "A statistical analysis of the impact of requirements for surgeon credentialing, office accreditation, and *the presence of an anesthesiologist* (emphasis added) could not be determined because of insufficient data on the patients who did not experience adverse incidents." Five sentences later, Vila et al. go on to speculate about how the presence of anesthesiologists may be a factor in more favorable outcomes, an assertion they had just acknowledged to be unsubstantiated by data!

- In stark contrast to what Vila et al. assert is a statement by George Bitar, MD, et al. in their study titled "Safety and Efficacy of Office-Based Surgery with Monitored Anesthesia Care/Sedation in 4778 Consecutive Plastic Surgery Procedures," published in the January 2003 issue of *Plastic and Reconstructive Surgery*. Bitar et al. concluded that "...office-based surgery with intravenous sedation, performed by board-certified plastic surgeons and nurse anesthetists, is safe. Appropriate accreditation, safe anesthesia protocols, and proper patient selection constitute the basis for safe and efficacious office-based plastic surgery."
- Also in stark contrast to Vila et al.'s assertion are written statements from 13 Florida-based office physicians protesting the study's implication that office surgery and anesthesia are not as safe as in ASCs. Collectively, these surgeons reported more than 35,000 procedures using CRNAs to provide the anesthesia care, without any patient deaths or significant complications. There were no anesthesiologists present for these cases. This begs the question: Is it office surgery in general that isn't safe, or merely surgery in a small number of selected physicians' offices?
- Vila et al. cite the adoption of office surgery guidelines by the Federation of State Medical Boards (FSMB) as a step toward improving patient safety. Significantly, the FSMB guidelines do not require anesthesiologist involvement in anesthesia care.
- Finally, in November 2000, an administrative law judge in Florida struck down a rule proposed by the Florida Board of Medicine that would have had the effect of preventing surgeons from using nurse anesthetists for procedures performed in certain office settings. In a 45-page opinion, Judge William Pfeiffer wrote: "In summary, there is no reliable data demonstrating that Level III office surgery is safer with an anesthesiologist than with a CRNA." (An appellate court overturned Judge Pfeiffer's decision on purely technical grounds unrelated to his factual finding.)

The Vila Study also suffers from numerous methodological flaws. Following are several examples:

- Vila et al.'s comments contain some speculation about possible reasons (e.g., presence of an anesthesiologist or type of facility) for differences in outcomes. These must be regarded as pure speculation because the data analyzed are inadequate to address these issues, as the researchers themselves acknowledge in their paper.
- In their current form the databases of procedures performed in ASCs and physicians' offices differ so substantially that an accurate comparison of the two is nearly impossible.

- Accurate data on the results of surgical procedures performed in physicians' offices is extremely difficult to obtain and, when available, is not directly comparable with publicly available information from hospitals and ambulatory surgical centers.
- The actual number of procedures performed in physicians' offices that would qualify for inclusion in the Vila study is unknown.
- The definition of adverse incidents used for ASCs differs from that used for physicians' offices.
- Vila et al. do not present any data on the completeness of incident reporting for either practice setting.
- The time frames encompassed by the ASC and office databases used by Vila et al. are markedly different.
- Vila et al. acknowledge the absence of risk adjustment for patient severity in their analysis.

Summary

This publication has demonstrated that CRNAs provide superb anesthesia care, and has refuted anesthesiologist contentions to the contrary. Anesthesia-related accidents are infrequent; those that do occur tend to result from lack of vigilance rather than the level of education of the provider. The federal Centers for Disease Control has considered conducting a large-scale study on anesthesia care, but decided such a study would not be worth the high cost such a study would entail. The reason is that the evidence is overwhelming that anesthesia care is very safe, regardless of whether the care is given by a CRNA or anesthesiologist. It is clear that studies to date demonstrate that there is no statistically significant difference between the anesthesia care provided by CRNAs working alone, CRNAs working with anesthesiologists, or anesthesiologists providing care alone. In addition, malpractice insurance premiums for CRNAs decreased significantly from 1988 to 2004, further demonstrating that CRNAs provide safe anesthesia care.

