# A 38-Year-Old Woman With Fetal Loss and Hysterectomy

Benjamin P. Sachs, MB, BS, Discussant

DR DELBANCO: Mrs W is a married, self-employed, healthy woman living in a community several hours from Boston. She has private health insurance. At age 38, she was admitted to the hospital for elective delivery of her first child, but the admission ended tragically with fetal loss, hysterectomy, and a prolonged hospitalization.

The pregnancy, her first, was wanted and uneventful. When seen initially by her obstetrician, Mrs W's blood pressure was 112/80 mm Hg. She showed no sign of labor at term. At 40 weeks of pregnancy, her blood pressure was 126/78 mm Hg, rising shortly thereafter to 144/85 mm Hg. She had trace proteinuria. Her creatinine level was 0.8 mg/dL (70.7 µmol/L), and her uric acid level was 6.3 mg/dL. At 41 weeks of gestation, her obstetrician, Dr F, decided to admit her for misoprostol induction. Dr F was not on call that night.

On admission, the cervix was closed and 50% effaced, and her blood pressure was 124/90 mm Hg. She was given misoprostol (25 µg, vaginally) and sent home that evening at 10 PM. On the way home she noted more contractions, turned around, and was admitted to the hospital at midnight in active labor. She was breathing uncomfortably with contractions, vomiting, and was hypertensive with a blood pressure of 174/104 mm Hg. The cervix was still soft and closed; the fetal heart rate was in the 130s, and no decelerations accompanied the contractions. At 1:30 AM, her membranes ruptured, and contractions were noted every 1 to 2 minutes. At 3:30 AM, her cervix was dilated to 2 cm and 90% effaced. The fetal heart rate was 120/min, with contractions every 1 to 2 minutes. She was given a test dose for epidural anesthesia (3 mL of 1%-5% lidocaine). At that point, her blood pressure dropped to 53/33 mm Hg, but it returned to 107/50 mm Hg with ephedrine. Accompanying the test dose, the fetal heart rate dropped to 80/min for 3.5 minutes, but then returned to the 130s. The epidural anesthesia was then initiated.

At 4:30 AM, the fetal heart rate was noted to have a saltatory (sawtooth pattern) with occasional late decelerations, and her cervix was dilated 4 to 5 cm. At 5:20 AM, she was fully dilated. She was having contractions every 1 to 2 minutes, and her medical record reveals that she was asked

CME available online at www.jama.com

©2005 American Medical Association. All rights reserved.

to start pushing. Thirty minutes later the fetal heart rate was 115/min, with late decelerations. It quickly dropped to 90/min for 3 minutes, followed by further slowing for about 11 minutes. A low-forceps delivery (+2 station, right occiput anterior with caput and molding) was attempted at 6:20 AM and failed. She was rapidly transferred to the operating room; the fetal heart rate was in the 130s. An emergency cesarean delivery was performed. When the abdominal cavity was entered, the uterus was found to have ruptured in the lower segment and the placenta was in the abdomen. A stillborn male fetus, weighing 10 lb, was delivered at 6:45 AM; the fetal weight was determined after extensive efforts at resuscitation. The uterus was repaired, and Mrs W was transferred to the recovery room.

At 7:30 AM, the patient received 4 units of blood, along with misoprostol again for uterine atony. By 10 AM, a hysterectomy was performed for uterine atony unresponsive to uterine massage and intravenous pitocin, rectal misoprostol, and intramuscular 15-methyl prostaglandin F2<sub>m</sub> (Hemabate). This was followed by numerous complications, including bleeding with disseminated intravascular coagulation requiring the transfusion of 38 units of packed red blood cells, 42 units of fresh frozen plasma, 60 units of cryoprecipitate, and 111 bags of platelets. She required 3 weeks of hospital care thereafter, including 18 days in the intensive care unit. She encountered and overcame complex medical issues including prolonged disseminated intravascular coagulopathy, acute respiratory distress syndrome, sepsis, and a wound infection. She recovered steadily, was transferred to a rehabilitation hospital for further care for a few days, and then returned home where she received intensive physical therapy, occupational therapy, and other supportive care.

This conference took place at the Department of Obstetrics and Gynecology Grand Rounds at the Beth Israel Deaconess Medical Center, Boston, Mass, on May 12,

Author Affiliation: Dr Sachs is Chief, Obstetrics and Gynecology, Beth Israel Deaconess Medical Center; Harold H. Rosenfield Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School; and Professor in the Department of Society, Human Development and Health in the Faculty of Public Health, Harvard School of Public Health, Boston, Mass.

Corresponding Author: Benjamin P. Sachs, MB, BS, Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center, 330 Brookline Ave, Boston, MA 02215 (bsachs@bidmc.harvard.edu).

Clinical Crossroads at Beth Israel Deaconess Medical Center is produced and edited by Risa B. Burns, MD, Eileen E. Reynolds, MD, and Amy N. Ship, MD. Tom Delbanco, MD, is series editor.

Clinical Crossroads Section Editor: Margaret A. Winker, MD, Deputy Editor.

