Commentaries

Commentary: What Conclusions Can We Draw from Recent Analyses of Anesthesia Provider Model and Patient Outcomes?

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In the April 2009 issue of *Health Services Research*, Needleman and Minnick (2009) explore the relationship between anesthesia provider credentials and maternal outcomes. They pose questions with potentially significant implications for the delivery of obstetric care in the United States, where hospitals vary in the models they employ for the provision of anesthetic care for labor and delivery.

This study builds upon the authors' prior work, which describes five distinct anesthesia provider models based on reports from 613 hospitals in eight states (Minnick and Needleman 2008). In the present study, they compare rates of mortality and key complications among mothers following delivery at facilities distinguished by the relative participation of anesthesiologists and Certified Registered Nurse Anesthetists (CRNAs) in obstetric anesthesia care at each hospital. Needleman and Minnick use multivariable regression models in an effort to adjust for a number of observed confounders, including patient comorbidities and hospital characteristics, and conduct propensity score-matched analyses in an effort to control for patient selection according to hospital type.

Despite the authors' efforts to limit the effect of important biases in this work, our review of the paper leaves us with concerns surrounding the authors' conclusions. Having found no systematic differences in the rates of patient complications in hospitals employing different anesthesia provider models, Needleman and Minnick (2009) conclude that "these findings do suggest, that at least in the area of obstetrical anesthesia services, there may be no gain in anesthesia safety from restricting which licensed providers can provide these

services.” The authors cite work by an author of the present commentary that emphasizes the need for caution in making clinical or health policy recommendations based on retrospective analyses of cross-sectional data (Fleisher and Anderson 2002). In the present commentary, we discuss sources of bias that may remain in Needleman and Minnick’s work due to the influence of unmeasured but potentially important clinical confounders. We ultimately find that the authors’ results support multiple conflicting interpretations with drastically different implications for health policy, and put forward a similar caution in using their analyses to generate specific health policy recommendations.

ADDRESSING PATIENT SELECTION

Needleman and Minnick point out that important differences may exist between patients receiving obstetric anesthesia care from differing provider models, stating that “selection may play a substantial role in the choice of hospital by women with high-risk pregnancies.” Indeed, the American College of Obstetricians and Gynecologists recommends selective referral of high-risk obstetric patients based on hospital resources for care. Providers at Level 1 facilities, which offer basic obstetrical care for uncomplicated labor and delivery patients, are required to conduct risk assessments to ensure appropriate referral of high-risk patients to centers capable of providing advanced subspecialty care (American College of Obstetricians and Gynecologists 2007).

As a result of these requirements, selection effects are likely to be important determinants of the risk profiles of the obstetric patients receiving care in a given facility. Such an observation has important implications for the present analysis; Level I facilities are disproportionately represented in hospitals that the authors classify as “CRNA-only,” where obstetric anesthesia care is provided primarily by CRNAs. In their prior work, the authors found 86 percent of “CRNA-only” hospitals to be Level 1 facilities; in contrast,

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the fraction of Level 1 facilities among hospitals employing other anesthesia provider models was smaller, ranging from 35 to 51 percent (Minnick and Needleman 2008). Comparisons of patient outcomes between “CRNA-only” and other types of hospitals are thus likely to reflect institutionalized processes of patient selection based on maternal and fetal risk factors.

The authors make efforts to adjust for selection effects by including controls for patient risk and hospital characteristics in their regression models, and use propensity scores to match patients on their likelihood of receiving treatment at a facility employing a particular model of anesthesia care. Despite these efforts, potentially important sources of bias would still remain if unobserved differences in clinically relevant risk factors existed among the groups under study.

While a theoretical risk of bias due to unobserved confounders exists for any cross-sectional analysis, there is reason to suspect that unobserved differences among the groups that Needleman and Minnick study may be of particular clinical relevance here. Important comorbidities known to be prevalent in the population occur at surprisingly low rates among their study sample. These include diabetes, which increases the risk of fetal macrosomia, in turn adding to the risk of a forceps or Cesarean delivery (Casey et al. 1997) and maternal obesity, which increases the risk of emergency Cesarean delivery and worsened maternal outcomes (Cedergren 2004; Villamor and Cnattingius 2006; Poobalan et al. 2009). While recent studies have estimated diabetes and obesity to occur in 6 (Ferrara 2007) and 22 percent (D’Angelo et al. 2007) of all U.S. pregnancies, these conditions were reported in only 0.54 and 0.59 percent of Needleman and Minnick’s sample. Such large differences in the rates of comorbidities known to increase the risk of adverse maternal outcomes suggest that the study dataset may not accurately reflect the true prevalence of these factors, limiting the authors’ ability to adequately adjust for them.

