An Ethically Justified, Practical Approach to Informed Consent for TOLAC Delivery

Frank A. Chervenak, MD; Laurence B. McCullough, PhD

Obstetric ethics can provide the basis for a practical approach to offering trial of labor after cesarean (TOLAC) in the consent process.

In 2010 both an NIH Consensus Panel[1] and ACOG[2] issued updated statements on vaginal birth after cesarean delivery (VBAC). Both agree that there should be a thorough, evidence-based informed consent process in which pregnant women with a prior cesarean delivery be counseled concerning VBAC. Based on our previous work,[3] we provide an ethically justified, practical approach to the informed consent process for TOLAC delivery.

Obstetric Ethics and Informed Consent

Using reasoned argument, obstetric ethics seeks to identify in a practical fashion the obligations of physicians and health care organizations to pregnant and fetal patients as well as the obligations of patients.[4] Two ethical principles play central roles in obstetric ethics and therefore in defining the obstetrician's obligations in the informed consent process.

The ethical principle of beneficence requires the obstetrician to act in a way that is reliably expected to produce the greater balance of clinical benefits over harms for the pregnant and fetal patients.[4] Nonmaleficence, sometimes expressed as "first, do no harm," should be incorporated into beneficence-based clinical judgment: when the evidence for expected net clinical benefit diminishes and the risks of clinical harm increase, then the obstetrician should proceed with great caution. The ethical principle of respect for the patient's autonomy requires the obstetrician to empower the pregnant patient to make informed decisions about the clinical management of her pregnancy.

The ethical principles of respect for autonomy and beneficence both shape the informed consent process.[4] This process starts with the obstetrician's beneficence-based obligation to identify the medically reasonable alternatives for the clinical management of pregnancy and its complications.

The next step is implementation of the obstetrician's autonomy-based obligations to: provide information about the clinical benefits and risks of each medically reasonable alternative; recommend a medically reasonable alternative when, in evidence-based clinical judgment, it is clearly superior; recommend against technically possible alternatives that are not supported in evidence-based, beneficence-based clinical judgment or violate nonmaleficence; ensure that the patient's decision-making process is voluntary, an especially important consideration regarding pregnant teens; and elicit the patient's value-based preference.[4] The

obstetrician should also recognize the capacity of each pregnant patient to deal with medical information and recognize the integrity of the values and beliefs of the pregnant woman.

The pregnant woman plays a crucial role in the informed consent process. She should: absorb, retain, and recall as needed information about her pregnancy and the medically reasonable alternatives for managing her pregnancy; understand this information; appreciate that this information applies to her; evaluate the medically reasonable alternatives on the basis of her own values and beliefs; and express a value-based preference. [5,6]

The legal obligations of the physician regarding informed consent were established in a series of cases during the twentieth century. In 1914, *Schloendorff v. The Society of The New York Hospital* established the concept of simple consent: did the patient say "yes" or "no" to medical intervention.[7,8]

"Every human being of adult years and sound mind has the right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."[7] The legal requirement of consent further evolved to include disclosure of information sufficient to enable patients to make informed decisions about whether to say "yes" or "no" to medical intervention.[8]

The informed consent process in obstetrics is unique among medical specialties, because both the pregnant patient and the obstetrician have beneficence-based obligations to the fetal patient during the intrapartum period.[4] These beneficence-based obligations shape the informed consent process for TOLAC in important ways.

Offering and Recommending TOLAC in the Informed Consent Process

Both elective repeat cesarean and TOLAC can be supported in evidence-based, beneficence-based, clinical judgment. When this is the case, both should be offered in clinical settings where TOLAC can be performed safely.

The NIH Consensus Panel[1] and ACOG[2] statements agree that TOLAC after a previous single low transverse uterine incision is medically reasonable and should be offered when there has been one previous low transverse incision. In the language of obstetric ethics, the evidence supports the beneficence-based clinical judgment that the clinical risks of TOLAC to both pregnant and fetal patients are acceptable when there has been one previous low transverse incision.

Elective repeat cesarean delivery also has acceptable risks to both pregnant and fetal patients. Both TOLAC and elective repeat cesarean delivery are therefore supported in evidence-based, beneficence-based, clinical judgment. Both therefore should be offered to the pregnant woman with one previous low transverse incision, because both are medically reasonable in this clinical circumstance.

There are some cases in which elective repeat cesarean delivery is substantively supported and TOLAC is not supported in beneficence-based clinical judgment. For example, when the pregnant woman has had a previous classical incision on

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Frank A. Chervenak, MD is Editorial Advisory Board Member, Chairman, Department of Obstetrics and Gynecology, Weill Cornell Medical College, New York-Presbyterian Hospital, New York, NY. **Laurence B. McCullough, PhD** is Dalton Tomlin Chair in Medical Ethics and Health Policy, Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, TX.

her uterus, cesarean delivery is clearly preferable to TOLAC because cesarean prevents the fetal and maternal risk of a ruptured classical incision in the uterus.

Vaginal delivery in such circumstances would result in a substantial increase in morbidity and mortality for both the pregnant and fetal patients and would therefore violate nonmaleficence. It follows that in beneficence-based clinical judgment only cesarean delivery should be offered and recommended to pregnant women with a previous classical incision. It also follows that the obstetrician has a beneficence-based obligation in the informed consent process to recommend against TOLAC in such cases.

There appears to be controversy about TOLAC after two low transverse incisions. The ACOG statement, on the basis of Level B evidence, states: "Women with two previous low transverse incisions may be considered candidates for TOLAC."[2] The NIH Consensus Panel was silent on this topic.[1]

Level B evidence is inherently controversial in beneficence-based clinical judgment. As a result, obstetricians should expect there to be competing evidence-based, beneficence-based, clinical judgment about the safety for pregnant and fetal patients of TOLAC when the pregnant woman has had two previous low transverse incisions. In the informed consent process, TOLAC may be offered but the obstetrician is obligated to explain the uncertainties of the current state of the evidence in this clinical circumstance.

Conclusion

Obstetric ethics provides the basis for an ethically justified, practical approach to offering and recommending TOLAC in the informed consent process with pregnant women with a prior cesarean delivery. For women with one previous low transverse incision, both TOLAC and elective repeat cesarean delivery should be offered. Obstetricians should recommend against TOLAC when the pregnant woman has had a previous classical incision. TOLAC after two previous low transverse incisions may be offered provided that the informed consent process presents the uncertainties of the evidence.

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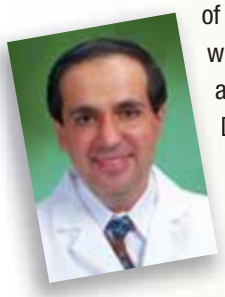
Frank A. Chervenak, MD, Elected to the Institute of Medicine

On behalf of the Editorial Board of *The Female Patient,* I wish to congratulate Dr Chervenak on his election to the Institute of Medicine. Election to the IOM is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.



Dr Chervenak is chairman of the Department of Obstetrics and Gynecology at Weill Cornell Medical College, New York-Presbyterian Hospital and is an active Board member for the Journal.

—Ronald T. Burkman, Editor-in-Chief