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There is no gold standard for decision-to-incision time

Don't accommodate plaintiff's attorneys who have reinvented an intended guideline as a requirement!

CASE Primigravida with ruptured membranes

A 21-year-old patient was admitted to the labor and delivery suite in active labor. After a reassuring fetal tracing was documented, active management with oxytocin was initiated.

Five hours later, the nurse noted a prolonged deceleration.

Resuscitative efforts failed to alleviate the deceleration. The nurse notified the attending OB of the situation. An emergency cesarean section was called because:

1) of a nonreassuring fetal heart rate tracing and
2) delivery was not imminent.

Now, the attending leaves her home promptly to perform the cesarean section; the anesthesiologist, who is not in the hospital, is notified.

The team is assembled and the patient is moved to the operating room; 34 minutes have elapsed between the time the decision was made to perform the cesarean section and the time the incision is made on the abdomen.

Two minutes later, the baby is delivered. Apgar scores are as follows: 0 at 1 minute; 0 at 5 minutes; 0 at 10 minutes; and 1 at 15 minutes.

Subsequently, the baby is determined to be severely brain-damaged. The parents file a claim of malpractice.

ObGyns have come to depend on ACOG's Committee Opinions, Educational Bulletins, Practice Bulletins, Policy Statements, and Technology Assessments to help us take the best care of our patients. To quote the College, each of these documents "is reviewed periodically and either reaffirmed, replaced, or withdrawn to ensure its continued appropriateness to practice."[1]

Sometimes, however, an ACOG bulletin, statement, or assessment may be misinterpreted and can actually contribute to some of the medicolegal problems that we face. The actual clinical situation just described, relating to ACOG's statement on the so-called decision-to-incision gold standard, is a case in point.

The parties in the case go to trial

During the subsequent trial, the plaintiff alleges negligence by claiming that the defendant:

- did not anticipate or recognize developing fetal problems
- failed to perform a C-section within 30 minutes after the decision was made to do so.

The defendant counters:

- There was no fetal indication of hypoxia or cause for concern until the fetal bradycardia was noted
- Brain damage was caused by an un-

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TABLE

Outcomes are no better when the decision-to-incision time is less than 30 minutes[3]

OUTCOME	INCIDENCE AT <30 MIN	INCIDENCE AT >30 MIN
Urine pH, <7.0	4.8%	1.6%*
Intubation in delivery	3.1%	1.3%*
Hypoxic–ischemic encephalopathy	0.7%	0.5%
Fetal death	0.2%	0%
Neonatal death	0.4%	0.2%
Apgar score at 5 min, <3	1.0%	0.9%
None of the above	92.6%	95.4%*

*P <.05

anticipated event that occurred more than 30 minutes before delivery

- The team responded as rapidly as it could given the circumstances of the hospital and staffing patterns.

No verdict was reached; instead, the parties agreed to a multimillion-dollar settlement that is based on **1)** more than 30 minutes having elapsed from "decision to incision" and **2)** the assertion that a 30-minute decision-to-incision time is the standard of care for an emergency C-section.

***FAST** TRACK*

Just over 95% of babies delivered in more than 31 minutes had none of the six adverse outcomes studied

Are we held to a standard that can't be met and has no basis in evidence?

To repeat, as reported in hospital records admitted into evidence at trial, the baby was delivered, with a low Apgar score, 34 minutes after the decision was called. The fact that the incision commenced after more than 30 minutes was a major factor contributing to the multimillion-dollar settlement.

That 30-minute mark is taken directly from the fifth edition of ACOG's Guideline for Perinatal Care:

> Any hospital providing obstetric service should have the capability of responding to an obstetric emergency. No data correlate the timing of intervention with outcome, and there is little likelihood that any will be obtained. However, in general, the consensus has been that hospitals should have the capability of beginning a cesarean section within 30 minutes of the decision to operate.[2]

The interpretation that all C-sections *must* be performed within 30 minutes of a decision is challenged by a recent study sponsored by The National Institute of Child Health and Human Development (NICHD) Maternal–Fetal Medicine Units Network.[3] The design of that study was observational, because no ethical means exist to randomize women to less than or more than 30 minutes from the time of a decision to perform a C-section to the time of the incision.