Further shortcomings in risk adjustment are suggested by the magnitude of the differences predicted by the study’s multivariable analyses, some of which are so large that it is difficult to reasonably attribute these findings to differences in anesthesia provider model. The study’s propensity-weighted regression results indicate that the odds ratio for mortality is 0.208 ($p < .05$) in hospitals where CRNAs provide the majority of obstetric anesthesia care versus those employing an “anesthesiologist-only” model. Similarly, mothers receiving care in facilities where anesthesiologists closely supervise CRNAs also have a pronounced decrease in the odds of death versus those receiving care in “anesthesiologist-only” hospitals (OR: 0.225, $p < .001$). Clinical experience makes it hard to attribute these four- to five-fold reductions in the odds

of death to differences in anesthesia provider model; rather, such differences are more likely to point to inadequate adjustment for important unmeasured differences in patient risk between these groups.

Alongside their analyses of maternal mortality and anesthetic complications, the authors examine other complications of labor and delivery that may relate to differences in the quality of general obstetric care provided to the comparison groups. They examine the Agency for Healthcare Research and Quality's (AHRQ) obstetric trauma indicator, which refers to the occurrence of a third- or fourth-degree perineal laceration (AHRQ 2007). The authors correctly note that this is "a complication in which anesthesia provider is unlikely to be involved operationally." Such an outcome would be inappropriate as a basis for comparison of anesthesia care models, but rather is likely to relate to nonanesthetic elements of obstetric care, such as performance of a midline episiotomy or an instrumental vaginal delivery (Angioli et al. 2000).

The authors observe a large *decrease* in the odds of death in facilities where anesthesiologists closely supervise CRNAs versus those where anesthesiologists work alone; however, they note a pronounced *increase* in the odds of a severe perineal laceration in both unweighted (OR: 1.299, $p < .05$) and propensity-weighted regressions (OR: 1.380, $p < .001$), when comparing these groups. If the AHRQ obstetric trauma indicator can reasonably be considered to reflect the quality of nonanesthetic obstetric care, the decrease in the odds of maternal mortality that the authors describe thus may occur despite worse obstetric care. Again, we find this pattern difficult to attribute to differences in the care provided by anesthesiologists versus CRNAs, and we posit instead that it points to the presence of clinically relevant unmeasured differences among the groups they study.

The authors report performing further analyses to estimate the impact of incomplete adjustment for selection bias by omitting from the sample those hospitals most likely to be referral centers for high-risk patients. The results of these analyses were unchanged from those presented in the body of the paper; still, potential shortcomings in adjustment for clinical risk factors would nonetheless limit the authors' ability to account for selective referral of patients that may still occur between lower-acuity centers.

Ultimately, we find Needleman and Minnick's results to be consistent with multiple interpretations, including conclusions opposite those which they draw from their results. The authors state that CRNA-only hospitals "do not have systematically poorer maternal outcomes" than do anesthesiologist-only facilities, and state that these results argue against restrictions on "which licensed providers" can deliver obstetrical anesthesia services. At the same

time, though, the study results also may argue *in favor* of such restrictions. In fact, the lack of systematic differences in patient outcomes occurs in the context of existing processes of triage that encourage referral of high-risk patients away from “CRNA-only” facilities. As a result, the study findings may document effective processes of selection and triage in which high-risk mothers are matched to appropriately skilled providers. Such processes could occur both through triage of high-risk patients among facilities of differing capabilities, as well as through selective referral within facilities of patients to anesthesiologists or CRNAs on the basis of underlying risk. Thus, Needleman and Minnick’s findings are consistent with the argument that current tiered provider privileges may offer benefits to patient safety by supporting effective processes of patient selection.

CONCLUSIONS

Needleman and Minnick employ multivariable regression techniques and propensity-score methods to examine an important and challenging clinical and policy research question, and they find few systematic differences in maternal outcomes according to obstetric anesthesia provider model. Based on these analyses, they challenge current restrictions determining which licensed providers may deliver obstetric anesthesia care. Their report, though carefully conducted, nonetheless faces challenges common to cross-sectional analyses of observational data, leaving the conclusions to be drawn from their data highly subject to interpretation. Ultimately, the potential for inadequate adjustment for selection bias makes it difficult to determine just how much their study tells us about the safety of differing provider models for obstetric anesthesia care.

The authors’ introduction cites a paper published in 2002 by an author of the present commentary. In that work, we emphasized a cautious approach to using analyses of secondary datasets to inform clinical and policy decisions, stating that “any clinical or policy recommendations to be derived from this article must recognize the limitations imposed by the data set and this type of analysis. Clinicians need to know that this type of analysis is designed to generate hypotheses, not test hypotheses” (Fleisher and Anderson 2002). Despite the analytic methods used by Needleman and Minnick, these cautions remain relevant to their present work.

Because of the possible effects of unobserved but important clinical confounders, this study cannot support definitive conclusions about the

relative safety of differing anesthesia provider models, nor can it speak meaningfully to the wisdom or folly of “legislating a specific educational credential” (Needleman and Minnick 2009) for the provision of obstetric anesthesia services. We thus urge a cautious approach to the interpretation of this nuanced work and emphasize the need for further research to provide clinicians and policy makers with a sound basis of evidence for decisions that can promote safety in obstetric anesthesia care.

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