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Below are our responses (in **BOLD** type) to the Reviewer's comments. The page and line numbers refer to our revised manuscript submitted 8/28/06.

Reviewer #1 –

The outcome evaluation of advanced practice nurses, such as nurse anesthetists (CRNAs), is a timely topic. The medical community has targeted CRNA practice for medical supervision through the use of the legislative process. Therefore, research that supports independent practice with comparative outcomes is needed.

However, the problem necessitating this retrospective analysis is not clearly delineated in the introduction. It is not until P6L4-13 does the reader become introduced to the implications of the study. P4-5 seem to be focused on a conclusion as to what the “study contributes to the literature” [P4L15], but not what problem the study seeks to solve. On P5L3, the author attempts to link CRNA staffing with research by Needleman et al. that has been focused on direct care providers. This research does not attempt to evaluate CRNA ratios, so the use of the Needleman paper to support the focus of the study seems forced. P 5 L12 to L3 describes the methodology of the article and do not add to the introduction. Overall, the reader would like to see a more focused attempt at delineating the problem. A focus on cost/benefit analysis, shortage of rural anesthesia services, and need to establish CRNA outcomes in this population could be discussed in depth with literature support.

Response: The introduction was rewritten to address the reviewer's concerns. The question is now clearly stated on P3L2-6, the Needleman reference is removed, and the problem is discussed in greater length on P3-4.

The literature cited supports the author's statements. P4L18 states that the majority of the studies found no difference and provides 5 references. It is noted that three of these are over 25 years old and probably not appropriate as anesthesia and surgical techniques have dramatically changed. The reader would appreciate a description and analysis of the 2003 and 2004 studies in the literature review, as well as a review of the Silber, 2000, study. A more in depth review of the available recent literature would offer a framework for the study.

Response: Done. See P5

There is no theoretical framework provided. The author may wish to describe the rationale for CRNA practice within an historical context. This framework plus an analysis of the research literature would then provide support for the hypothesis of no difference [P6L2].

Response: Corrected on P4

The research design appears to be a secondary analysis of data supported with an updated survey to obtain retrospective information about available anesthesia staff. In the ABSTRACT, the objective is stated as “to compare frequency” [P2L5] In the INTRODUCTION [P4L2; P5L10] the objective is stated “to examine the relationship”. However, there is a proposed hypothesis of “no difference in deaths and complications rates associated with these two types of staffing” [P6L2-3]. Thus, the reader becomes confused, wondering whether the study is looking at relationships or differences.

Response: Abstract and body now use the term “differences”.

The focus of the study is the difference in outcomes between two groups of anesthesia providers: MD’s and CRNA’s. The description of the staffing models on P4L7-12 describes four groups. Groups 3 and 4 are actually similar staffing models, the difference being employer. This may be confusing to individuals not familiar with anesthesia practices.

Response: The focus of the study is difference in outcomes between two groups of hospitals: those that employ only CRNAs and those that employ only anesthesiologists. Emphasis was made on this point on P6L16-23. The references to the other groups was removed, since this study only looks at CRNA-only vs. Anesthesiologist only.

The organization of the Methods section describes the dependent variable first (outcomes) and then the independent variable (staffing). It would be helpful to the reader to reverse this organization. The material under the title “Hospital Data” P7 is also confusing in terms of organization as demographic data is identified in the first sentence. The material presented on P7L15-21 is key, and would be best described first. The material presented on P7L22-P8L1-4 is demographic, and it is not clear to the reader why this material is significant to the study. If teaching hospitals were excluded, as might be expected, then this should be clearly stated.

Response: Rearranged per the reviewer. Teaching hospitals were not excluded, since both types of hospitals included teaching hospitals, and the question of whether or not to teach CRNA students vs. anesthesiology residents is also important to hospitals and anesthesiology groups. To account for this, however, teaching hospital (or not) was made part of the risk-adjustment.

