MASTER CLASS

Quality of Care in Obstetrics

E. ALBERT REECE, M.D., PH.D., M.B.A.

Patient safety has become an emphasized area of medicine in recent years. This is not to suggest that the issue of patient safety is new to medicine. Historically, it has been assumed to be a natural part of good medicine and the provision of good medical care.

In 1999, the Institute of Medicine released shocking statistics, estimating that as many as 98,000 people die in any given year as a result of medical errors that occur in hospitals. In the now well-cited report "To Err Is Human: Building a Safer Health Care System," the IOM asserted that errors occur because good physicians and health care providers work within a bad system. It set a minimum goal of reducing errors by 50% over the next 5 years, and laid out a national agenda for improving patient safety.

This report was followed up by another IOM report published in 2001, "Crossing the Quality Chasm: A New Health Care System for the 21st Century." This report further defined what kind of change is needed to "close the quality gap." It provided overarching principles for clinicians, among others, and looked at how systems approaches can be used to implement change.

With both reports—two of many IOM studies and publications aimed at improving the nation's quality of care—a light has been shown nationally and internationally on the importance of not simply assuming that good quality care is part of medicine but, instead, emphasizing and critically analyzing the state of affairs relative to patient safety and quality of care.

Most of our institutions by now have implemented major organizational and structural changes aimed specifically at introducing safety and quality measures. These changes and structures—and the ensuing outcomes—must be monitored so that deviations from the currently available national best practices and standards of care can be identified and corrected.

In obstetrics in particular, where the litigious environment is so challenging, patient safety initiatives become even more important. For this reason, we believe that a Master Class highlighting a particular safety and quality of care initiative in obstetrics may both provide guidance and serve as a catalyst for other centers to emulate.

We have invited Dr. Alfred Z. Abuhamad to be our guest professor. Dr. Abuhamad serves as chairman of the department of ob.gyn. at the Eastern Virginia Medical School, Norfolk, and is the Mason C. Andrews Professor of Obstetrics and Gynecology there. He has played a key role in establishing a patient safety initiative in labor and delivery at EVMS and Sentara Healthcare, and will share, in detail, what he and his colleagues have learned in implementing this initiative. ■

Dr. Reece, who specializes in maternal-fetal medicine, is Vice President for Medical Affairs, University of Maryland, as well as the John Z. and Akiko K. Bowers Distinguished Professor and dean of the school of medicine. He is the medical editor of this column.

Near-Miss Reporting and the OB Right Program

BY ALFRED Z. ABUHAMAD, M.D.

Hospital safety issues have been widely reported and have received significant attention recently. However, solutions have been slow in coming. Thus, the ongoing challenge of creating the safest labor and delivery environments possible has been left with obstetricians. Although the problem is daunting, there are many steps that obstetric and gynecologic practices can take on their own that will reduce adverse events in labor and delivery as well as optimize maternal-fetal outcomes.

Separate reports published almost a decade ago by the Institute of Medicine and the American Hospital Association estimated that 44,000-98,000 patients die each year from errors made during hospital stays.

That higher death rate accounts for almost double the number of people who die in motor vehicle accidents each year in this country, and double the number of women who die annually from breast cancer, according to the Centers for Disease Control and Prevention.

The problem is so severe that Dr. Mark R. Chassin, president of the Joint Commission (an independent, not-for-profit organization that accredits and certifies more than 15,000 health care organizations and programs in the United States), noted recently that the chance of any of us being injured from simply being in a hospital and not as the result of an illness is 40% greater than the likelihood of an airline mishandling our luggage.

The problem of inconsistent and dysfunctional clinical patterns of care in both the inpatient and outpatient settings is even more alarming. One large study involving the review of 18,000 patient charts found that only 55% of patients received care in keeping with current best practices ("Epidemic of Care: A Call for Safer, Better, and More Accountable Health Care." San Francisco: Jossey-Bass, 2003).

Approximately 5 years ago, the Joint Commission examined all perinatal "sentinel" events across the country in all types of institutions, and found that 72% of such events were linked to breakdowns in communication.

Other identified root causes included staff competency (47%), staff orientation and training (40%), inadequate fetal monitoring (34%), unavailable equipment or drugs (30%), and physician-credentialing issues (30%).

Major issues of concern in the labor and delivery setting involve the fetal heart rate tracing, iatrogenic prematurity, shoulder dystocia, and operative delivery, as well as all the verbal and written communications that are involved with each of these areas.

An American College of Obstetricians and Gynecologists survey noted that the fetal heart tracing accounts for the majority of liability claims pertaining to labor and delivery.

Labor and delivery safety programs should therefore focus primarily on these issues, and on the following:

- ► Simplifying and standardizing protocols for care.
- ► Adopting evidence-based practices.
- ► Relying more on simulation and training.
- ► Working together as a team to accomplish defined goals.

Near-Miss Reporting

The real crux of any patient safety initiative—and the element that goes hand-in-hand with each of these aspects of a program—is a "near-miss" reporting system. This is a concept that medicine borrowed from the airline industry; it involves reporting any occurrence that could have resulted in an adverse event.

