FAX

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Number of pages (including cover page): 5

DATE: September 12, 2000

TO: CHRIS JENNINGS

FROM: TIMOTHY J. KEATING

Chris,

Please see the following information.

Attachment

ASA COMMENTS ON HCFA SUPERVISION RULE
(Revised HCFA Draft dated August 14)

1. In the preamble, HCFA goes to great lengths to establish that critics of the proposal to eliminate physician supervision have not established the negative, that is, that the proposed change is not safe. In particular, HCFA savages the Silber study – which shows better outcomes when an anesthesiologist rather than a surgeon provides supervision – as not relevant because it does not measure outcomes when a nurse anesthetist is not supervised at all. All agree that the issue here is whether more seniors will die from anesthesia. Shouldn't HCFA have an obligation to show that the rule change is safe, rather than forcing opponents to show that it is not safe? How can HCFA conclude that the Silber study is "irrelevant": is the agency seriously saying that outcomes could be better when there is no supervision, rather than at least some physician supervision.

2. Notwithstanding its comment in the preamble that States can handle the issue (pp. 54-55), HCFA's draft retains the existing requirement for ASCs and CAHs that a physician perform the pre-op and post-op anesthesia exam and for hospitals that a physician run the department. HCFA says its objective is to eliminate procedural requirements when there is no compelling evidence that they should be retained. What evidence has HCFA reviewed or offered to indicate that these procedural requirements should be retained? Moreover, how does HCFA justify retaining the pre-op and post-op exam requirements for ASCs and CAHs, while not requiring such exams in hospitals – where the more serious anesthesia procedures are performed.

3. HCFA's draft of revised rule states that "anesthesia must be administered only by a licensed practitioner permitted by the State to administer anesthetics" (emphasis added). No definition of the emphasized term is provided. Nurse anesthetists are registered, not licensed. Equally significant, anesthesiologist's assistants – expressly authorized under current law to provide anesthesia under supervision of an anesthesiologist – are "licensed" in only two States, are registered in two more, and practice under delegated authority from a physician in still more. Although HCFA attempts to claim in the preamble of the August 14 draft that it is not impeding AA practice (p. 63), the use of the term "licensed practitioner" calls this claim into serious question and created an unnecessary ambiguity.

4. HCFA's draft of revised rule does not deal with the issue of the inappropriateness of its existing requirement that the individual providing anesthesia prepare a post-op note within 48 hours. ASA has regularly (most recently in its comments on the proposed rule) criticized this requirement as

inconsistent with modern "team" practice. Does HCFA have compelling evidence that this procedural requirement is necessary to patient safety?

Changes in anesthesia-related Conditions of Participation contemplated by HCFA proposed rule (August 14, 2000 draft). Deleted language is in brackets, added language is in italics.

Ambulatory Surgical Centers

(a) Standard: Anesthetic risk and evaluation. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.

(1) Standard: Administration of anesthesia. *Anesthesia must be administered by a licensed practitioner permitted by the State to administer anesthetics.* [Drops specific references to various types of practitioners, including anesthesiologist's assistants].

Hospitals

If the hospital furnishes anesthesia services, they must be provided in a well organized manner under the direction of a qualified doctor of medicine or osteopathy. If outpatient services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) Standard: Organization and staffing. The organization of the anesthesia services must be appropriate to the scope of services offered. *Anesthesia must be administered by only a licensed practitioner permitted by the State to administer anesthetics.* [Drops references to individual practitioners, including anesthesiologist's assistants].

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

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

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.
(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

Critical Access Hospital

Anesthetic risk and evaluation. A qualified practitioner, as described in paragraph (a) of this section [a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine] must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner as described in paragraph (a) of this section.

Administration of anesthesia. The CAH designates the person who is allows to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. *Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.* [Drops reference to individual practitioners, including anesthesiologist's assistants].

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DATE: September 12, 2000

TO: CHRIS JENNINGS

FROM: TIMOTHY J. KEATING

Chris,

Please see the following letter sent to Congressman Weldon.

Attachment

Jeanne Holmberg

From: Tim Keating
Sent: Tuesday, September 12, 2000 11:08 AM
To: Jeanne Holmberg
Subject: FW: Letter to Dr. Weldon

Please forward to CHRIS.

-----Original Message-----
From: Scott, Michael [mailto:m.scott@asawash.org]
Sent: Tuesday, September 12, 2000 11:04 AM
To: 'Keating, Tim'
Subject: FW: Letter to Dr. Weldon

Here is a letter from one of the authors reviewed by HCFA in developing its
proposed final rule. He is highly critical of HCFA's approach. You may want to forward this the Chris Jennings. I leave it to your discretion.