There is no note in the Methods section related to permission to use the database or human use approval for the staffing survey.

Response: Added, P7L10

Again on P8 the dependent variable is presented first. It is unclear on L6-13 if the author is describing the coding in the original database, or if these ICD-9 codes were recoded for the purpose of this study. The use of the words “death rates and other obstetrical complications were measured” L11-12 is difficult to understand unless the author is discussing the original derivation of the database.

Response: Independent variable was placed first P7L14. The dependent variable was better described on P9L1-P10L3. Steps in processing datasets were described at greater length in this section. Death was described as a dependent variable (see reviewer comment at end of next paragraph).

The material described under the heading “Independent Variables” do not seem to agree with the literature review or the proposed hypothesis. This reader understood the IV to be type of anesthesia staffing. The introduction of patient demographics is confusing at this point of the manuscript, as are geographic location, and teaching status. Additional explanation for including these variables is needed. Finally, the last “independent variable” presented is “discharge status (death or living). This reader interprets this as an important outcome variable that should be presented as a dependent variable.

Response: Inclusion of all of these variables is important if we are to accomplish meaningful risk adjustment. To avoid confusion, we added an explanation on P8L7.

The data analysis, using hierarchical modeling, was first introduced to the reader on P9. It would have been helpful to indicate that it was suspected that there were numerous variables that might impact the staffing outcome, and that this method was intended to remove the variability they contributed. The author should be commended for consulting with statistical experts.

Response: Thanks! See response above – we added the reference to risk adjustment earlier in the paper (P8L7) to help the reader understand the necessity of measuring these additional variables.

The results section [P10L3-7] presents a discussion of the sample of hospitals in the first paragraph. The sample is actually the number of patients cared for by CRNAs and those cared for by MD's. Information about the patients for whom the outcome is being measured is not referenced until P11L19 refers to Table 3. The reader would appreciate this information sooner in the results section. A description of the hospitals from which the sample has been drawn can be presented in a Table.

Response: We again remind the reader that the sample is number of patients cared for at hospitals that employ only CRNAs vs. hospitals that employ only anesthesiologists. This distinction is very important, as it more accurately reflects the nature of the data. We are only able to measure hospital-level effects, not provider-level effects. We are convinced that this does not detract from the importance of the study, however, as it is at the hospital level that these types of policy decisions are made.

P10L13 describes the “majority of obstetrical complications” yet no percentages or numbers are provided either in the narrative or the Tables. If the author believes that these data are important, then specific values should be included.

Response: Table 4 (P26) was added to address this issue.

P11L7-17 presents data analysis that is not related to the study, was not presented in the literature review or the hypothesis. However, this is important information for the study. The reader would recommend a heading of “Additional Findings” to focus on this information. In addition, the raw numbers of these complications should be provided.

Response: Both of these recommendations were followed – see P28 for the table and P13L17 for the narrative.

P11L21-22 The statement that death rates were extremely low and there was no significant difference needs clarification. It is very likely that the reason there is no significant difference is because the rate was low, the cell size to appropriately analyze these differences should be noted.

Response: Reference to low death rates was removed P12L21-P13L3. Death rates were shown but not remarked upon except to say that only one had an associated anesthetic complication. We removed any discussion of the death rate because we felt it did not add to the study (since it was so low) and only left in the few notations (along with a *p* value showing no difference) in the text and Table 5 to answer the inevitable questions about what it was.

P12L12-16 describes CRNA-only and MD only hospitals. The reader is confused as to the description; does the author mean CRNA only C-section hospitals? P13L1-6 discusses co morbidities. It is unclear whether the author is inferring that there are sample differences between the CRNA and MD C-section patients. This difference could be a major influence on the study findings and needs further description or analysis.

