CRNA
Certified Registered Nurse Anesthetists
American Association of Nurse Anesthetists

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Quality of Care
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[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 (The January 18 rule was rescinded on November 13, 2001, with the publication of a new rule that allows state governors to write to CMS and opt out of the federal physician supervision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 supervised 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 out- comes

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 and Forrest. 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.

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