-----Original Message-----
From: Abenstein, John P., M.D. [mailto:abenstein.john@mayo.edu]
Sent: Monday, July 31, 2000 4:11 PM
To: 'Scott, Michael'; Mackenzie, Ronald A., D.O.; Warner, Mark A., M.D.
Subject: Letter to Dr. Weldon

Gentlemen,

I sent the below text to Congressman Weldon this afternoon.

July 31, 2000

The Honorable David Weldon
332 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Weldon:

Thank you for sending me copies of the documents from HCFA regarding the issue of physician supervision of CRNAs. Unfortunately, this is one of the
worse examples of the problems generated by the convergence of public policy
and medical science that I've ever seen. When all of this is over, no matter how it turns out, you may want to use this to produce a case study
for how not to formulate public policy.

In any event, the letter from Nancy-Ann Min DeParle to you is shocking in
it's circularity. Her reasoning is as follows: 1. HCFA has always required
physician supervision of CRNAs since the inception of the Medicare program.
2. Therefore, there can be no studies that document any adverse outcomes
associated with CRNAs not supervised by physicians since that practice model
does not exist. 3. Therefore, removing the requirement for physician

supervision of CRNAs is perfectly acceptable because there is no evidence that adverse outcomes will occur secondary to the change. Not only is this circular reasoning, but it totally ignores the role of scientific studies.

It is very important to understand the basic philosophy of the scientific method; everything in science must be disprovable. What this means is that no matter how a scientific study is designed or what the results of the study are, it must be disprovable by future research, or it is not science. Therefore, no study or collection of studies can ever be conclusive. What is "known" today, by definition, is transient, merely waiting till the next study is published. In addition, scientific investigations must be designed to answer very specific questions. Therefore, study results cannot cover all possible variations. Because of this, disprovability, lack of conclusiveness, and limited scope is both the strength and weakness of scientific investigations.

It's also important to understand the role of statistics and what statistical significance means. When we see a paper conclude that its results are statically significant because the p-value is less than 0.05 that means that there is a less than 1 in 20 chance (i.e. 5% or 0.05) that the results were a coincidence. That means that the results could still be a coincidence, that a future study could have different finding and so on. There is always a degree of ambiguity in science, particularly in medical science.

Keeping this in mind, what do we really do in medicine? In other words, how do we decide what to do, whether it's a specific treatment plan for a specific patient or a practice policy for a population of patients? Of course, we make use of the scientific literature, but rarely is the information found in the studies without ambiguity. Studies will disagree with each other, they will have significant differences in design, in the questions asked, in the populations included and so on. As physicians we weigh the evidence, based on knowledge, training and experience, and at the end of the day make a decision. We decide to give one medication or another to treat a disease. We decide to operate or to wait. We decide to get a CT-scan or an MRI. This is medical judgment built on a foundation of medical science.

I would argue that the same process is used in the formulation of public policy. The available objective information is gathered, in this case scientific studies. Subjective information is also gathered, often by asking for the opinions of knowledgeable leaders and the public. Based on this information, judgments are made on the importance of the objective and subjective information and policy is made. Unlike the scientific

process,
statistical significance is not required. For example, as a society we have
decided that the possible risks of second hand smoke are such that we don't
allow smoking in public buildings or airplanes. The decision was made
without conclusive scientific studies. I'd even venture to say that a risk
of 50-50, much less than 5%, is considered too great to allow this activity
to continue. Another example is that of asbestos abatement. As a society,
we now expend great sums of money because of the perceived health risk of
asbestos exposure, even though there are no conclusive studies to show that
low level exposure associated with asbestos in buildings are associated with
adverse health outcomes. None the less, the risk is considered too great,
policy is made without the demand for conclusive scientific evidence. The
list of examples of health policy generation without conclusive scientific
evidence, particularly by the federal government, is virtually endless.
It's striking, that this policy, of removing the requirement of physician
supervision of CRNAs, is being forwarded to OMB based on the argument that
since there's no evidence to conclusively show associated adverse outcomes
(i.e. the risks have not be measured) it's acceptable to move forward.