Response: See our responses above with regard to hospital-level effects vs. provider-level effects. We hope that we clarified this point in the

Introduction (P6L16) and in our hypothesis (P7L6), as well as being careful to always state our emphasis was on type of staffing hospitals or groups choose (a hospital-level effect), not type of provider. We hope we have not disappointed the reader because of this distinction.

The discussion section reports a finding of no difference in complication rates, an important finding. The author would appreciate framing this finding in light of the proposed hypothesis.

Response: Done – P16L11-16

The discussion section is presented in 5 pages of narrative text. Woven throughout the discussion are pieces of the research conclusion [P13L16-18, P15L5-12] methodological decisions [P14L8-10, P14L18-20, 22-23, P17L3-22, P18L12-16], findings [P14L12-13, P15L1-4] better relocated to their respective sections. There is little discussion of how this study compares or adds to the body of existing literature as few citations are found. The only relevant item is found in the limitations section [P18L3-4]

Response: the paper was re-written to relocate this text. References to adding to the body of literature was added (P14L11-P15L5), as well as pointing out that this is the first use of this unique measure (P15L5-11)

The limitations section is useful for the reader to better understand the methodology. Some of these limitations would have been better placed under the data sources earlier in the manuscript [P15L18-23]. The statement on P16L13-17 is confusing and seems to minimize the findings. This reader believes that the intent of the study was to compare the two providers. The economic explanation that follows [P16L17-22] is not supported and this reader feels that health care providers would not be likely to sacrifice patient outcomes for economic reimbursement.

Response: Re-written to accomplish these changes, and emphasis made so that the reader will understand that the comparison is between two types of hospitals. Economic explanation was removed. We also made the point that it may be an anesthesiology *group* that is making the decision, as it is often anesthesiologists who head the hospital anesthesia department who make the decision to employ only CRNAs for OB (P14L11).

There are four Tables which supplement the results section. Table 1 is very detailed. The category and content of the ICD codes does not add to the discussion. Perhaps a simple list of general complications with an example would be adequate, for example: pulmonary e.g. aspiration. Table 2 list the variables considered for risk and how the variables were dichotomized. The reader would suggest actual n values for each category as well as the incidence of the co morbidities. Staffing is the independent variable and does not belong in the Table

2 but could be moved to Table 3. Table 3 has several items that were not part of the original study, i.e. number of deaths for all obstetrical procedures and deaths per 100K procedures. The rationale for including this data is not clear. The information in Table 4 also is not clear as to why it was included, i.e. postpartum hemorrhage which is not an anesthetic complication.

Response: There are now 6 tables to address reviewer's request for more data. Tables were changed to add more specific data.

The organization of the paper has been addressed. A clearer presentation adhering to steps of the research process would assist the reader in understanding the method and findings of this important work. The writing style is clear with few grammatical errors. The writing style of the data analysis differs from that of the remaining manuscript and could use some editing for clarity and flow.

Response: The data analysis section was re-written with an eye to a more flowing style. See P10L17-P11L10.

Reviewer #2 –

An interesting paper on a contentious area in health policy and of ongoing concern to nurse anesthetists and advanced practice nurses more broadly. The authors are to be congratulated on creative use of secondary data.

I find the results credible and the methods appropriate. There are a few details that I think would provide additional credibility, especially when attacked from the “outside” (interest groups outside nurse anesthesia):

1) Methods are really important here. I agree with the modeling strategies used. The analysis section of methods should be broader than the “Model Development” description and should directly anticipate the material presented in the Results section (point by point). The tables are incomplete as provided.

Response: Tables were revised and added. The analysis section was re-written to give a better step-by-step explanation of how the datasets were constructed and manipulated.

2) Descriptive statistics regarding the demographic and clinical characteristics and actual outcomes in the two groups (CRNA vs. anesthesiologist staffing model) should be provided (i.e. fill in Tables 1 and 2 somehow with some descriptive data and put material in “Variation in Demographics” in its own table—in addition to descriptive text). The “Incidence of Comorbidities” text at the top of page 13 is not sufficient—the readers need to see the actual numbers.

