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Covering Practice and Risk Management Issues for Physicians

Obtaining Informed Consent When the Fetus is at the Threshold of Viability

BY MICHAEL KATZ, MD

One of the most difficult tasks confronting a practicing obstetrician is obtaining informed consent from pregnant patients who are facing the possibility of delivering a fetus at 24 weeks gestation, i.e., an infant who is at the threshold of viability. Although this situation is fraught with unpredictable and unknowable variables, recognizing and anticipating specific challenges in advance can help the physician to maximize the chances for a favorable outcome from both a clinical and risk management perspective. Some of the challenges to keep in mind when obtaining informed consent in this complicated clinical situation include the following:

Although this situation is fraught with unpredictable and unknowable variables, recognizing and anticipating specific challenges in advance can help the physician to maximize the chances for a favorable outcome from both a clinical and risk management perspective.

- At this stage of pregnancy even a change of a week or two in the estimated gestational age can make the difference between the infant having a 50 percent chance for survival and an 80 percent chance. Yet even educated and sophisticated couples may be unable to recall exactly when conception took place.
- Not only can the maternal and fetal risk and prognosis literally change with every passing day and week, sometimes the clinical situation demands that decisions be made on very short notice. Thus, the informed consent process is further challenged by the emotional burden of parents having precious little time in which to make potentially life-and-death decisions about their unborn child.
- It is not uncommon to face a situation where the fetal interests would favor to continue a pregnancy, while the maternal interests would favor to shorten it; e.g., a patient with rapidly worsening severe preeclampsia. Rarely are two separate "patients" affected by a single clinical decision. Knowing how to weigh the interests of mother and infant when this "conflict" arises presents a unique challenge.
- To obtain truly informed consent at the threshold of viability, the physician must navigate the murky territory between predictions for a healthy infant versus the risk of heartbreaking and financially ruinous lifelong disability. Physicians who promise too

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much may build unrealistic expectations, while those who predict too little may reduce the chances of making decisions that can result in a healthy infant.

- Whether a child was impaired by the extremely early birth may not be known for many years when there is relatively little, if anything, that can be done about it. Therefore, whether or not the parents and physician made the "right" decision may be subject to retrospective contemplation (and potential medical-legal criticism).

When decisions have to be made well before 24 weeks, the threshold of fetal viability, it is substantially easier to give the highest priority to the immediate maternal medical needs. There are relatively very few instances where physicians would recommend that a pregnant mother take significant personal risks when the chances of neonatal survival are small. On the other hand, at 26 weeks' gestation, fetal/neonatal considerations often become the dominant factor in decision-making as the neonatal survival rate often exceeds 80 percent. Therefore even relatively small risks to fetal/neonatal well-being are taken into account. An example is the current universally accepted recommendation to deliver all breech presentations at 25+ weeks via cesarean section. In this situation the mother is exposed to the risk of surgery in order to avoid a relatively minor increase in the risk of fetal/neonatal birth trauma.

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Unfortunately, the data about fetal/neonatal outcome at the threshold of viability is somewhat "murky" and lends itself to different interpretations. Let's take the specific example of Julia, a 45-year-old pregnant woman, and her husband, Robert. Julia presented at the obstetrics reception unit last year at exactly 24 weeks' gestational age and was found to be completely dilated with a fetus in breech presentation. Delivery could be imminent, and if the intent is "aggressive" management (to spare fetal delivery trauma), one would recommend a cesarean section. On the other hand, if the parents would choose not to pursue "aggressive" intervention, she will be delivered vaginally. A similar decision dilemma commonly arises when a non-reassuring fetal heart rate is observed at this gestational age. There is a limited amount of time to share critical information with the couple because without moving immediately to cesarean section, a vaginal delivery is imminent. The complexity of giving informed consent in this situation can be summarized by recognizing that performing a cesarean section will result in a 56 percent chance of taking home a live infant, but only 18 percent of these neonates will be without some medical disability. This disability can range from some minor hearing loss all the way to mental retardation and cerebral palsy. On the other hand, not performing a cesarean section will result in a 32 percent chance of taking home a live infant, but only 13 percent will be without some medical disability. How does one present these data? On the one hand the physician could say "The difference in the chance of a perfectly healthy baby between the "aggressive" and "non-aggressive" approach is only five percent (18 percent vs. 13 percent)"or one could say "An aggressive" approach will increase the percentage of taking home a healthy infant by 41 percent (the percentage difference between 13 percent and 18 percent)."

Julia and Robert decided, as many of our patients do, to proceed with the "aggressive" approach. Their daughter was born and spent the first 22 weeks of her life in the Newborn ICU. She was discharged home with some ongoing oxygen needs and seemed to be neurologically intact. The ultimate outcome however may not be known for several years. In discussion with the parents during follow up visits a few months postpartum, they felt at peace with their decision and felt that they

RISK MANAGEMENT TIPS

At times we are all faced with the challenge of obtaining informed consent under pressure—whether that pressure is time, emotional impact, or imperfect medical certainty.