In the letter to you, Dr. Weldon, the first point made is that Medicare has
had a consistent policy of respecting State control and oversight of health
professionals by deferring to State licensing laws to regulate health
professional practice and that the policy requiring physician supervision of
CRNAs is the sole exception. Although, I do not know the full body of
Medicare regulations I find the suggestion that this requirement is the only
one to be farfetched. Several examples come to mind. The first is the
effective requirement for hospital accreditation by JACHO in order to be
approved under the Medicare program. Accreditation by JACHO requires
numerous supervision and documentation requirements. The rules associated
with CLIA for medical labs again make demands for supervision. Finally, the
HCFA reimbursement rules regarding concurrency has clear implications
regarding the issue of supervision. I'm sure you can find many other
examples.

HCFA's superficial analysis of the Silber paper published this month in the
Journal Anesthesiology is, frankly, laughable. This study clearly and
convincingly shows that by decreasing the level of supervision of CRNAs
leads to an increase in the 30-day mortality rate and failure-to-rescue
rate. It does not take a great intellectual leap to conclude that a further
decrease in supervision would be expected to lead to even greater rates of
adverse outcomes. But the letter states that since the study does not
specifically look at CRNAs not supervised by a physician, the Silber results
are not applicable. As I stated above, one uses the scientific

literature as a guide for decision making. Ms. DeParle is demanding an impossible level of evidence to counter their proposed rule making. Evidence cannot be gathered on a practice that does not currently exist and evidence cannot be found regarding state oversight for an activity that does not exist. It's as if the HCFA administrator is putting on intellectual blinders and is refusing to think.

The letter states that the Silber study has methodological shortcomings, but does not comment further. It's surprising that HCFA discounts such an important paper, out-of-hand, without explaining why the results are somehow suspect. Certainly, the results of the Silber study point to a public policy which would require an anesthesiologist to either administer or medically direct every anesthetic in the United States and that may or may not be practical, but this is not the question at hand. The question is whether or not to remove the longstanding requirement for physician supervision of CRNAs. The administrator seems to suggest that since a policy to require the involvement of an anesthesiologist in every anesthetic in the United States would be impossible to implement that the results of the Silber study cannot be used to guide the development of a different public policy. Again, I point out that the Silber results showed worse outcomes with less supervision. The policy question is whether or not to reduce supervision requirements. The results of the Silber study and the proposed policy change are clearly linked.

As to the feasibility of conducting a study comparing the practice models, there's not much to say. A retrospective study of patient outcomes following anesthesia care by unsupervised nurse anesthetists clearly cannot be done. The other issues brought up are insincere objections. They have substituted 30-day mortality with anesthesia-related mortality (i.e. two totally different markers for perioperative outcomes) and then concluded that the study size is too high. They point out that they can't use non-Medicare patients since all hospitals have to follow Medicare rules, admitting to some degree the fact that the current rules apply to the vast majority of Americans. Finally, the statement regarding the waiving of State law is simply wrong. Many states have no supervision rules per se because they have depended on Federal regulations in this regard. If they so choose, they certainly could compare outcomes in Medicare patients between different states with different rules. The results could be adjusted for acuity and complexity and examined. They just don't want to gather any data.

In summary, the letter from Ms. DeParle makes use of circular reasoning, glosses over the complex web of Federal regulation of medical practice, more or less refuses to make use of any of the information available in the medical literature, particularly the Silber study, since the studies do not specifically answer a very narrow question, and finally refuses to gather any additional information because it would be too difficult. Truly

amazing.

In their review of the literature they again gloss over the information and appear to almost gleefully misinterpret the data.

In the review of my paper, they seem to not understand to the structure of the article. They freely quote from the paper regarding the complexities of anesthesia-related death rate and the fact that anesthesia outcomes have improved dramatically over the last three decades. But as was noted above, in order to make policy decision one must use what data that is available. The two studies that we review (Bechtoldt and Forest) had limitations (as do all studies). As noted in the review, the studies did not reach statistical significance but the review does not even mention the fact that the difference in outcomes in both studies were on the order of 30% and that in the Forest study other statistical measures favor hospitals with anesthesiologists! The review also fails to mention additional evidence for improved outcomes with anesthesiologists such as the ASA closed claims study and the decrease in malpractice premiums. Do any of the studies or evidence on their own prove conclusively that outcomes improve with anesthesiologists? No they don't, but in a policy context how can one justify a 30% higher mortality rate? All the evidence points to the same conclusion - improved outcomes with physician-based care. Although I should not be surprised, I can't believe they are hiding behind the skirt of "science" in order not to make appropriate use of the information.

