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In Reply:

We appreciate the thoughtful attention that Dr. Hofer and colleagues have given our article describing the advantages and disadvantages of reliability, or “shrinkage” adjustment.¹ Their title, “Current Quality Registries Lack the Accurate Data Needed to Perform Adequate Reliability Adjustments” may be accurate for the anesthesia data collections they mention but not for all surgical quality registries.

Dr. Hofer and colleagues’ message about the importance of measurement error cannot be understated. Measurement error, whether in administrative data or in registries, undermines both the validity and utility of quality measurement. When reliability adjustment is applied, unmeasured patient and case-mix factors leave “residual” variation that may be falsely attributed to hospitals or physicians rather than inadequate risk adjustment.² With or without reliability adjustment, measurement error is critical when benchmarking quality across hospitals or physicians because federal mandates are linking payment to outcome-based performance measurement.

Physicians and hospital leaders already appreciate that meaningful outcomes comparisons are very costly to produce, particularly when accrued through a clinical registry and analyzed with the necessary statistical expertise. The first question is whether physicians believe that meaningful outcomes comparisons are important enough to pay for them. The American College of Surgeons (ACS) and the Society of Thoracic Surgeons (STS) staked out their positions on this issue decades ago and currently generate the highest-quality outcomes data in surgery while stewarding multiple measures in the National Quality Forum.^{3–5} Some may wonder why anesthesiologists have not taken a similar leadership position.⁶ However, it is important to consider that (1) participation in these registries is costly, (2) neither the ACS nor STS registry outcomes are part of current or proposed Centers for Medicare and Medicaid Services payment programs, and (3) the jury is still out on whether participation in ACS or STS registries improves quality.^{7,8}

So how can anesthesiologists improve the quality of quality measurement? This is crucial because mandated links between payment and “performance” are moving forward with or (more commonly) without high-quality measurement science. Solutions are many: investing in anesthesia registries, fostering partnerships with surgeons to share the costs of registries, and uniting with surgeons and nurses for a stronger political voice. In brief, anesthesiologists must

either “pony up” the financial and leadership costs of performance measurement or risk being left in the dust.

Competing Interests

The authors declare no competing interests.

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Steroids Do Not Reduce Persistent Pain after Cardiac Surgery: Should This Be the End of the Question or the Beginning of Newer Questions?

To the Editor:

We read with interest the study by Turan *et al.*¹ on the use of methylprednisolone for persistent incisional pain after cardiac surgery. This substudy was done on 1,110 of the 7,500 patients included for the Steroid In caRdiac Surgery (SIRS) trial.² The

This letter was sent to the author of the original article referenced above, who declined to respond—Evan D. Kharasch, M.D., Ph.D., Editor-in-Chief.

James C. Eisenach, M.D., served as Editor-in-Chief for this exchange.

treatment group received 500 mg methylprednisolone (given as 250 mg doses at induction and cardiopulmonary bypass), and the placebo group received comparable placebo. The study failed to show any difference in the incidence of persistent incisional pain, measured as 0 to 10 numerical rating scale, both at 6 months (primary) and 30 days (secondary). Considering that this is the largest study ever published on the use of steroids for reducing persistent postsurgical pain (PPSP), it could be interpreted as an argument against the use of steroids in PPSP for future studies. However, we would like to highlight some important considerations with regard to this argument and say that this should probably lead to newer questions and hypothesis on the future use of steroids, rather than making it a death knell on the use of steroids for PPSP.

Like any other intervention, the use of steroids for reducing PPSP has to be considered from two different fronts. *Mechanistically*, there is a strong argument for modifying the inflammatory response associated with surgeries with a significant potential for PPSP, more so of the neuropathic type. The inflammatory mediators can sensitize and stimulate peripheral nerve endings, cause excitation of dorsal horn cells, and also cause activation of microglia and astrocytes, which are now appreciated to play an important role in neuropathic pain.^{3,4} Among inflammatory mediators, neutralizing the responses to interleukin-6 can also alter the perception of pain, beyond the changes in thermal and mechanical sensitivity.⁵ Overall, there is increasing appreciation that chronic inflammation and nerve injury have strong pathophysiologic link, with one feeding to another in more than one way. Inflammation can be considered as a potent driver of PPSP, more so with nerve injury, and hence the neuropathic type of pain.

