In 2008, the Eunice Kennedy Shriver National Institute of Child Health and Human Development published guidelines for categorizing fetal heart rate patterns. However, even if universally adopted, they will fail to improve outcomes unless they are integrated into a “bundle” of activities. Bundles reduce risks by assuring that key steps in a process are always taken. A fetal monitoring bundle would have four components: credentialed staff, an escalation policy, a known responsible party, and the capability for rapid response. The first requirement would be that all providers are qualified to appropriately interpret and respond to fetal heart rate tracings. Education should be uniform across disciplines, and there should be a credentialing process. Second is an escalation policy: an algorithm for nurses to use when getting help. It would avoid delays that occur when a nurse requesting a check on a tracing is required to call a hierarchical series of residents who must all concur before the attending who can move the patient to the operating room is called. Third, there must be an identified responsible provider at all times, ie, an obstetrician who can be readily contacted in emergent circumstances. Finally, there must be the capability of a rapid response; whenever a patient is monitored, the institution must have the obstetric, anesthesia, and pediatric resources necessary to respond to deteriorating fetal status. This bundle is a key, but not sole, piece of the perinatal safety pie; perinatal safety is advanced through a multifaceted approach anchored in a culture that values and invests in safety.

(Obstet Gynecol 2009;114:1332–5)
A seminal moment in the history of the checklist was described by Gawande, who recounted its first use in American aviation. It occurred in 1935 in the wake of the crash of a Boeing 299 shortly after takeoff during a competition to determine which aircraft would become the Army Air Corps’ new heavy bomber. The 299, dubbed the “flying fortress” by a newspaperman at the site, was heavily favored in the competition because of its obvious advantage in payload, speed, and distance capability, as well as being captained by Major Ployer B. Hill, the best pilot the Air Corps had to offer. Unfortunately, it was also one of the most complex machines constructed up until that time: “The new plane required the pilot to attend to the four engines, a retractable landing gear, new wing flaps, electric trim tabs that needed adjustment to maintain control at different airspeeds, and constant-speed propellers whose pitch had to be regulated with hydraulic controls, among other features. While doing all this, Hill had forgotten to release a new locking mechanism on the elevator and rudder controls.” Because the Air Corps’ best pilot had died in the crash, proposals to fix the problem by focusing on improving the skills of pilots seemed doomed to failure. Instead, the checklist, to be used on every takeoff, flight, and landing, was born.

Gawande transitioned from the story of the flying fortress to recount a more recent event at the John Hopkins Medical Center to demonstrate the potential utility of checklists in medicine. To try to reduce the rate of central line sepsis, Peter Provonost, a critical care specialist at the hospital, proposed a checklist with five simple steps for his colleagues to follow whenever a central line was inserted: 1) Wash your hands; 2) wear a sterile hat, mask, gown, and gloves; 3) clean the insertion site with chlorhexidine; 4) place a sterile drape over the surrounding area; and finally, 5) put a sterile dressing over the line when finished. When this suggestion was not met with enthusiasm by the staff, Dr. Provonost asked the nurses to observe central line placements and simply document the rate at which one of the steps was not performed. It turned out that in more than a third of the cases, at least one step was skipped. The checklist was adopted shortly thereafter, and over the next 15 months, only two central line infections occurred. It was calculated that in that one hospital, the checklist had prevented 43 infections and eight deaths and saved $2 million.

Checklists have now become a standard part of hospital protocol; in fact, they are now required by the Joint Commission, with a preprocedure verification checklist mandated for all operative and other invasive procedures that expose patients to more than minimal risks, as of the beginning of 2009. The World Health Organization has also embraced the use of checklists, launching the Safe Surgery Saves Lives campaign in June 2008. That initiative included a “surgical safety checklist” to ensure that the entire operating room team had a common understanding of the patient’s unique characteristics and the precise procedure to be performed, and that interventions such as antibiotic prophylaxis or deep vein thrombosis prophylaxis were given as appropriate. Their 19-item checklist is completed in three stages: before induction of anesthesia (“sign in”), just before skin incision (“time out”), and before the patient leaves the operating room (“sign out”). The World Health Organization Safe Surgery Saves Lives Study Group published a study of close to 4,000 patients before and after use of the checklist. After its implementation, deaths were reduced by 47% (from 1.5% to 0.8%, P=.003), and in-hospital complications were reduced by 36% (from 11% to 7.0%, P<.001).

