

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 Surge*. 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