(Reprinted) JAMA, August 17, 2005-Vol 294, No. 7 833

Now, 3 years after her disastrous hospitalization, she reports she has almost fully recovered physically. She has mild generalized weakness and labile emotional symptoms that she ascribes to hormonal imbalance. She and her husband have recently adopted a healthy, happy child.

# THE PATIENT AND HER HUSBAND: THEIR VIEWS

MRS W: The induction was on a Tuesday evening around 9 PM. The drug that was used was a sort of quick method of bringing labor on, without my knowledge. And unfortunately, knowing that after was troublesome to me. The risks of that drug were not indicated to me. And so we went through all phases of the labor, which was really, although painful, very exciting for us. My husband and my sister were with us. We were taking photographs when we arrived at the hospital, just doing all those things that need to be documented on the most special day in your whole life. We trusted a lot. We were at what I thought was the best possible hospital.

As things began to unfold, we sensed that there was a problem, but just kept looking outside of ourselves for help. I felt so out of control. We sensed some chaos in the room. What could we as patients have done differently to be an agent of change and force more productivity, or better communication, or clarity around our situation? There was panic in the air, and panic in the room. Looking back, had I just gotten up and yelled out in the hallway, right outside the door, I feel like that would have made something different happen. And the evening passed on, it seemed rather quickly, into the morning. It was about 6 AM when the attending physician came into my room and pretty much panicked, and we all felt that sense of panic in the room.

I guess the next thing that I remember are my last words before I closed my eyes for, I guess, many weeks. I looked at my husband, and he looked at me. He told me, "He didn't make it." And I said, "I know," because I had that sense. And he said, "I love you." And I said, "I love you too," and I closed my eyes.

When I did start to come around, I do remember intensive care. I remember a lot more than I think most people would think I would remember. Heavily medicated and very, very sick, I was able to begin to process as I guess the medication started to clear. Once my eyes opened, I watched everything.

MR W: Some of the questions that I would have for Dr Sachs would be: procedurally, how are things changing? How are mothers, patients, being informed of the use of misoprostol, or any drug that may be used on them? You know it is important to make the ultimate decision as a patient. The only way to do that is with knowledge. The trust is already there, because they would not be a patient with that particular doctor if they didn't trust the doctor . . . especially with pregnant women. So my question is: How are things changing so that every pregnant woman is informed and able to make her own decision? We had a nurse who was deal-

ing with 2 or 3 rooms, including ours. Is that type of coverage standard, or are you now limiting a nurse to one particular pregnant woman? Has the communication between residents and the doctor on duty assigned to the particular case improved? That night, I saw residents who were afraid. They were either unable or unwilling to get the doctor, when clearly things weren't going the right way.

#### THE PRIMARY OBSTETRICIAN: HER VIEW

DR F: When Mrs W went past her due date, I decided to initiate antepartum testing because she was a little bit older, was past her due date, and her blood pressure was slightly elevated at her last visit. This included a fetal heart rate nonstress test and an ultrasound for the amniotic fluid index. All the tests looked good; all of it was reassuring. But her blood pressure was still slightly elevated, so we discussed the pros and cons of continuing expectant management vs inducing her. We decided there was no benefit to be gained in waiting and her induction was scheduled for the next day. She did have an unfavorable cervix at that time. It was closed, so we talked about beginning the induction with misoprostol, which is a cervical ripening agent. I reviewed with Mrs W that the risk of an induction is that it might fail and necessitate a cesarean delivery. However, as misoprostol is viewed as a safe medication, I did not discuss any specific complications.

I wasn't there the night all this happened. Someone else was on call. In talking with the W family, I know one of the concerns of Mr W was that he felt that he didn't voice his concerns that night strongly enough. And he felt guilty about that and responsible. It's not his responsibility to do that. We are taking care of his wife. But, at the same time, he should feel comfortable in voicing concerns, and we should be willing to listen to those concerns and welcome them, even though he doesn't have a medical background. He knows his wife better than any of us.

One thing that all of us learned from this event is how important it is for house staff to feel comfortable expressing if they are worried. At the same time, we were reminded how vital it is for the attending to be responsive to the issues residents may have, without putting them down or making them feel their concerns are not legitimate.

In medicine, it is a challenge to be the one to criticize or evaluate a colleague when you perceive that mistakes are being made, or when you disagree with management. It's also a challenge to be on the receiving end of that criticism without feeling that you're being demeaned or criticized in a negative way. We're in a culture where we are not taught how to do that, and often we don't have the channels of communication to do that. One thing I think this whole event has done for our department is really open up channels of communication not only among doctors, but also with the nursing staff, the support staff, and resident staff. It's really brought the department together. We have a different culture now in labor and delivery, primarily to enhance pa-

©2005 American Medical Association, All rights reserved.

tient safety. While a patient still has her primary team, there is now a broader network of support from other physicians who may not be directly responsible for that patient. It's much more acceptable to step in and to voice your concerns if you think the management should go in a different direction.

# AT THE CROSSROADS: QUESTIONS FOR DR SACHS

What individual errors and what system failures occurred in Mrs W's care? What should have been done differently? Following these events, what interactions did you have with the patient and her family? What is the national and local experience with efforts to prevent errors and diminish obstetrical complications? How might recent concerns with physician working hours and medical liability insurance affect the care such patients receive? What steps have you taken to prevent such events from occurring again? What evidence do you have that today childbirth is safer in your department?