The review of the first three Silber articles more or less discounts the articles since they speak neither to the question of CRNA supervision or to the States' ability to decide who needs to be supervised. They seem totally unwilling to incorporate the data that shows improved outcomes with board-certified anesthesiologists or in other words, better outcomes with better training and experience. Admittedly, in regards to this question, since CRNAs were not included in any of the studies, the information in these three studies is useful in the context of supporting the argument that better supervision leads to better outcomes.

Their review of the Silber abstract appears to hold the abstract to the level of a full manuscript. Clearly, in an abstract of just a few hundred words the authors were unable to flesh out their methodology or to perform a full adjustment for acuity, complexity, and hospital characteristics. The abstract reports highly statistically significant differences in outcomes between CRNAs supervised by surgeons as compared to CRNAs medically directed by anesthesiologists. When added to the previous information, how in good conscience could you propose to decrease supervision when all the

evidence already shows worse outcomes with less supervision? Why the review discounts the outcomes, since there's not an explanation for why the outcomes are worse, simply makes no sense. In the scientific and medical practice environment there would be calls for further study while at the same time changes would be made to decrease the observed worse outcomes.

In regard to the review of the IOM report and the Chassin follow up it is gratifying to note the dramatic improved outcomes in anesthesia-related mortality. What is missing, though, is the fact that the reported improved outcomes are all from practices with anesthesiologists (i.e the papers these numbers come from). If the reviewer is to be scientifically correct, the only study, that I know of, that reports anesthesia-related mortality with CRNAs is the Bechtoldt study with an anesthesia-related mortality rate of approximately 1:20,000 or ten times worse than current reported anesthesia-related mortality rates. Since there have been no studies published since Bechtoldt, we don't know if the outcomes in these practices (CRNAs supervised by surgeons) have or have not improved. This is the same standard we appear to be held to - if the data is not there we can draw no conclusion. Therefore, based on this standard we can only conclude that anesthesia-related mortality is still 1:20,000 when CRNAs are supervised by surgeons.

In this regard, I again ask the question - in the IOM report of medical errors the authors call for changes in process to decrease medical errors and improve outcomes, but proposed policy is to go in the exact opposite direction and decrease what supervision there is when we know less supervision leads to worse outcomes. WHY?

Finally, in terms of a literature review, the Silber study published this month is not included in their review, this is a glaring omission. It makes one wonder if the agency has ever had any intention of really looking at the medical literature and honestly making use of the information or all they did was to interpret the data only in a manner that was consistent with their policy decision and either to ignore or to denigrate the information that does not support the proposed change.

I find the literature review to be superficial, lacking in understanding the importance of these papers, and lacking in completeness, particularly in regard to the omission of the Silber study. They have framed the question so narrowly that no study would fit their criteria and they then conclude that since there is not data that answers their questions there's no reason not to move ahead. Clearly they continue to play political games with seniors lives. I'd be embarrassed if I were they.

Congressman Weldon, thank you again for the opportunity to review and provide feedback on the documents sent to you from Ms. DeParle and her staff. Please let me know if I can be of any additional assistance.

Sincerely,

J.P. Abenstein, M.S.E.E., M.D.

To Jason Schechter
202 456 6201
DEVORAH

GOVERNOR GRAY DAVIS

September 22, 2000

The Honorable Bill Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear President Clinton:

We are writing to request your support and assistance to find a means to extend states' annual funding allotments for the State Children's Health Insurance Program (CHIP), such as California's Healthy Families program, which otherwise will be lost. It is imperative that California retains access to its 1998 and 1999 CHIP funds in order to cover more children and provide coverage to uninsured working parents.

California has made significant strides to expand coverage for children in the past few years. In July 1998, the State began its Healthy Families program. Since that time, we have significantly improved the program by expanding children's eligibility from 200 percent to 250 percent of FPL, simplifying the application and the enrollment process and increasing outreach funding. As a result, enrollment has increased by about 500 percent since January 1999. Currently, Healthy Families covers about 340,000 California children.

As you know, the Health Care Financing Administration (HCFA) recently released 1115 waiver guidelines to allow additional expansions with CHIP funds. California is developing a waiver proposal to further increase coverage for children and to extend coverage to parents of eligible children. Our primary commitment is to enroll all eligible children. We intend to use any remaining funds from our existing federal allotted funds to extend coverage to parents as well. To that end, we ask for your assistance in preserving the use of our existing 1998 and 1999 federally allotted CHIP funds.