A near-miss reporting program is nonpunitive, and empowers everyone involved in the care of a patient to report events and happenings that they believe have the potential to cause problems for patients. Reports are made before injury happens and are reviewed in a blame-free environment. Systems can then be analyzed and modified to minimize recurrence of these events.

In fall 2005, a collaborative effort among the academic faculty at Eastern Virginia Medical School (EVMS) in Norfolk, the obstetric community faculty in that city, and Sentara Healthcare established the OB Right program, with the mission of minimizing iatrogenic injury to the mother and infant and reducing adverse patient safety events at labor and delivery. The "near-miss report form" used by the patient safety program at EVMS and Sentara Healthcare asks for descriptions of events that were "out of the ordinary" or "made you uncomfortable." It also asks for suggested solutions.

The program has been enormously successful. Over the past 3 years, almost 230 near-misses have been reported by our physicians, residents, and nurses. Echoing the 2004 Joint Commission report, our near-miss reports have shown us that communication issues account for at as many as 60% of these potentially dangerous situations. These reports also have helped solidify a patient safety approach that gives special attention to fetal heart rate monitoring, shoulder dystocia, iatrogenic prematurity, and operative deliveries.

Setting Up a Program

At the time the OB Right program was established, it encompassed two hospitals in the Sentara Healthcare System: Sentara Norfolk General Hospital (the academic tertiary hospital of EVMS) and Sentara Leigh Hospital, (a community hospital in Norfolk that has no 24-hour in-house obstetric coverage). The purpose of including both hospitals was to ensure that the program is successful in both settings.

A steering committee was established immediately to oversee the program, and a clinical nurse specialist was recruited to coordinate program activities and serve as the link between the program and the staff. One of the nurse specialist's first tasks was identifying ways of communicating with physicians and staff, and later, letting them know early on of program successes.

The steering committee included physician leaders from the academic and community obstetric faculty, neonatol-

Continued on following page

Key Points About Patient Safety

- ► An estimated 44,000-98,000 patients die each year from errors made during hospital stays.
- ► Two-thirds of perinatal sentinel events are primarily linked to communication issues.
- ► Experience with the OB Right patient safety initiative at Eastern Virginia Medical School and Sentara Healthcare has demonstrated the importance of common language and common understanding when it comes to fetal heart rate monitoring.
- ► To significantly diminish unnecessary prematurity and its associated morbidity, patient safety initiatives should include elective induction and C-section bundles that require either a gestational age of at least 39 weeks or documented fetal lung maturity.

Continued from previous page

ogy and anesthesiology physicians, nurse leaders, hospital administrators, risk managers, and representatives from liability insurance companies.

An education and practice committee was formed to review and recommend educational modules for physicians and staff, to research and develop protocols on best practices, to review practice patterns and recommend changes, to establish a simulation lab, and to implement emergency drills.

A data committee was established to identify retrospective and prospective variables for data collection, as well as data collection methods. Its members were also assigned the jobs of conducting patient and physician satisfaction surveys and of developing a system to collect, report, and debrief faculty and staff on reported near-misses.

Members of the technology committee led an effort to identify and develop technology that would improve patient safety at labor and delivery.

Building the Program

A critical look at all available protocols is a key component of a safety initiative. Simplifying and standardizing the oxytocin order set, for instance, was something we did early on.

It's important to ensure that everyone is speaking the same language. We were particularly struck by the importance of common language and common understanding in fetal heart rate monitoring. For example, early on we surveyed EVMS residents and labor and delivery nurses about how they defined uterine tachysystole. Responses were all over the board, with more than 20 different definitions.

Without a common definition, we realized, we would have not only varying recognition of the problem at labor and delivery, but also poor communication among health team members and the potential for harming the patient.

To prevent errors of mistaking fetal heart rate for maternal heart rate during labor, we adopted the National Institute for Child Health and Human Development's definitions of uterine tachysystole and fetal heart rate patterns. This was an important precursor to the development of protocols for addressing tachysystole and enhancing communication.

We also established universal monitoring of maternal and fetal heart rates. The maternal heart rate is continuously displayed on the fetal heart rate monitor, which substantially reduces the chance for error.

In addition, we studied our cesarean section response time and developed new response time guidelines that enabled us to clearly and efficiently communicate with anesthesiology regarding the various levels of urgency involved. Ultimately, we created four cesarean section categories that provided clear communication among health care teams and allowed for data collection and review. (See box above.)

To significantly reduce unnecessary prematurity and its associated morbidity, we implemented elective induction and cesarean section bundles that require either a gestational age of at least 39 weeks or documented fetal lung maturity.