DR SACHS: This sentinel event occurred at the Beth Israel Deaconess Medical Center in late 2000. This case became a "burning platform," resulting in a major analysis of our department's procedures and the introduction of team training, a major reorganization of the way care is provided. I discuss herein the lessons learned and the changes we made

Mrs W and her husband endured a tragic circumstance that might have been prevented. What happened to Mrs W is rare: in the United States in 2003 there were 4.09 million births, with a cesarean delivery rate of 27.6%. The intrapartum stillbirth rate in term infants is reported between 1.5 per 1000 and 1 per 3500, <sup>2,3</sup> and the incidence of uterine rupture in an unscarred uterus is between 1:17 000 and 1:20 000. In this series, only 22% of the uterine ruptures were in primigravidas, which makes the case of Mrs W even rarer. Although the complication that occurred is rare, unfortunately the types of failures in communication and teamwork are not.

Mrs W, a primigravida, was a low-risk obstetric patient with mildly elevated blood pressure at 41 weeks of gestation. For these reasons, it was appropriate that she was induced. Her preeclampsia screening laboratory tests were normal, and the fetal nonstress test was reactive (normal). Following placement of misoprostol, a prostaglandin  $E_2$ , she was sent home at 10 PM. Patients usually are not sent home if there are any complicating factors such as hypertension; Mrs W's blood pressure was 124/90 mm Hg, and she should not have been discharged. On readmission, at midnight, her blood pressure was 174/104 mm Hg. In this case, Mrs W's hypertension was ascribed to the pain of uterine contractions, rather than the possibility of preeclampsia. Even though her laboratory tests were normal, including no proteinuria, I would have considered both possibilities. Given that new-onset hypertension at term in a 38-year-old primigravida is likely to be preeclampsia, this was an error in judgment.

©2005 American Medical Association. All rights reserved.

At 4:30 AM, Mrs W was evaluated by a resident for preeclampsia and concern for the fetal heart rate changes. Laboratory tests were ordered but never sent because of miscommunication. Between 4 AM and 5 AM, the fetal heart rate tracing was hard to interpret and included episodes of a saltatory pattern (exaggerated fetal heart rate variability of >25/min). The etiology and significance of this type of fetal heart rate pattern is unknown.6 In addition, there were very frequent uterine contractions that could have signaled an abruptio placenta caused by maternal hypertension or preeclampsia. However, there were no ominous signs requiring emergency cesarean delivery, such as fetal heart rate decelerations that begin after the peak of a uterine contraction (late decelerations), seen in utero placental insufficiency. 5 Despite the confusing picture in this case, no further action was taken. In hindsight, a cesarean delivery should have been performed because of the lack of reassuring fetal heart rate.

Mrs W began to push at 5:20 AM; by 5:30 AM her nurse correctly noted late decelerations on the fetal heart rate monitor. By 6 AM, her obstetrician noted recurrent late decelerations. Therefore, at approximately 6:10 AM, a low-forceps delivery was attempted but failed. Mrs W went on to have an emergency cesarean delivery, at which time the physicians discovered that her uterus had ruptured and that the baby had not survived. In hindsight, the fetal heart rate, noted in the operating room to be in the 130s, was probably the maternal pulse. The fetus was probably already dead when the cesarean delivery started. The fetal heart monitor may display the maternal pulse if the fetus is dead and particularly in the case of maternal tachycardia.

#### Diagnosis and Risk Factors

For Mrs W, the final diagnosis was placental abruption and uterine rupture with stillbirth and subsequent hysterectomy for severe hemorrhage secondary to uterine atony and disseminated intravascular coagulopathy. Mrs W's risk factors for abruption were hypertension and uterine hyperstimulation. The only possible causes of her uterine rupture were uterine hyperstimulation or low-forceps delivery in the face of a weakened lower uterine segment. Given the late decelerations on fetal heart tracing, cesarean delivery should have occurred around 5:30 AM. This would probably have resulted in a live birth without complications.

The 25 µg of misoprostol that Mrs W was given at 8:45 PM the previous evening was unlikely to have caused the uterine rupture 9 hours later, although she did have uterine hyperstimulation. Misoprostol has been associated with an increased rate of uterine tachysystole at doses of 50 µg or more. However, uterine rupture has only been reported at much higher doses and nearly always in women who had prior uterine surgery.

## The Outcome

Mrs W spent 3 weeks in the hospital, including 18 days in the intensive care unit. As department chair I met with the

(Reprinted) JAMA, August 17, 2005---Vol 294, No. 7 835

family almost daily to help coordinate care and answer questions. The family stayed in a local hotel at our expense. A financial settlement was reached with the patient within 4 months, without a suit being filed, which included an annual lectureship devoted to enhancing patient safety in the memory of Mrs W's child. Above all, we needed to evaluate what went wrong to prevent anything like it from happening again.