Senator Feinstein has been working hard in the Senate toward this end, organizing 59 of her Senate colleagues to support extending the use of states' allotments, and we applaud her efforts. We will similarly work with our colleagues in the House, and ask that you actively support extending the use of states' allotments for both our FY 1998 and FY 1999 allotted funds for several additional years. With a multi-year extension, California can continue to increase

enrollment for its eligible children and successfully pursue an 1115 demonstration proposal to further extend coverage to children and to their parents.

Thank you for your consideration of this matter.

Sincerely,

GRAY DAVIS
Governor

JOHN BURTON
Senate Pro-Tempore

ROBERT HERTZBERG
Speaker of the Assembly

cc: John Podesta
Jack Lew

FAX COVER SHEET

American Association of Nurse Anesthetists
Federal Government Affairs Office
The Capitol Hill Office Building
412 First Street, S.E., Suite 12
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Phone: (202) 484-8400
Fax: (202) 484-8408

DATE: 9/12 **PAGES (including cover sheet):** 5

TO: Chris Sonnhalt
The White House

FROM: Dave Holmes

MESSAGE:

If there are any problems with the transmission of this fax please call (202) 484-8400.

Questions and Answers about the Deferral to the States on Physician Supervision of Nurse Anesthetists

1. What was HCFA's proposed rule?

There is currently a regulation requiring physician supervision of Certified Registered Nurse Anesthetists (CRNAs) in order for hospitals to be reimbursed under Medicare. This requirement may be fulfilled by a surgeon, podiatrist, dentist, or anesthesiologist. Anesthesiologist supervision is NOT required nor has it ever been. In 1994, HCFA issued a draft regulation to defer to the states on the issue of physician supervision. Then in 1997, HCFA issued a proposed rule once again to let the states determine whether physician supervision of nurse anesthetists is necessary. That proposed rule has been pending. Currently, 29 states do not require physician supervision of CRNAs in nursing statutes or rules.

2. What has HCFA decided to do?

HCFA advised the AANA on Thursday, March 9th that they expect to finalize this pending rule as proposed and therefore defer to the states on the issue of physician supervision of nurse anesthetists. AANA was also advised that the American Society of Anesthesiologists (ASA) received the same message. HCFA sent a letter to Senator Arlen Specter advising him of their intention to finalize the proposed rule by June 2000.

3. Does the letter specifically state that HCFA intends to defer to the states?

> HCFA's letter states: "We have proposed the change because the clinical evidence supports that anesthesia outcomes have improved substantially in recent years such that anesthesia is a relatively safe procedure. In view of this, the existing across-the-board supervision requirement did not seem to be supported by the existing scientific evidence."

It is also our understanding that HCFA cannot be more definitive in writing until the final rule is published in the Federal Register.

4. Why is this issue important?

For many years, CRNAs have been concerned that the federal supervision requirement has been used improperly by some members of the physician community to dissuade surgeons and hospitals from using CRNAs, arguing in effect that somehow the federal requirement would impose automatic legal liability upon the surgeon or hospital. While there is no automatic legal liability, it has been effectively used to disemploy CRNAs and thereby deprive hospitals and ambulatory surgical centers of their services. For patients in rural areas and underserved urban areas in particular, it means that they could be deprived of access to anesthesia services if these hospitals or ASCs are dissuaded from utilizing CRNAs.

5. Does this expand scope of practice rights for CRNAs?

This will not change any state scope of practice laws.

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS – FEDERAL GOVERNMENT AFFAIRS OFFICE
The Capitol Hill Office Building, 412 1st Street, S.E., Washington, D.C. 20003
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6. Does it alter state supervisory requirements?

No, states are free to impose whatever requirements they deem appropriate. For that matter, hospitals have been free to do so and they may continue whatever requirements they believe are necessary.

7. What about studies which are being circulated concerning this issue?

There is currently a scientific abstract titled "*Do Nurse Anesthetists Need Medical Direction by Anesthesiologists?*" The researchers and authors are Jeffery H. Silber, M.D., and David E. Longnecker, M.D., et. al.

