Learning From Others:

A Case Report From the Anesthesia Incident Reporting System

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Review of unusual patient care experiences is a cornerstone of medical education. Each month, the AQI-AIRS Steering Committee abstracts a patient history submitted to the Anesthesia Incident Reporting System (AIRS) and authors a discussion of the safety and human factors challenges involved. Real-life case histories often include multiple clinical decisions, only some of which can be discussed in the space available. Absence of commentary should not be construed as agreement with the clinical decisions described. Feedback regarding this article can be sent by email to **airs@asahq.org**. Report incidents or download the AIRS mobile app at **www.aqiairs.org**.

Case 2019-12: Whose life is it anyway? Mandatory pregnancy testing and the concept of patient autonomy

Patient was located in the preoperative area when seen by the anesthesia team. Consent and H&P reviewed; the patient was A&O x1 and no family was available. Once we arrived in the operating room the operating room supervisor came in and told us not to proceed with the surgery since we did not have a pregnancy test. The patient was then taken back to the preoperative area and fully monitored while the O.R. supervisor talked to the patient. The surgeon was called and decided to cancel the case for today.

Discussion

ASA's Task Force on Preanesthesia Evaluation published a practice advisory for preanesthesia evaluation in 2001. The Task Force believes that the literature is inadequate to inform patients or physicians on whether anesthesia causes harmful effects on early pregnancy.[1] The Advisory recommends that pregnancy testing be based on *risk for fetal harm during the procedure*, and focuses on surgeries that involve female reproductive organs or their blood flow.[2] For the rest of women presenting for surgery, the Advisory recommends that pregnancy testing "may be offered to female patients of childbearing age and for whom the result would alter the patient's management."[2] This is based on the evidence that anesthesia agents are not teratogenic; although we cannot conclusively state that anesthesia in early pregnancy does not increase fetal loss or affect neurological development, neither pose a known or quantified risk in the first weeks of gestation. A comprehensive review of the topic was published in a *Monitor* article in 2018; it is clear from this incident that many perioperative teams have not followed ASA's lead.

As stated by ASA, there are clear indications for pregnancy testing. Certainly testing should be performed whenever there is a clear risk to the fetus, such as surgery involving the uterus, the ovaries or fallopian tubes, or surgeries that could disrupt blood flow to these organs. Not stated by ASA, but certainly within the same context, would be procedures involving radiation exposure to the pelvis, or administration of non-anesthesia drugs that ARE known to be teratogenic. One can also postulate other indications for pregnancy testing, such as prior to bariatric surgery, where pregnancy after surgery could obviate the benefits of the surgery (i.e., intended weight management and weight loss).

Despite these clear recommendations from ASA, which are supported by medical ethicists, many hospitals across the U.S. continue to require that every female of child-bearing potential undergo a pregnancy test prior to surgery, due to perceived risk that is based more on dogma and physician protection than on scientific certainty. This routine, non-consented screening poses significant conflict with one of the core tenets of medical ethics, that of patient autonomy, i.e., the concept of self-determination. Anesthesiologists and surgeons alike may point to a second tenet, that of nonmaleficence, or "do no harm," defending mandatory testing in the mistaken belief that anesthesia or surgery in the first trimester presents a real danger to the fetus. The data do not support this fear. Furthermore, even if a small risk would be present, the parochial view that we as physicians will make better decisions for these women than they can make for themselves is misguided at best, and arrogant and over-reaching at worst. As our daughters would say, "definitely not woke."

We do know with certainty that no anesthetic agents are teratogenic, with perhaps the exception of cocaine. As stated by Dr. Jackson in a recent article in the *ASA Monitor,* "there now exists a large body of scientific evidence

supporting the safety for the fetus and pregnancy."[3] What is less certain is whether or not anesthesia or the stress of surgery increases the risk of spontaneous abortion in these early pregnancies. The relatively high incidence of spontaneous abortion in the first 6 weeks of pregnancy (generally accepted to be at least 30 percent) coupled with the very low risk of unrecognized pregnancy at presentation for surgery (in several studies, only 0.3 percent)[4] make an RCT impractical due to the massive sample size, even if an IRB would endorse such a study. Two studies, one from Canada[5] and one from the U.K.,[6] seem to indicate a slight increase in the rate of spontaneous abortion in women having surgery at any time in the pregnancy. The studies in question involved obstetrical and gynecological surgeries such as those to prevent miscarriage (cerclage) and ovarian surgery. To be blunt, there are no data that support an increased risk in the first few weeks of conception.

We agree that the tenet of nonmaleficence, that of "do no harm," should be invoked but it should also include possible risk to the woman in question. The evidence stated above would indicate that there is virtually no known harm that would come to the fetus through proceeding with anesthesia and surgery in a case of unrecognized pregnancy; one can, however, postulate harm from not proceeding, whether it is delay in needed therapy, loss of wages inherent in taking time off for a procedure that is cancelled or, perhaps most importantly, the willful dismissal of the patient's right to choose for herself, to determine what happens to her.