Response: Tables added and revised - see Tables 3 and 4

3) The exact nature of the final risk adjustment model (that enables fair comparisons between these hospitals that clearly treat quite different patient populations) should be stated clearly (does it include everything other than pulmonary embolism?) as well as some indication of goodness of fit and/or C-statistic performance. What exactly is Panchal's revision of the Charlson index—does it consist of the comorbidities listed on pages 27 and 28?

Response: Explanation of variables used in risk adjustment was added (P8L7). Reference to Charlson index was removed, and a better explanation of the method used by Panchal was given (P8L21-23)

4) How does death rate fit into the modeling done in this paper? How does non-C-section mortality fit into the story? (I'm not entirely clear where these statistics come from given that the only subjects of the study are declared to be C-section patients only (p. 6)). [These are all points that could be at least partly clarified by walking the reader through the analysis that was done to obtain the results reported—step by step.] Also, some explanation of the relevance of C-section rates in the hospitals would be helpful. Overall, the flow of findings, particularly outside the major one (no difference in risk-adjusted anesthesia complications) is not as clear as it might be. I believe I understand the points the authors are trying to make, but sequencing needs to be clearer.

Response: We removed references to all OB patients, sticking just to C-section patients, as the reader is correct that this was our sample. We walk the reader through this in the "Model Development" section, P9L2-P10L12. We also dropped many references to death rates, as this was not the variable we studied- we just kept it in because it would be such an obvious question for anyone reading the paper.

5) There needs to be some discussion on a conceptual or theoretical level about death as an outcome, complications as an outcome (how would provider credentials potentially affect either or both) and the statistical power considerations involved. These ideas belong in the introduction and methods sections—and should not be reserved for the discussion section alone.

Response: Death as an outcome (and as an unsatisfactory outcome measure) was written in more extensively in the introduction (P5L1-L15, P6L1-2), and also (briefly) in the data section (P9L8-11)

6) The authors include multiple years of data (a decade) in their modeling. Did complication rates remain identical across these years? Do results change at all if year dummy variables are included? Such results probably the ones presented.

Response: In our analysis, complications were randomly distributed across the years, and there were no trends noticed. For that reason, we decided to treat the entire period as one cohort.

7) Table 4 is not sufficiently documented to allow readers to interpret it on a stand-alone basis and is referred to out of sequence if the readers are following the article text.

Response: Table 4 was redone and simplified. It is now Table 5. The additional findings were placed into table 6.

I am wondering if the authors might consider doing a little more thinking (and writing) about conclusions that can and cannot be drawn about safety of care on the basis of complication codes of questionable reliability and validity (these limitations are of their own admission and are endemic to this type of research). I am not suggesting the authors undermine their paper, but a little more thought that lines up limitations (particularly in the key outcome variable) with the conclusions being drawn would take this article “to the next level” (to use the vernacular).

Response: Our discussion section now includes a greater discussion of the role of the anesthesia complication codes in identifying quality outcomes (P15L7-P16L3). The limitations section was also re-written.

More of the material about the underlying policy issue belongs in the introduction of the article rather than the discussion. The relevance of the article as boiled down in the last paragraph of the introduction is oversimplified and needlessly inflammatory. Salaries are an issue—availability of the anesthesia providers for work in specific geographical areas is another. The financial implications for a hospital that staff with CRNAs are a little more complicated than the authors let on. Mention of CRNA versus physician anesthesiologist salaries on page 6 is probably gratuitous without more context. This particular paragraph needs more work.

Response: The introduction was completely re-written. The inflammatory portions of the discussion were removed. A point we tried to make is that it may be anesthesiologists who are making the choice to use all-CRNAs in OB- reimbursement may make it the only way the group can profitably provide the service.

Thanks to both reviewers for the thoughtful and thorough review. Hopefully we have addressed all of your concerns.