A bundle is similar to a checklist. It is made up of a series of clinical steps that should occur every time a given process occurs. The Institute for Healthcare Improvement has pioneered efforts to introduce bundles into medicine generally and obstetrics specifically. They emphasize that the inclusion of each individual component within a bundle must be supported by science. The components must be performed for every patient every time; ie, bundle requirements are only fulfilled by fulfilling all parts of the bundle, which, when executed together, result in better outcomes than when implemented individually. The goal of these steps is to improve a system, rather than relying on the actions of individual members of the health care team. An example of an Institute for Healthcare Improvement bundle that is currently being used in many hospitals and for which there is already evidence of benefits is one for obstetric inductions. That bundle consists of four steps: 1) assessment of gestational age, 2) cervical assessment before starting the induction, 3) monitoring the fetal heart rate before and throughout the induction, and 4) monitoring uterine contractions for hyperstimulation. Through this process, inductions are limited to women who have completed 39 weeks of pregnancy (or have a medical/obstetric indication or evidence of fetal lung maturity), and the status of the fetus and cervix is known before the induction has begun. In institutions that have implemented this bundle, rates of inductions and time in labor have both decreased dramatically.
As noted in the previous paragraph, one component of the induction bundle is monitoring the fetal heart rate. Fetal heart rate monitoring has been a mainstay of intrapartum management, for women with inductions and for women in spontaneous labor, for well over a quarter of a century. Although debate still rages over the benefits and burdens that have accompanied the routinization of electronic monitoring, the reality is that the overwhelming majority of women laboring in hospital settings in the United States will be monitored during their labors, and monitoring is currently recognized as a standard of care by the American College of Obstetricians and Gynecologists. Revisiting arguments about the appropriateness of that standard is beyond the focus of this piece. Rather, we believe that whatever potential benefits can be derived from monitoring will be abridged or even abrogated if it is not implemented in a manner that would have four components: credentialed staff, an escalation policy, a known responsible party, and the capability for rapid response to an acute change in fetal status.

The first requirement of a monitoring bundle is to ensure that all providers on labor and delivery are qualified to read, appropriately interpret, and respond to fetal heart rate tracings. The education that would allow that standard to be met should be uniform across all disciplines whose members could potentially be responsible for reading and interpreting a tracing. The implementation of the bundle will require a credentialing process. There are many existing online courses that provide both education and examinations that require individuals to demonstrate their competence in fetal heart rate monitoring before their successful completion. Ultimately, it would be useful if professional organizations developed standards for these educational programs similar to those that have been developed for measuring nuchal thickness. However, as a first step that we believe is both reasonable and practical, individual institutions should develop their own privileging criteria for interpreting fetal heart tracings, in the same manner that they comply with Joint Commission mandates by independently developing privileging criteria for other hospital-based procedures, eg, awake intubation. It is hard to imagine an argument against documenting the competence of everyone who may at some point assume responsibility for interpreting a fetal heart rate strip. From a safety perspective, it is also advantageous to have all providers reading from the same “playbook,” so that training and credentialing in interpretation of strips should be the same for physicians, midwives, and nurses. The uniformity of expertise that should follow from joint training and universal credentialing would allow the second component of the bundle to be instituted.