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APPENDIX

Nurse Anesthetist Professional Liability Premiums Premium Changes from 1988 to 2004 (Comparing 1988 data provided by St. Paul Fire and Marine Insurance Company to 2004 data provided by CNA Insurance Company)

| State | 1988 Premium | 2004 Premium | Overall Change (%) |
|---------------|--------------|--------------|--------------------|
| Alabama | 2,537 | 2,092 | -441 (-17) |
| Alaska | 2,603 | 1,498 | -1,105 (-43) |
| Arizona | 5,414 | 3,445 | -1,969 (-36) |
| Arkansas | 1,196 | 2,034 | 838 (70) |
| California | 7,148 | 3,901 | -3,247 (-45) |
| Colorado | 2,461 | 2,039 | -422 (-17) |
| Connecticut | 4,704 | 1,600 | -3,104 (-66) |
| Delaware | 2,689 | 2,228 | -461 (-17) |
| D.C. | 3,032 | 2,437 | -1,056 (-35) |
| Florida | 3,588 | 2,690 | -898 (-25) |
| Georgia | 2,219 | 1,491 | -728 (-33) |
| Hawaii (1) | 2,600 | 2,447 | -153 (-6) |
| Idaho | 4,221 | 2,132 | -2,089 (-50) |
| Illinois | 6,989 | 3,128 | -3,861 (-55) |
| Indiana | 5,809 | 1,753 | -4,056 (-70) |
| Iowa | 3,317 | 1,710 | -1,607 (-49) |
| Kansas | 3,272 | 1,471 | -1,801 (-55) |
| Kentucky | 2,972 | 1,809 | -1,163 (-39) |
| Louisiana | 3,358 | 2,703 | -655 (-20) |
| Maine | 2,598 | 1,380 | -1,218 (-47) |
| Maryland | 2,921 | 2,000 | -921 (-32) |
| Massachusetts | 2,678 | 1,571 | -1,107 (-41) |
| Michigan | 4,980 | 1,624 | -3,356 (-67) |

| | | | |
|----------------|----------------|----------------|-----------------------|
| Minnesota | 2,369 | 699 | -1,670 (-70) |
| Mississippi | 2,198 | 1,317 | -881 (-37) |
| Missouri | 7,806 | 3,456 | -4,350 (-56) |
| Montana | 3,872 | 1,371 | -2,501 (-65) |
| Nebraska | 2,228 | 1,279 | -949 (-43) |
| Nevada | 8,231 | 4,389 | -3,842 (-47) |
| New Hampshire | 2,530 | 2,294 | -236 (-9) |
| New Jersey | 5,013 | 3,318 | -1,695 (-34) |
| New Mexico | 2,249 | 2,559 | 310 (14) |
| New York | 6,061 | 4,378 | -1,683 (-28) |
| North Carolina | 1,476 | 1,234 | -242 (-16) |
| North Dakota | 2,461 | 983 | -1,478 (-60) |
| Ohio | 5,392 | 3,045 | -2,347 (-44) |
| Oklahoma | 2,309 | 2,455 | 146 (6) |
| Oregon | 5,737 | 2,214 | -3,523 (-61) |
| Pennsylvania | 1,771 | 1,145 | -626 (-35) |
| Rhode Island | 3,412 | 1,348 | -2,055 (-60) |
| South Carolina | 1,935 | 674 | -1,264 (-65) |
| South Dakota | 2,736 | 1,078 | -1,658 (-61) |
| Tennessee | 2,352 | 1,713 | -639 (-27) |
| Texas | 2,865 | 4,885 | 2,020 (71) |
| Utah | 3,876 | 2,130 | -1,746 (-45) |
| Vermont | 2,330 | 1,191 | -1,139 (-49) |
| Virginia | 1,431 | 1,813 | 382 (27) |
| Washington | 2,687 | 2,229 | -458 (-17) |
| West Virginia | 2,592 | 1,724 | -868 (-33) |
| Wisconsin | 2,744 | 1,013 | -1,731 (-63) |
| Wyoming | 3,947 | 2,866 | -1,081 (-27) |
| TOTAL | 177,916 | 107,983 | -69,933 (-39%) |

⁽¹⁾ St. Paul did not provide coverage in Hawaii until 1990