# What Went Wrong?

Our department is responsible for approximately 5000 deliveries annually. One third of our physicians are full-time, a third are in private practice, and a third work for a community-based, managed care practice. The service is responsible for a significant number of high-risk deliveries, with 7 staff perinatologists and a newborn intensive care unit with an average daily census of 40 infants. To determine the factors that contributed to the tragic outcome for Mrs and Mr W, we performed root cause analysis, a structured method of analyzing an adverse event, in which all the factors that occurred during the event are examined and human and system failures are identified.8 With the help of our quality assurance (QA) committee and QA nurse, I reviewed Mrs W's medical records and interviewed her family, and, with the QA nurse, interviewed individually all of her attending physicians and nurses and the residents on call that night. It was made clear to all that our goal was to understand what happened, not to lay blame. Furthermore, we looked for trends in complication rates and poor outcomes in our departmental database, which had been started 7 years before this case. Finally, we reviewed the literature. To get an independent perspective, our findings were then discussed with the hospital QA director.

Our analysis concluded that this case involved numerous failures in terms of communication and planning, including 4 errors in judgment. First, Mrs W should have been monitored in the hospital, rather than discharged, due to her blood pressure. Second, on return to the hospital with an even higher blood pressure, and later with a nonreassuring fetal heart rate, a clear plan should have been developed, discussed with the patient, and documented. A contributing factor was that the night in question was extremely busy in labor and delivery. Third, a cesarean delivery should have been performed at 5:30 AM for a nonreassuring fetal heart rate. Fourth, the trial of forceps at 6:10 AM, if done at all, should have been attempted earlier and in the operating room so that, if it failed, there would be no delay in performing a cesarean delivery. We were not able to determine why the low-forceps delivery failed.

Six system failures were also identified. First, communication was poor. During Mrs W's last 5½ hours of labor, despite 12 personal assessments by attending physicians and residents in obstetrics and anesthesiology, no clear clinical plan was effectively communicated to all the health care staff and the patient, and little was documented. The plan should

have addressed the management of Mrs W's pain and vomiting, elevated blood pressure, and the changes in the fetal heart rate tracing from about 4:30 AM. Second, mutual performance cross-monitoring,9 the concept of a team approach in which another physician or nurse identifies issues and informs the attending physician, was not in place. The nurse caring for Mrs W was relatively new to labor and delivery and was not being supervised by other nurses due to the number of patients in labor and delivery. The fetal heart rate tracing changes were unusual and so noted but not fully appreciated by the nurse or the resident. The attending physician was very experienced but was focused on another patient and therefore did not address the issues in Mrs W's case. Third, there was inadequate conflict resolution. Although the resident believed that the patient's baby should have been delivered, she did not seek additional help. Both the chief resident and other attending physicians were on the unit that night. Furthermore, the department's conflict resolution policy instructs the chief resident, in cases such as this, to call the director of obstetrics at home. Fourth, the team displayed poor situational awareness, in that they did not comprehend the essential elements in Mrs W's case and anticipate future events based on this understanding. 10 The already overstressed unit was further challenged by Mrs W's emergency cesarean delivery and affected the overall safety on the unit. No one was anticipating the needs or prioritizing the care of all the patients in labor and delivery. Fifth, the physician workload was too high and there was no contingency plan in place to deal with the overload such as calling for backup and reassigning patients. Sixth, the attending physician had been on call for 21 hours, which may have impaired the physician's judgment. In this case, the physician displayed "vigilance fatigue," or sticking to a diagnosis despite evidence to the contrary, between 5:30 AM and 6 AM and remained convinced by the fetus's caput and molding that the patient would deliver spontaneously in a short period of time.

#### **Patient Safety and Long Shifts**

In this case, a significant contributor to the outcome was likely the overwork of the attending physician, having been on call for 21 hours with several patients in active labor in the unit. Although US teaching hospitals have taken serious steps to reduce work hours for residents, similar steps have not been taken for attending physicians, and their jobs may have become more complicated because of reduced resident work hours. At some point, the frequency of call and the volume of patients cared for by any one physician could affect the quality of care. In industrial settings, individuals who work 24 consecutive hours make errors at a rate equivalent to an individual with a blood alcohol level of 0.10%,11 which in most states exceeds the level used to define drunken driving. Interns working more than 24 hours in a row made 36% more serious errors than interns working shorter shifts. 12 Future research should examine whether this also applies

836 JAMA, August 17, 2005-Vol 294, No. 7 (Reprinted)

©2005 American Medical Association. All rights reserved.

to attending physicians. Before limiting shift lengths for all physicians, however, the consequences of reduced continuity and need for increased communication among staff should be considered and assessed.

## Improving Quality of Care

The Institute of Medicine report To Err Is Human estimated that approximately 55% of adverse events were preventable.11 However, there is no national information on the number of obstetric cases with preventable adverse outcomes. National initiatives to improve the quality of obstetric care have almost entirely relied on the development of evidence-based clinical guidelines by specialty organizations, such as the American College of Obstetricians and Gynecologists (ACOG). 13 This approach has led to a national standard of care. However, there is little evidence that clinical guidelines have reduced preventable errors. 14,15 Aside from clinical guidelines, there has been a move to develop national standards and quality measures. The Agency for Healthcare Research and Quality has recommended that quality measures be measurable, clearly defined, modifiable, validated, risk-adjustable, and precise.16 Unfortunately, in my opinion, none of the measures developed by organizations meet the Agency for Healthcare Research and Quality standards.