Whether the clinical scenario is a fetus at the threshold of viability, a patient at the end of life, or explaining a medical complication, how we conduct ourselves can have a significant impact on the future course of events. Here are ten risk management tips to guide your discussion:

1. **Have Timely Discussions:** Begin as early as possible and provide updates as the clinical situation evolves.
2. **Involve Family Members:** They are often the ones who will be providing support and care afterwards.
3. **Use Lay Terminology:** Make sure what is being communicated is well understood. Have the patient repeat back critical information to ensure understanding.
4. **Advocate for the Patient(s):** Acknowledge your patient's emotions and needs.
5. **Express Support and Regret:** If the medical outcome is less than desired, an apology is not an admission of fault and is not admissible in court.
6. **Be Honest:** Present information in a factual and straight forward manner. Do not ascribe blame.
7. **Avoid Creating Guilt:** Many situations, especially pregnancy related, are highly emotionally charged. Support and reassurance are what is needed.
8. **Be Prepared to Deal with Anger:** Do not fall into the trap of defensiveness or respond in a hostile manner.
9. **Employ Effective Communication Skills:** Practice active listening. Be aware of non-verbal messages expressed through your body language. Repeat what you have heard to confirm your understanding. Allow enough time for discussion.
10. **Continue the Dialogue:** Maintain your connection to the patient with support and compassion even after the difficult decisions have been made. ■

were adequately informed prior to the decision to proceed with a cesarean section.

SUMMARY AND MEDICAL-LEGAL RISKS

When decisions have to be made in very stressful circumstances under time pressure and in the absence of complete information, the potential medical-legal risks are high. Memory tends to be "selective" when considering the huge financial and emotional burden of a severe lifelong disability. If the physician obtaining the consent is not the regular attending (thus not always familiar with the patient's personal, cultural, or religious background), the situation can easily turn into a medical-legal nightmare. Here are some prudent steps to consider when faced with this clinical situation:

- Make sure that the pre-operative note contains language describing that a discussion about the potential short- and long-term risks associated with a delivery at the threshold of viability took place.
- If time permits, a documented Neonatal consult would be preferable under these circumstances.
- In those patients who are not immediately delivered, consideration should be given to an updated discussion as the statistics change significantly with every passing week and the "better" statistics may cause some patients to modify their wishes.
- In those circumstances where informed consent cannot be obtained in a timely manner, e.g., an irresolvable language barrier, there is no clear answer. Using an "aggressive" approach may be less risky for the obstetrician.

If one practices obstetrics for a long enough time, there will always be recollections of those babies who were delivered at 24 weeks and did well in spite of our "non-aggressive" approach as well as those who we "went all out for" and are still now suffering from the consequences of severe prematurity. At this point, the jury is still out and unfortunately, it may be out for a long time to come. ■

Dr. Katz, a member of Physicians Reimbursement Fund, is Chief of Obstetrics at California Pacific Medical Center.

Tracking Test Results

Most practicing physicians order thousands of medical tests every year. Some tests are routine but others may be critical to making a correct and timely diagnosis. Just the sheer volume of data being generated day in and day out creates a risk management nightmare. In fact, failure to keep track of diagnostic test results was recently found to be responsible for over one-quarter of all malpractice claims—a percentage that climbed to over a third when cancer was misdiagnosed.

These sobering statistics make it clear that implementing an office tracking system, whether paper or electronic, is no longer merely an option. The message that this is a challenge that must be recognized needs a positive approach that comes directly from the physician. The focus should be on improvement, not blame.

The concept underlying any tracking approach is to create a "closed loop" for every test. An example of the steps in a closed loop tracking system follows:

1. A test is ordered
2. The test is tracked to ensure that it is performed and that the test result is returned to the office
3. The clinician reviews and signs off on the results
4. Patients are notified of both normal and abnormal tests and are monitored for follow-up
5. This notification is documented and patients instructed to call if they have not received the results
6. Recommendations for follow-up care are documented

An effective office tracking system will not only mitigate the chance of errors and legal exposure, but improve patient outcomes as well. Here are some risk management principles that should be incorporated into your office tracking system:

- Standardize the notification process and inform patients in advance of the process
- Have a system to assess the timeliness of patient notification
- Document when, how, and by whom the patient was notified
- Document if a patient refuses a test
- Patients should be informed of abnormal tests directly by the physician
- Abnormal tests should be re-addressed at the next visit
- Critical tests require special attention. Document the action taken and how the patient was informed
- Establish a policy to investigate results not tracked in a timely fashion
- Create a blame free approach to address corrective actions for system and human failures. ■

Documentation Is Critical

As most of you will have noticed, PRF includes a copy of the Professional Liability Newsletter along with our own PRF newsletter. In Vol. 41, No. 2 an article entitled "Not Documented = Not Done?" describes two cases where physicians did not document important information. In an obstetrical malpractice suit resulting from shoulder dystocia, the dictated note did not document that the patient had been placed in the McRobert's position before delivery. In the second case, an emergency physician did not document that he had instructed the parents how to observe their son for signs of serious head injury. In both instances, the plaintiffs prevailed, and the jury awards were significant.

