“Intra-abdominal Irrigation at Cesarean Delivery: A Randomized Controlled Trial”
(Reagan Viney, MD, Christine Isaacs, MD, and Dave Chelmow, MD)
Click Here to Read the Full Article

1. Review the trial as posted in ClinicalTrials.gov. How does the “Purpose” of the study in ClinicalTrials.gov compare to the abstract “Objective”? Why might these be differently reported?

2. Review the primary completion date in ClinicalTrials.gov. Why might it take 16 months to report the findings? How long might you expect it to take from completion of the trial to submission for publication? How long is too long?

3. The authors hypothesize at the end of the introduction that irrigation would decrease intra-operative nausea and vomiting. What is the clinical rationale for this hypothesis? Why might irrigation decrease nausea?

4. The authors state that the patient was blinded to treatment assignment. Review what is blinding and why is it important.

5. The surgeons were not blind to the treatment. How might this affect outcome? Given that the primary outcomes were infectious or gastrointestinal related, is it possible that a surgeon who believed one treatment was better than another might affect the findings?

6. How was nausea assessed in these patients? How objective is this outcome? If you were to design this trial, is this an outcome you would choose? Why or why not?

7. Discuss the timing of the consent process. Why would they obtain consent on admission to labor and delivery, given that many patients will not be eligible due to vaginal delivery? Why might this be the optimal time to obtain consent? If you were to design a similar study, when would you obtain consent from the patient?

8. Randomization occurred at the time of cesarean. The authors state specifically that “block design was not used.” What does this mean? Why would you use a block design? Why do you think they did not? Are there times when block design is more appropriate or essential?

9. In the “Methods” section, the authors state that the study was “stopped halfway through to allow for planned midpoint data analysis for resident research day.” Discuss interim analyses. Is it appropriate for the principal investigator of the trial to review the results midway through the trial? Is it appropriate to present them? Is there any concern to presenting them? How might it affect the trial if the results appeared favorable or nonfavorable? Is it more likely to be a concern in a blinded or unblinded trial?

10. How do you handle the post-hysterotomy closure—do you routinely irrigate? Why or why not?

11. Will the findings of this trial alter your practice? Why or why not?