# Responding to Mrs W's Tragedy

The tragic outcome of Mrs W's hospitalization shook the Beth Israel gynecology/obstetrics department to its very core. Until this case, department staff had always prided themselves on providing high-quality care. Response to the tragedy occurred in 2 phases.

In the first phase, after the root cause analysis, we changed our QA and quality improvement (QI) departmental programs. The QA committee now uses indicators developed by the Joint Commission on Accreditation of Healthcare Organizations, ACOG, and Harvard's Risk Management Foundation<sup>13,17</sup> to identify cases, and all such cases are reviewed. Physicians, nurses, students, and ward clerks also are all encouraged to identify cases for review. The QA committee includes full-time and part-time physicians, nurses, midwives, and allied specialties, and all physicians in the department rotate through the committee. The process is designed to be educational rather than punitive. The QI committee, also an interdisciplinary group, uses lessons learned from the QA process to improve the process of care.

Despite these improvements, our department realized that more fundamental change was required, and we initiated the second phase, team training. Team training was first evaluated systematically in the United States in 1978, when the Military Inspector General reported that human error was involved in more than 70% of aircraft-related fatalities in the 1970s, and that poor teamwork was the underlying cause of these accidents. "Crew (Cockpit) Resource Management" (CRM) evolved to mean an "error management capability to detect, avoid, trap or mitigate the effects of hu-

man error and therefore prevent fatal accidents." <sup>18-20</sup> By 1989, all 3 branches of the US military instituted CRM training, and by 1997, the Federal Aviation Administration mandated CRM for all commercial airlines in the United States. <sup>18</sup> The Institute of Medicine report *Crossing the Quality Chasm* speculated that individual instruction in teamwork skills and implementation of teams might reduce medical errors and improve safety. <sup>21</sup>

In 2001, Harvard's Risk Management Foundation, the Armed Forces Institute of Pathology, the Office of the Assistant Secretary of Defense (Health Affairs) TRICARE, and Dynamics Research Corporation approached the department to adapt the concepts of team training to obstetrics. The communication issues laid bare by Mrs W's case suggested that team training could potentially help the staff address issues of communication, cross-monitoring, mutual support, situational awareness, conflict resolution, and variable workload.

Obstetric care has long involved teams of health professionals and requires intense, error-free vigilance and effective communication among many different clinical disciplines, including obstetricians, midwives, nurses, anesthesiologists, and pediatricians. Therefore, the techniques of CRM are highly relevant. For our department of obstetrics, team training requires 4 hours of classroom instruction to introduce the concepts of CRM to all physicians (obstetricians, anesthesiologists, pediatricians) and nurses who have direct patient contact. Following the didactic sessions, a physician and nurse team, as part of their on call, work as coaches for about 6 months, rotating on every shift to reinforce teamwork behaviors. No additional staffing was required.

Our adaptation of CRM includes 3 types of teams: core, coordinating, and contingency teams. Regardless of the team a person is part of at a given time, all need to be knowledgeable about and aware of all patients, not just their own. <sup>10</sup> Although errors of judgment will always occur, the goal of team training and coordination is to anticipate potential complications and identify mistakes early so that they do not result in bad outcomes.

We have 2 interdisciplinary core teams of health professionals that change each shift and are responsible for monitoring mutual performance. Each core team includes 2 oncall obstetricians from different call groups and the nurses caring for their patients. The anesthesiologists and residents make rounds, at least once every 8 hours, with both core teams. Just as pilots review checklists with the flight crew and air traffic control to anticipate potential problems and make contingency plans, the interdisciplinary groups anticipate potential problems. For example, if the anesthesiologist finds a difficult airway, the obstetrician can be alerted to the need for an epidural to be administered in early labor to avoid an emergency cesarean delivery under general anesthesia. Similarly, a woman admitted for a repeat cesarean delivery with a history of dense bowel adhe-

©2005 American Medical Association. All rights reserved.

(Reprinted) JAMA, August 17, 2005---Vol 294, No. 7 837

sions will undergo her procedure with a general surgeon standing by. To promote patient safety, call cycles are often 12, rather than 24, hours and the team approach facilitates the multiple handoffs among attending physicians that have become necessary. To ensure continuity of care, clear documentation of the patient's management plan is required, the handoffs are formalized, and more team meetings are held.

The second group is the coordinating team. Led by the charge nurse and a senior physician who is on call, the coordinating team both oversees and supports the core teams. They also are responsible for managing the workload on the unit and can delay elective cases to free up personnel and resources. Our guidelines now call for no more than 3 active patients to be cared for by any one attending physician at any time. The third group is the contingency team, activated when there is an emergency on the unit.

We also have developed a process of cross-monitoring, also known as mutual performance monitoring, 9 to address the issue of vigilance fatigue that was a factor in Mrs W's case. Cross-monitoring is provided by the physicians and nurses in the core team as well as the coordinating team. This is aided at night by team meetings that are usually held at approximately 10 PM and 6 AM. For example, if there is a clinical issue such as a patient with a nonreassuring fetal heart rate tracing, another attending physician ensures that the patient's physician is addressing the problem and that all options are considered. The same approach applies to nurses. Finally, as part of the conflict resolution policy, everyone is trained to challenge those more senior to them if they disagree.