> In a review of that abstract conducted by Michael Pine, M.D., M.B.A, he stated in part:"Risk-adjusted complication rates in the two groups of patients are not significantly different. Poor anesthesia care is far more likely to result in significant increases in complication rates than in significant increases in mortality rates. Therefore, this finding strongly suggests that medical direction by anesthesiologists did not improve anesthesia outcomes . . . ." He states further, "There was a significant difference in failure-to-rescue between the two groups with superior outcomes in patients whose anesthesia care was supervised by anesthesiologists. But failure-to-rescue is, for the most part, a measure of the quality of post-operative medical care. This finding supports the earlier conclusions that the nature of the supervision of anesthesia care is not directly related to differences in mortality."
>
> Dr. Pine notes further: "In the concluding paragraph the authors completely avoid their initial question: do nurse anesthetists need medical direction by anesthesiologists? Instead, they indicate that whether higher death rates and failure-to-rescue rates are a hospital or care giver effect 'remains to be determined.' Differences of 10 percent among hospitals' risk-adjusted death rates are common, and HCFA published differences greater than 50 percent for several years.... As for caregivers, higher-than-average mortality rates associated with higher-than-average rates of failure-to-rescue also may indicate important deficiencies in operative and post-operative medical care. However, it is almost inconceivable that these findings are attributable to differences in the supervision of anesthesia care, which is associated with virtually no mortality and generally is completed before processes that affect failure-to-rescue begin." (Pine, 9/98).

This abstract has been circulating for approximately a year and a half and has yet to be published in a peer-reviewed journal before finally being published this summer.

8. Are there any other recent studies relating to anesthesia?

Yes, an article published in the AANA Journal (December 1998.) It was co-authored by Lorraine Jordan, CRNA, Ph.D., and Robert Oshel, Ph.D., Research Director, Division of Quality Assurance, U.S. Department of Health and Human Services and discussed malpractice codes in the National Practitioner Data Bank for physicians and nurse anesthetists. In that article, it was determined that "there were more physician than nurse malpractice payments identified with anesthesia-related reason codes, 3,548 for physicians to 525 for nurses. We cannot compare adverse anesthesia events for anesthesiologists to nurse anesthetists because anesthesiologists are not directly identified. Nevertheless, anesthesia-related malpractice payments for nurses are rare

events. On average, there are only about 72 such payments a year reported to the NDB. Almost seven times as many physician anesthesia-related malpractice payments are made in an average year."

9. Are seniors really opposed to having nurse anesthetists provide their anesthesia without physician supervision?

No. According to the results of a nation-wide survey of Medicare patients conducted in October 1999 by the independent research firm Wirthlin Worldwide, almost two thirds of seniors find it acceptable for the nurse anesthetist to not be supervised by their surgeon, but work collaboratively with the surgeon who would be present throughout the surgery.

10. Why are the anesthesiologists so upset about deferring to state law on this issue?

We can only surmise that these are the same concerns that were reflected by their former president when he said:

> "ASA members should recognize the socioeconomic impact of HCFA's proposal as well. Although the proposed change in the 'Conditions of Participation' would not affect the Medicare reimbursement rules for medical direction of nurse anesthetists, it takes little imagination to see that a move away from required supervision of nurse anesthetists potentially erodes the number of cases in which medical direction will apply..." (Dr. William Owens, ASA President's Update, December 31, 1997).

Translation: It appears that the anesthesiologists are concerned about the financial impact to their practices.

11. What is the next step?

AANA is urging Congress to stay the course and not stop the rule from moving forward. Perhaps the anesthesiologists said it best when they said:

> "ASA believes issues relating to treatment of Medicare patients, including anesthesia care, are best dealt with in the context of thoughtful dialogue among the affected parties, and ultimately through the reliance on rule-making process by HCFA, the agency charged by law with the responsibility." (Letter to Congress, May 23, 1995).
>
> Or, when they said that the issue "belongs there (with HCFA) and not in Congress." (ASA Newsletter, November 1995, Vol. 59, Number 11, page 5).

AMERICAN ASSOCIATION OF NURSE ANESTHETISTS – FEDERAL GOVERNMENT AFFAIRS OFFICE
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Published Paper Not About Nurse Anesthesia

"Pennsylvania Study" Examines Post-Operative Physician Care

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 has been published in the July issue of *Anesthesiology* with the title, "Anesthesiologist Direction and Patient Outcomes" (2000; 93:152-163). 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.

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.

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. Jeffrey H. Silber, MD, PhD, headed a research team that included three anesthesiologists.

Study Does Not "Compare Anesthesiologists Versus Nurse Anesthetists"

According to David E. Longnecker, MD, 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.

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 do 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." (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., postoperative 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 (Bechtoldt AA Jr. Committee on Anesthesia Study. Anesthetic-Related Deaths: 1969-1976. *North Carolina Medical Journal.* 1981;42:253-259.) and Forrest (Forrest WH. Outcome—The Effect of the Provider. In: Hirsh R, Forrest WH, et al., eds. *Health Care Delivery in Anesthesia.* Philadelphia, Pa: George F. Stickley Company. 1980:137-142.). 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."

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.

7-13-00