One can also point to the fact that mandatory pregnancy testing does not align with the rest of medical care vis-à-vis nonmaleficence and unrecognized pregnancy. It is well established that doxycycline or any of the major anti-depressive agents are teratogenic; mandatory pregnancy testing does not occur prior to initiating antibiotic therapy or treatment of psychosis, *unless it involves anesthesia* (ECT). If our rationale for testing women for pregnancy prior to surgery were actually to prevent any harm from coming to the fetus, we would surely also test in these instances. To date, the only medication that routinely involves pregnancy testing is Accutane; a recent study found that only 22 percent of women who were prescribed teratogenic drugs (FDA category X) received pregnancy testing prior to the prescription.[7]

We need to consider as well our vulnerable patients, especially our mentally challenged and our adolescents. This reported simply notes "A&O x1" which appears to indicate a mentally challenged patient; family was not available. This is a particularly difficult case: with no guardian or individual with medical decision-making legal rights, there was no one to make the decision around whether or not pregnancy testing should be done. In this case, then, cancellation was likely appropriate.

Our adolescents pose unique challenges as well. Some girls begin menstruating as young as 9 or 10; despite the fact that this is clearly a child, mandatory pregnancy testing is performed regardless of parental wishes. In some circumstances, an unexpected pregnancy in a young unmarried woman could have dire consequences, including death, when a family member commits murder in a ritual of familial honor. Granted, the issue of a pregnancy in a minor or unmarried young woman would have to be addressed eventually, but at a time and place of the young woman's choosing. In addition, many parents are rightly outraged that they cannot refuse this test on their child, feeling that (rightly so) they are being deprived of their parental right to make decisions for their child. Although some hospitals make provisions for telling the patient her pregnancy results in private, the mere fact of asking the parents to leave the room will arouse suspicion. Savvy parents will likely assume correctly that the pregnancy test is positive, making the attempt to give the result in private nonsensical, particularly if the surgery is then cancelled.

Continuing with the tenet of patient autonomy, every woman of child-bearing age, where there is not a clear risk to the fetus, should certainly be offered the opportunity to have a pregnancy test prior to proceeding with surgery. She should be offered both information and the opportunity to ask questions about this issue, including the possibility of a false negative or a false positive, the non-existent risk of teratogenicity from anesthesia, and the fact that we cannot guarantee that there are possible risks that have not been quantified, such as those of miscarriage or altered neurological development. Again, we have no data that demonstrate a risk, but absence of proof is not proof of absence. It is likely that the average woman of childbearing age who is potentially pregnant (sexually active with inconsistent contraception) will opt to have a pregnancy test.

That brings us to the decision of whether to proceed with surgery if the woman chooses to not have a test or the test is positive. The ASA position is that testing be offered "if the result would alter medical management"; the "change in medical management" should not include a knee-jerk cancellation of the surgery. Given that there are no

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known risks to the fetus of proceeding with surgery in a very early pregnancy, the choice to go forward with surgery should be the woman's. After all, even if testing is uniformly performed, and the test is negative, the known false negative rate guarantees that we will provide anesthesia for some women who are early in a pregnancy.

Most women, learning that they are pregnant, will likely opt to delay any elective surgery. However, the concept of patient autonomy must drive this decision as well, with the woman allowed to choose for herself whether or not she wishes to proceed. Certainly shared decision-making must be in play, with a discussion between surgeon, anesthesiologist and patient about the risks of proceeding. However, the discussion must adhere to the evidence about risks to the fetus and mother, and not be influenced by the provider's concern about possible litigation. Cases that are simply cancelled without any patient or family participation in the decision go against all recognized ethical principles of health care.

Finally, we should touch on a final tenet of medical ethics, that of social justice. Given the extremely low rate of unrecognized pregnancy, it is estimated that identifying a single unrecognized pregnancy costs around $2,500 to $3,000,[8] a cost with no proven benefit. Across the United States, with 6.7 M surgeries each year performed on women aged 15-44 (2010), the annual cost of testing (estimated cost $5 per test) on all women prior to surgery would have been $33M to uncover 20,000 unrecognized pregnancies: again, without any clear evidence of benefit returned for millions in health care costs.

Proposed discussion day of surgery:

For a woman having surgery with known risks (uterine surgery, etc.):
"This surgery poses a definite risk to the baby, if you are pregnant. Even though you are sure you are not pregnant, because of this very real risk, we need to do a pregnancy test."

For women undergoing all other surgeries:
"There is a small chance that any sexually active woman could be pregnant and not know it. There are many studies of the effects of anesthesia medicines and surgery on a possible pregnancy, and there are no known risks that we have found. However, we cannot guarantee that there are not some risks that we have not yet found, like the chance of a miscarriage, or changes in neurological development of a baby. So we are happy to do a pregnancy test if you would like us to, at no cost to you. If you decide not to have the test and are willing to accept that there could be risks however tiny, we will go ahead with surgery. If you chose to have a pregnancy test and it is positive, we can discuss with you and your surgeon whether we should go ahead with the surgery. It is your right to make this decision for yourself."

Summary

The tenets of medical ethics indicate that mandatory, non-consented testing for pregnancy should not be performed prior to surgery. Pregnancy testing should be based on a potential risk to a fetus, such as surgery on the uterus, ovaries or fallopian tubes, or involving blood supply to these organs. In all other cases, the woman should be offered information about the risks of anesthesia and surgery and allowed to decide for herself whether or not she wishes pregnancy testing. The discussion about risks should include the potential for a false positive or false negative. If the women opts to not have pregnancy testing, the surgery should proceed as though the test were negative. If the test is positive, again, the woman should be offered a discussion of the potential risks, but be allowed to choose whether to proceed with surgery or not.

References:

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