### **Evaluating Systems Changes**

Evaluating outcomes is critical to any efforts at systems change.22 Because there are no nationally accepted standard measures to assess obstetric outcomes, an expert panel developed an Adverse Outcomes Index, with input from ACOG's Committee on Patient Safety and Quality Improvement. The concept of a composite score of infrequent adverse events has been reported previously. 23,24 We have been carefully tracking the Adverse Outcomes Index and other measures designed to indicate whether our interventions are improving the quality of our care. While it is too early to report outcomes, we are encouraged by our results and are moving ahead aggressively to implement further change along the lines I have described. This includes evaluating these techniques in other team-intensive areas of medicine, such as the emergency department, operating rooms, and intensive care units.25,26

On a broader scale, the Department of Defense is conducting a randomized controlled trial involving 15 hospitals in the United States to determine whether teamwork improves (1) patient safety, by reducing the occurrence of adverse outcomes in obstetrics, (2) the efficiency of care, as assessed by process measures, and (3) patient and health

care professional satisfaction. In fiscal year 2005, the Department of Defense will spend almost \$37 billion on health care for service members, military retirees, and their dependents, with childbirth accounting for 40% of hospitalized patients. As part of its commitment to providing high-quality health care, the Department of Defense funded this study. They are interested in the potential of CRM for improving patient safety with more than 20 years of experience in the use of CRM for improving safety in complex systems. These results may offer more definitive evidence as to whether team training improves obstetric outcomes.

Since the tragic case of Mrs W, the changes we have made have affected the culture of safety in our department, and we believe these changes have improved outcomes. However, we need to continue to improve and refine aggressively the care that we provide. No health care professional can be complacent when it comes to patient safety.

Mrs W and her husband have openly shared their experience in hope of preventing this from happening to others. We have learned, as have others, that to develop a culture of safety, we must be open about our mistakes<sup>29</sup> and consider offering financial settlements to patients such as Mrs W. On behalf of our department, I publicly apologize to Mrs W and her family for our failures and want them to know that we have learned a great deal and have significantly changed the way we practice.

#### **QUESTIONS AND DISCUSSION**

A PHYSICIAN: I think we should change how we deliver babies in this country. On labor and delivery, instead of having a primary obstetrician who has followed patients and perhaps knows them, we could turn to a system more like inpatient medicine, where the management is a hospitalist system. It would be more of a specialty service. It might relieve some of the fatigue factors. It might be a hard sell to patients. But if patient safety is an outcome we're looking at, that might be a model.

DR SACHS: In essence, we have adopted this approach by requiring each call group to have an in-house attending. The question we are now addressing is whether, because of fatigue, this call should be 12 rather than 24 hours.

A PHYSICIAN: How about the midwifery model? We have turned obstetrics into a medical illness and not an event that's about the making of a family. If we could take care of low-risk women with a midwifery model, then we could have more alert doctors to care for patients at high risk.

DR SACHS: I am very supportive of the midwifery model for low-risk obstetrical patients. However, I do not believe that midwives are any less susceptible to making medical errors. Most of the serious adverse events we have seen in the last few years occurred to patients that started out being low-risk. In these cases, a series of small errors compounded on each other resulted in a bad outcome. I believe that the team approach is necessary for caring for low-risk, as well as high-risk, patients.

©2005 American Medical Association. All rights reserved.

DR DELBANCO: With respect to the national patient safety movement, I am fascinated by what the patient and family can bring to that table. The W family spent a lot of time thinking afterwards what they might have done differently that night. What do you think they might have done?

DR SACHS: I'm reminded of a recent article indicating that approximately 35% of physicians or their close family members had experienced a medical error. Thinking about some of the comments, the one that made the most sense to me is that patients ask their attending, "What's going on, and what are the plans?" As doctors or nurses, we should not feel threatened by a patient asking that, and also "How are things going?" I think it's a simple approach, not a complicated one.

A PHYSICIAN: How do you think the extraordinary malpractice premiums we in obstetrics/gynecology pay affect patient safety?

DR SACHS: A recent survey conducted by ACOG showed that the medical liability crisis is affecting access to obstetrical care in 23 states.31 In Maryland, New York, Pennsylvania, and Florida, for example, insurance premiums are skyrocketing, and obstetricians are paying upwards of \$150 000 a year for liability coverage. In those states where hospitals can also be sued, the cost of obstetrics has risen. Given the generally poor margin for obstetrical cases, coupled with the cost of litigation, some hospitals in states like Pennsylvania and Massachusetts no longer provide maternity care. The growing shortage of obstetrical care is very likely to affect poor women first. For the individual obstetrician confronted with enormous annual expense for insurance, the choices are either to give up the practice of obstetrics or to increase the number of patients cared for. And because of such costs, obstetricians will be reticent to take on a partner. I worry that at some point, the frequency of call and the volume of patients being cared for by any one physician will affect the quality of care.