These cases underscore the importance of proper documentation. Without documentation in the patient's records, a malpractice suit may come down to a "he said vs. she said" dispute—which is not helpful to the defense of a medical malpractice claim. Your documentation in a patient's medical records can be your best defense. Physicians should always keep this fact in mind when they are dictating notes or writing in patients' charts. If there is ever a medical legal action, what the physician writes at the time of the incident may be the strongest piece of evidence in assisting the defendant prevail at trial or arbitration. ■

IUDs Pose Liability Risk

The modern intrauterine device (IUD) contraceptive has been achieving greater acceptance and is even recommended for use in adolescents by the ACOG. However, there are four potential medical-legal liabilities associated with IUD use.

1. PERFORATION

The greatest risk associated with the IUD is perforation. Although perforation usually occurs at the time of insertion, it may go unrecognized until some time later when the IUD string is not able to be felt or visualized. The PRF's experience is that two-thirds of the IUD perforations occurred after insertion during the postpartum period. Lactating women are also at increased risk for perforation. As a result, IUD insertion should be postponed until a minimum of 6 weeks postpartum (or 12 weeks if involution is delayed). An ante- or retro-flexed uterus also increases the risk of perforation and the uterus should sound to at least 6 cm before the IUD is inserted.

2. INFECTION

The risk of contracting PID is increased 7-fold in the first 20 days post IUD insertion, but then returns to the baseline risk of the general population. However it is not recommended to give prophylactic antibiotics at insertion. Even women who have positive Chlamydia cultures at the time of insertion can retain the IUD and are unlikely to develop PID if treated promptly.

3. ECTOPIC PREGNANCY

The IUD lowers the overall risk of both ectopic and intrauterine pregnancies. The rate of ectopic pregnancy in women using an IUD is one-tenth of the rate in women who are not using any type of contraceptive. However, if a woman with an IUD becomes pregnant, she is at a higher risk of ectopic pregnancy than other pregnant women. Patients need to be counseled as to the risk of ectopic pregnancy and the need for immediate evaluation should they suspect pregnancy.

4. USE OF NON-FDA APPROVED DEVICES

The only two IUDs currently approved by the FDA are the Mirena and the ParaGard. IUDs must be obtained from an appropriately registered, permitted, or licensed manufacturer, wholesaler, or distributor. It is against the law to purchase, obtain, sell, dispense, or give away any IUD that is not approved by the FDA. **Malpractice insurance does not cover illegal acts.** A recent advisory warns that a counterfeit IUD is being marketed by Web-based pharmacies. Labeled as a "T-Safe", these devices are usually shipped from overseas. An FDA approved IUD will have labeling in English along with insertion and patient information.

Prior to an IUD insertion, informed consent should be obtained documenting a discussion of the risks of ectopic pregnancy, perforation and infection. Patients must be contacted if they fail to make a follow-up appointment after insertion. If a complication occurs, a management report should be filed with the PRF. Discuss whether Code Green is appropriate with the Patient Care and Management Committee. ■

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Licensing Board Coverage

BY JUNE RILEY, MBA

In the November 2010 edition of PRF News we ran an article about Medical Board Coverage. The article generated enough interest from our non-physician Insureds (i.e., oral surgeons and allied healthcare practitioners) that PRF is now offering the same coverage to all PRF Insureds. To broaden the group of practitioners who can benefit from this coverage, PRF has given Medical Board Coverage a new name—Licensing Board Coverage.

PRF Insureds can choose to purchase Licensing Board Coverage for the nominal premium of $324.00 per year. Licensing Boards are becoming increasingly proactive in their review of consumer complaints as well as reported medical malpractice settlements, awards and judgments. Often the Board's inquiry will be satisfied with a review of the medical records and a written summary of the case from the physician or other healthcare practitioner. If the written inquiry does not suffice, you may be called to appear before the Licensing Board. If this should occur, it is inadvisable to attend a Licensing Board hearing without legal representation.

Insureds who purchase Licensing Board Coverage are covered for up to a maximum of $35,000 in attorney fees and costs per case. Without Licensing Board Coverage, if called to appear before a licensing Board, you would have the choice of making the appearance without legal counsel or paying for an attorney out of your own pocket. It doesn't take a great deal of time to accrue thousands of dollars in legal fees. Considering the costs of attorney fees, Licensing Board Coverage makes sense and is a good value.

If you would like a copy of the November 2010 PRF News for review, please visit PRF's website at www.prfrrg.com or email June Riley at june@prfrrg.com. ■

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