Categories Developed Under the OB Right Patient Safety Program

Category	Timing	Examples
Category 1 (Stat)	Delivery to be accomplished immediately because of risk of morbidity/mortality to mother and/or fetus.	Cord prolapse Uterine rupture Ominous fetal heart rate pattern
Category 2 (Urgent)	Delivery to be accomplished in a timely fashion in first available room; should be expedited to avoid increasing risk to the fetus.	Failed vacuum or forceps Nonreassuring fetal heart rate pattern
Category 3	Early delivery needed; time to be determined by consultation between obstetrician and anesthesiologist.	Prolonged second stage Arrest of descent
Category 4 (Elective)	Generally scheduled in advance and categorized as nonurgent/elective, without immediate risk of maternal or fetal harm insofar as timing is concerned.	Elective repeat cesarean section

Source: Dr. Abuhamad

These criteria are currently part of the national voluntary consensus standards for perinatal care in 2008 that were developed by a committee of the National Quality Forum.

Following much debate, we also implemented, at both hospitals, the universal collection of arterial and venous cord pH with every delivery. We have found this practice to be cost effective and to provide objective documentation of fetal intrapartum oxygenation. It also identifies neonates for targeted resuscitation and is a mechanism for continuous quality improvement. Given its potential controversy, however, this practice should not be at the top of the list for safety initiatives at labor and delivery.

Plans in the immediate future include a focus on shoulder dystocia, operative delivery, and triage of patients at labor and delivery.

Given the early success of OB Right, we decided to expand this program to the five other Sentara Healthcare hospitals that provide obstetric services in southeastern Virginia.

In order to achieve this goal, we have created a Clinical Effectiveness Council with physician/nurse team representation from each of the hospitals. The council meets monthly and is currently in the process of implementing key components of the OB Right program.

Keys to Success

We have learned that "buy-in" is key to an effective patient safety initiative. Hospital administration must devote the resources necessary for the success of the program, and both physicians and nurses must be at the table together and be involved as a team with a common safety goal.

A clinical safety coordinator is also essential to the success of a program. This person provides the consistency required and plays a critical role in communicating with the staff in the trenches.

Additionally, it is important to establish methods of communication early on, and to deliver and communicate tangible successes as soon as possible.

The OB Right program communicates with the health care team through posters on labor and delivery, and a newsletter that reports every 3 months on the issues and successes of the program. It also has a Web site with educational modules, near-miss reporting, meeting schedules and minutes, and other interactive tools.

Since OB Right began, we've almost eliminated elective deliveries at less than 39 weeks' gestation, and have achieved an almost-universal compliance with simultaneous maternal and fetal heart rate tracing and measurement of arterial and venous cord pH at both hospitals.

One of the major liability insurance companies sends a representative to the OB Right steering committee meetings and provides premium discounts for physician participation in the OB Right program.

As reported in the Institute of Medicine report "Crossing the Quality Chasm: A New Health System for the 21st Century," the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated not as personal failures but as opportunities to improve the system and prevent harm. ■

Early, Late Preeclampsia May Be Hemodynamically Distinct

BY SUSAN BIRK
Contributing Writer

CHICAGO — A retrospective study of 1,300 women at 24 weeks' gestation suggests that early preeclampsia and late preeclampsia may be two different hemodynamic forms of disease.

Early preeclampsia was associated with normal prepregnancy BMI, high total vascular resistance (TVR), and bilateral notching of the uterine artery on Doppler evaluation, and late preeclampsia was associated with high prepregnancy BMI and low TVR, Dr. Barbara Vasapollo of University of Rome Tor Vergata reported in a presentation at the World Congress on Ultrasound in Obstetrics and Gynecology.

"This is not the first study to suggest that early and late preeclampsia are two different entities, but it is the first to demonstrate that they are two different hemodynamic entities in the latent phase," Dr. Vasapollo said in an interview.

Researchers reviewed data on 1,345 nulliparous normotensive women who had undergone uterine artery Doppler and maternal echocardiography to determine TVR at 24 weeks' gestation between 1999 and 2007.

Of these patients, 155 had bilateral notching of the uterine artery, and 107 of this group developed preeclampsia (defined as blood pressure greater than 140/90 mm Hg and proteinuria greater than 300 mg/dL).

Thirty-two patients developed late preeclampsia (more than 34 weeks' gestation), and 75 developed early preeclampsia (less than 34 weeks' gestation).

Significantly more early preeclampsia patients (60%) showed bilateral notching of the uterine artery than late preeclampsia patients (15.6%) at the 24 weeks' examination.

TVR was significantly lower in the group who subsequently developed late preeclampsia than in the group who developed early preeclampsia (741 dyn-s/cm^5 vs. 1,605 dyn-s/cm^5). Prepregnancy BMI was significantly higher in the late preeclampsia (28) group than in the early preeclampsia group (24).

Dr. Vasapollo said the findings are consistent with other research that links late preeclampsia with maternal constitutional factors such as BMI and early preeclampsia with defective trophoblast invasion (Hypertension 2008; 51:970-5, 989-90).

TVR appears to be one of the most reliable predictors of early or late preeclampsia, she said.

"The ROC curves built to predict early and late preeclampsia show a very good sensitivity and specificity," according to a study by Dr. Vasapollo and her colleagues. "When considering early severe complications, almost all preeclamptic women show a TVR of greater than 1,400," she noted (Hypertension 2008; 51:1020-6).

Dr. Vasapollo and her colleagues plan to investigate a preventive pharmacologic approach to treatment that is guided by maternal hemodynamics. ■