A PHYSICIAN: One other question from our patient is, "How do we counsel our patients?" My personal approach can involve talking to women about the option of elective cesarean, something controversial in our country. I do not recommend it routinely to my patients. However, for patients who feel that the possibility of an emergency is intolerable, the only way to prevent an emergency delivery is to plan it. And that may be a planned primary elective cesarean. In our department, one of the changes we have made is to establish a policy to honor such a request.

A PHYSICIAN: Do you know what has happened to patient satisfaction in your new system of care?

DR SACHS: We've been tracking patient satisfaction now for many years. Prior to 2000, communication between patients and clinicians was not highly rated by our patients. We held a series of staff meetings addressing communication issues. As groups got bigger, and the physician who was likely to be on call the night you came in labor was less likely to be the physician who cared for you prenatally, the issues

of communication certainly became more apparent. Since we have introduced these measures, it looks as if patients are noting better communication and expressing greater satisfaction overall.

A PHYSICIAN: One thing we have to admit to both our patients and ourselves is that when the patient asks how the baby's doing inside, half the time we don't know. Fetal monitoring doesn't tell us how babies are doing. I don't know how many cases you have in labor and delivery when you see your fetal monitoring tracing and you wonder, "Is this baby okay?"

DR SACHS: Electronic fetal monitoring is the best we have, and it is such an imperfect science. It has a very high false-positive rate, and it has some false negatives. We all know this. Until the science and technology improve, we do not have a way with a better predictive value to assess the outcome for the fetus. We saw in this particular case a saltatory pattern. If I showed 10 physicians this pattern and asked for opinions, there would be 12 different answers. However, between 5:30 AM and 6:00 AM, there were classic late decelerations. Given her hypertension/preeclampsia and the nonreassuring fetal heart rate tracing, she should have been delivered by cesarean by 5:30 AM at the latest.

MRS W: Does ultrasound help at all?

DR SACHS: During labor, ultrasound really is not of great value to assess the fetus. It cannot easily diagnose a ruptured uterus, although if the patient is bleeding internally one may be able to pick it up. But intrapartum ultrasounds really don't have much of a place. They're useful to tell whether the baby is head first, or bottom first, but not much more than that.

A PHYSICIAN: This is sobering, but there probably is not a person in this room who has not made a mistake. We all have made mistakes when taking care of patients in labor and delivery. The only thing that has saved us is that the majority of deliveries go well. We have to turn up our antennae and become more vigilant. When you get that feeling that things are not going well, seek other opinions. Look elsewhere. Look outside the box. Don't just sit and let one mistake fall into the next mistake and take false reassurance that because things have gone well in the past, they're going to go well again.

Dr Sachs: Points well taken.

Financial Disclosures: Dr Sach's department has received funding to collaborate with the Department of Defense and the American Research Institute to develop a new curriculum for team training that will be made freely available to the public. Dr Sachs is developing, with Harvard's Risk Management Foundation, quality assurance and team training programs that will be provided through a limited liability company, of which Dr Sachs is part owner, chairman, and a member of the board. Funding/Support: This Clinical Crossroads was made possible in part by a grant from the Sidney and Esther Rabb Charitable Foundation. Obstetrical Teamwork Study Funding: The work described in this article was performed through a subcontract with Dynamics Research Corporation under contract to the Armed Forces Institute of Pathology and Office of the Assistant Secretary of Defense (Health Affairs) TRICARE Management Activity (contract DAMD171-C-0052); Risk Management Foundation of the Harvard Medical Institutions; and Beth Israel Deaconess Medical Center, Obstetrics and Gynecology Foundation. Quality Assurance Programs and Training Funding: Beth Israel Deaconess Medical Center, Obstetrics and Gynecology Foundation.

©2005 American Medical Association. All rights reserved.

(Reprinted) JAMA, August 17, 2005-Vol 294, No. 7 839

Disclaimer: The views expressed in this article are those of the author and do not reflect the official policy or position of the Department of Defense or the US Government. The American College of Obstetricians and Gynecologists does not officially endorse the Adverse Outcomes Index measure.

Acknowledgment: I would like to acknowledge Tom Delbanco, MD, for his wisdom and support in tackling this difficult topic and for his help in preparing this article, and Erin Hartman, MS, for her skillful editorial assistance. I would like to recognize the physicians and nurses in our department for their commitment to patient safety and in particular the leadership of the nurses Penny Greenberg, RN, and Patricia Mcnamee, RN, and the physicians Susan Mann, MD, Ronnie Marcus, MBBCh, and Steven Pratt, MD.