From an *existing clinical evidence perspective*, corticosteroids, being potent antiinflammatory agents, have shown perioperative benefits for various surgical outcomes such as improvement in postoperative nausea–vomiting, acute pain, and even overall surgical recovery.^{6,7} Unfortunately, other than for postoperative nausea–vomiting prevention, the dose–effect relationship, choice of corticosteroid agent, and its necessary duration of treatment have not been established for specific surgical outcomes. Although most studies tend to use a single dose, the actual dosage (in equivalent doses) has a very wide range. For major abdominal surgeries, the doses ranged from 8 mg dexamethasone (40 mg methylprednisolone) to 30 mg/kg methylprednisolone.⁸ For cardiac bypass, the most common dose was 60 mg/kg, which is eight times the dose that was used in the SIRS trial. Dexamethasone has a much longer half-life than methylprednisolone (36 to 54 h *vs.* 18 to 36 h), and it was used in a dose of 1 mg/kg for the Dexamethasone for Cardiac Surgery trial.⁹

Thus, a failure to show a significant reduction in PPSP in the SIRS substudy could be attributed to several factors. The inflammatory response, including its intensity and temporal trend, and its correlation to persistence of pain could be different for different surgical categories. It is possible that

surgeries with a higher proportion of neuropathic pain have a much closer link with inflammation, possibly as an autoimmune reactivity.¹⁰ Only a total of 10 patients had neuropathic pain in the SIRS substudy at 6 months.¹ Finally, as reported by the SIRS substudy investigators, other important factors such as differences in surgical and anesthetic techniques and postoperative analgesic management, which were not controlled, could have played an important role.¹

We believe that future studies must consider assessing the potential value of steroids in a different population, possibly with a much higher risk of neuropathic pain such as amputation, thoracic surgeries, or radical mastectomy procedures, perhaps as more than a single dose and using longer acting agents. Although the potential adverse effects of steroid remain a cause of concern, it is reassuring to know that studies (including large studies such as dexamethasone for cardiac surgery and SIRS) so far do not support this claim.

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Competing Interests

The authors declare no competing interests.

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Is It Time to Ask Different Questions about Aspiration?

To the Editor:

I read with interest the report by Beach *et al.*¹ on the relationship between nil per os (NPO) time and major adverse events, with special attention to pulmonary aspiration. The authors conclude that NPO status is not an independent predictor of major complications.

As reported in other studies,^{2,3} the incidence of pulmonary aspiration was found to be quite low, with only 10 cases out of over 139,000 pediatric sedations collected between 2007 and 2011. It is noteworthy that NPO definitions within the Pediatric Sedation Research Consortium database (solids, 8 h; nonclear fluids, 6 h; and clears, 2 h) are out of step with the most recent American Society of Anesthesiologists guidelines from 2011,⁴ which recommend 6 h for formula/milk and “light” solids, 4 h for breast milk, and 2 h for clear liquids. Many Anesthesiology departments, including ours at Vanderbilt University, Nashville, Tennessee, have moved all solids to a fasting time of 6 h. By this measure, all of the 10 cases of aspiration would have been NPO appropriate with no episodes in those not NPO.

A look at Emergency Medicine literature^{5,6} shows a low incidence of aspiration even in nonfasted patients, many of whom are likely to be in pain. The American College of Emergency Physicians published a clinical policy in 2014⁷ recommending that procedural sedation in the Emergency Room not be delayed solely due to NPO time. Unfortunately, the data presented in the study by Beach *et al.* are not broken down into elective *versus* emergent procedures. Additionally, the type of provider (emergency physician *vs.* other) cannot be used as a surrogate marker as emergency physicians often provide elective sedation services outside of the Emergency Room.

So where does this leave us? We are not suggesting, based on current evidence, that we reduce the NPO times for elective general anesthesia cases with planned airway instrumentation. But perhaps we should rethink the questions that we need answered regarding NPO in pediatric sedation.

What about emergent procedures without planned airway instrumentation? Many in emergency medicine would counter this question has already been answered. Can we quantify the risk of aspiration with planned airway instrumentation *versus* unplanned *versus* none at all? Does ketamine or dexmedetomidine, which preserve respiratory drive and airway tone better than propofol, offer a safer alternative in the nonfasted patient? All of these questions will be difficult to answer given the very low incidence of aspiration but we should certainly try.

Competing Interests

The author declares no competing interests.

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In Reply:

We appreciate the careful review of our article.¹ We agree with the authors that other studies also support the low incidence of aspiration in pediatric sedation. While the study by Walker² of 118,371 pediatric patients is also large, only information on the 24 cases of aspiration was collected. Our study collected data on all patients, allowing us to evaluate risk