The data collected came only from primagravid women in active labor who had an infant that had a birth weight of more than 2,500 g. Indications for C-section included: nonreassuring fetal heart rate, umbilical cord prolapse, placental abruption, placenta previa with hemorrhage, and uterine rupture. A total of 11,481 cases were analyzed over a 2-year period, with 2,808 C-sections performed for those indications (a 24.5% rate of C-section). Ninety-four per cent of the C-sections were undertaken because of a nonreassuring fetal heart rate.

In a university setting, where one would expect in-house OB coverage and anesthesia to be available, only 65% of emergency C-sections commenced within 30 minutes of a decision (17% in less than 10 minutes; 27% in less than 20 minutes). Investigators also found that, in cases in which a C-section was performed for a nonreassuring fetal heart rate, only 62% were performed in fewer than 30 minutes.

The data are clear: More than one third of all C-sections for these indications did not comply with the "30-minute rule."

Notably, the study also found that:

- when the decision-to-incision time

was less than 30 minutes, the rates of fetal acidemia and intubation in the delivery room were higher
- 95% of infants delivered in more than 31 minutes did not experience any of the adverse outcomes listed in the accompanying **TABLE** (page 64)
- only one of eight neonatal deaths occurred in the group of infants delivered after 31 minutes (at 33 minutes).

The investigators also found that decision-to-incision time had no impact on maternal complications.

30 minutes? It's not a mandate

The study supported by NICHD shows that:

- the decision-to-incision interval appears to have no impact on maternal complications
- an infant delivered within 30 minutes for an emergency indication was more likely to be acidemic and to require intubation than an infant delivered in longer than 30 minutes for an emergency indication
- delivery within 30 minutes does not guarantee that there will be no adverse outcome
- 95% of infants delivered in more than 30 minutes did not have compromise.

Where did it originate? These facts make us wonder: How did the controversial, seemingly random time of 30 minutes crawl into the courtroom and become a benchmark? Why have attorneys and expert witnesses for the plaintiff taken this 30-minute rule to be fact?

The ACOG guideline is, as stated, clearly not a requirement. It does not mandate that all C-sections commence within 30 minutes from the time of the decision to perform one. Rather, the guideline clearly states that the hospital should be capable of performing the procedure within 30 minutes.

To be clear, we are not advocating a guideline or policy of waiting to perform a C-section! We believe rapid delivery is proper. But the optimal time, or even minimal time, to delivery has not been defined by data—and may never be.

What should it really mean? Thirty minutes, therefore, should be a goal, not a finite time. Data published by NICHD should now be used to temper notions that exceeding the so-called 30-minute rule necessarily **1)** is an indicator of substandard care and **2)** has adverse effects on outcome for the newborn.

Perhaps it's time for ACOG to review these recent data and then reaffirm, replace, or withdraw the statement from the perinatal guidelines proposing that 30 minutes be the maximum time from decision to incision.[1]

Here's what you should do until the matter is clarified

If you must defend yourself against an accusation of not having performed a C-section in a timely fashion, data from the NICHD Perinatal Collaborative may offer a helpful defense. Because 38% of C-sections for a nonreassuring fetal heart rate tracing are not performed within 30 minutes of a decision to proceed, even in a university setting, this cannot be considered a standard and not meeting this arbitrary time should be looked on as a frequent occurrence.

Based on current data, therefore, any medicolegal case in which the plaintiff's attorney implies that failure to conform to this putative standard resulted in a bad outcome should be defended vigorously—and should not be settled. ■

***FAST** TRACK*

Don't settle a case in which you've been accused of a bad outcome just because a C-section wasn't begun in less than 30 minutes

References

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