#### REFERENCES

- 1. Hamilton BE, Martin JA, Sutton PD; Centers for Disease Control and Prevention, National Center for Health Statistics. Births: preliminary data for 2003. *Natl Vital Stat Rep.* 2004;53:1-17.
- 2. Foley ME, Alarab M, Daly L, Keane D, Macquillan K, O'Herlihy C. Term neonatal asphyxial seizures and peripartum deaths: lack of correlation with a rising cesarean delivery rate. Am J Obstet Gynecol. 2005;192:102-108.
- 3. Richardson BS, Czikk MJ, daSilva O, Natale R. The impact of labor at term on measures of neonatal outcome. Am J Obstet Gynecol. 2005;192:219-226.
- 4. Ofir K, Sheiner E, Levy A, Katz M, Mazor M. Uterine rupture: differences between a scarred and an unscarred uterus. *Am J Obstet Gynecol*. 2004;191:425-429. 5. Electronic fetal heart rate monitoring: research guidelines for interpretation. National Institute of Child Health and Human Development Research Planning Workshop. *Am J Obstet Gynecol*. 1997;177:1385-1390.
- 6. Parer JT. Handbook of Fetal Heart Rate Monitoring. 2nd ed. Philadelphia, Pa: WB Saunders Co; 1997:181.
- 7. American College of Obstetricians and Gynecologists. Induction of labor. ACOG Pract Bull. November 1999;94(10).
- React Bull. November 1999;94(10).

  8. Vincent C. Understanding and responding to adverse events. N Engl J Med. 2003;348:1051-1056.
- McIntyre RM, Salas E. Measuring and managing for team performance: emerging principles from complex environments. In: Guzzo RA, Salas E, et al, eds. Team Effectiveness and Decision Making in Organizations. San Francisco, Calif: Jossey-Bass; 1995:9.
- Wright MC, Taekman JM, Endsley MR. Objective measures of situation awareness in a simulated medical environment. Qual Saf Health Care. 2004;13:i65-i71.
   Kohn LT, Corrigan JM, Donaldson MS, eds. To Err Is Human: Building a Safer Health System. Washington, DC: Institute of Medicine; 1999.
- 12. Landrigan CP, Rothschild JM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med*. 2004;351:1838-1848.
- 13. American College of Obstetricians and Gynecologists. 2005 Compendium of Selected Publications. Washington, DC: American College of Obstetricians and Gynecologists; 2004.
- 14. Grinshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. 2004;8:iii-iv-1-72.

- 15. Williams JG, Cheung WY, Price DE, et al. Clinical guidelines online: do they improve compliance? *Postgrad Med J.* 2004;80:415-419.
- Agency for Healthcare Research and Quality. Choosing Performance Measures.
   Available at: http://www.ahrq.gov/chtoolbx/backup/choosing010111.htm. Accessed May 17, 2005.
- 17. Joint Commission on Accreditation of Healthcare Organizations. Overview of the Pregnancy and Related Condition (PR) Core Measure Set. March 22, 2002. Available at: http://www.jcaho.org/pms/core+measures/pr\_overview.htm. Accessed May 17, 2005.
- 18. Helmreich RL, Merritt AC, Wilhelm JA. The evolution of Crew Resource Management in training in commercial aviation. Int J Aviat Psychol. 1999;9:19-32.
- 19. Hamman WR. The complexity of team training: what we have learned from aviation and its application to medicine simulation and team training. Qual Saf Health Care. 2004;13:i72-i79.
- 20. Howell WC. When applied research works: lessons from the TADMUS Project. In: Cannon-Bowers JA, Salas E, eds. Making Decisions Under Stress—Implications for Individual and Team Training. Washington, DC: American Psychological Association; 1998:415-425.
- 21. Committee on Quality of Health Care in America; Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press; 2001.
- 22. Ellrodt G, Cook DJ, Lee J, Cho M, Hunt D, Weingarten S. Evidence-based disease management. JAMA. 1997;278:1687-1692.
- 23. Waterstone M, Bewley S, Wolfe C. Incidence and predictors of severe obstetric morbidity: case-control study. *BMJ*. 2001;322:1089-1093.
- **24.** Pomposelli JJ, Gupta SK, Zacharoulis DC, et al. Surgical complication outcome (SCOUT) score: a new method to evaluate quality of care in vascular surgery. *J Vasc Surg*. 1997;25:1007-1014.
- Moorman DW. On the quest for Six Sigma. Am J Surg. 2005;189:253-258.
   Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. Qual Saf Health Care. 2004;13:85-i90.
- 27. US Department of Defense Military Health System. TRICARE: your military health plan. Available at: http://www.tricare.osd.mil/. Accessibility verified July 19, 2005.
- 28. US Department of Defense. Department of Defense Instruction 6025.17: Military Health System (MHS) Patient Safety Program (PSP) (MHSPSP). August 16, 2001. Available at: https://134.11.61.26/CD9/Publications/DoD/I/I%206025.17%2020010816.pdf. Accessibility verified July 19, 2005.
- 29. Gallagher TH, Waterman AD, Ébers AG, Fraser VJ, Levinson W. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA*. 2003;289: 1001-1007.
- Blendon RJ, DesRoches CM, Brodie M, et al. Views of practicing physicians and the public on medical errors. N Engl J Med. 2002;347:1933-1940.
   American College of Obstetricians and Gynecologists. ACOG's Red Alert on
- 31. American College of Obstetricians and Gynecologists. ACOG's Red Alert on Ob-Gyn care reaches 23 states. August 26, 2004. Available at: http://www.acog.org/from\_home/publications/press\_releases/nr08-26-04.cfm. Accessed May 17, 2005.
- 32. Thacker SB, Stroup D, Chang M. Continuous electronic heart rate monitoring for fetal assessment during labor. *Cochrane Database Syst Rev.* 20012: CD000063.