The second component would be an explicit escalation policy that would have to be audited and enforced. An escalation policy is in essence an algorithm for nurses or house staff to use when getting help in the setting of a worrisome fetal heart rate tracing. The most valued attribute of that algorithm would be economy; it would have to be rapid and therefore avoid unnecessary duplication of effort, ie, the types of delays in response that occur when a nurse requesting a check on a tracing is required to call an intern, who then calls a midlevel resident, who in turn calls a chief, and only after they have all concurred with the nurse’s initial assessment is the attending, the individual empowered to move the patient to the operating room, called. Although generations of obstetricians have been weaned on the pedagogic principle that experience is the best teacher, such an approach is fraught with risk when used in circumstances in which time is of the essence. It brings to mind the aphorism that “good judgment comes from experience, and experience comes from bad judgment.” Fetal interests argue forcefully against an allowance for bad judgment acting as a teacher. Clearly, there will be less emergent circumstances in which reporting up the traditional chain of command (eg, bedside nurse to supervising nurse, intern to resident) will be appropriate, and learning opportunities can be afforded. Dealing with a deteriorating heart rate tracing is not such a circumstance. Therefore, nurses or junior residents who have been trained and credentialed in the same manner as the senior house staff should be encouraged—indeed, required—to immediately notify someone capable of mobilizing a response whenever a worrisome tracing is seen. Even if the institution has no residents, nurses must know when to contact midwives or house physicians and when to call a provider in from home. This approach is in keeping with the emerging safety paradigm that decreasing the authority gradient within a team, whether it be a flight crew or the staff on labor and delivery, reduces risks. Implementation might be facilitated by a checklist that makes the escalation process explicit.

Third, because even a well-designed escalation policy will fail unless there is an identified responsible provider at all times, one must always be so designated. The Institute for Healthcare Improvement induction bundle states that a physician capable of performing a cesarean delivery should always be available and willing to intercede. This physician...
should be named, meaning essentially that the obstetrician who can be contacted to respond to emergent events is known by all staff on the unit. Thus, if Mrs. Smith is a patient of Dr. A, and Dr. A goes for lunch, it is critical that in the circumstance of a cord prolapse, nurses need not search for Dr. A or wonder if Mrs. Smith in Dr. A’s absence. The same holds if a private obstetrician asks the “covering” attending to “watch the Pitocin” while he is in the office seeing other patients. The coverage arrangement should be documented in the chart (or on the “chalkboard”) and the staff, as well as the patient, should know who is responsible for responding to emergencies at all times.

Finally, there must be the capability of a rapid response. Whenever a patient is placed on a monitor, the institution must have in place all the resources necessary to respond to evidence of deteriorating fetal status. First, tracings should be reviewed frequently, per American College of Obstetricians and Gynecologists guidelines, whether an institution has central monitors or only bedside monitors. Then, an operating room must be available, and the ability to rapidly assemble a team that can render obstetric, anesthesia, and pediatric care must be assured. Because the need to respond will inevitably occur at the least convenient times, each shift on the intrapartum unit should undergo drills on a regular basis to demonstrate and maintain the ability to respond in an appropriate time frame.

Although this bundle is designed to integrate the steps needed to optimally monitor and respond to concerning fetal heart rate tracings, it should be seen as only a piece of the perinatal safety pie. As has been demonstrated in many settings,\textsuperscript{12} perinatal safety is advanced through a multifaceted approach involving many steps and anchored in a culture that values and invests in safety. In the absence of a culture of safety, a safety champion, and team training, the ability of a hospital to institute and sustain a fetal monitoring bundle will inevitably degrade. Finally, it must be recognized that the process of implementing all components of the bundle will take commitment, time, and resources. Institutions will vary in their ability to provide each of those. However, although some steps may be costly, eg, providing education and credentialing of all staff (ie, paying for online courses, backfilling nurses who go to be trained), others will merely require institutional will (eg, instituting an escalation policy). Even if there are direct costs, the short-term fiscal sacrifice of the institution should be balanced against the potential offset of decrements in liability payouts. Ultimately, whether the net is savings or cost, patient safety should be seen as an end unto itself, not merely as a means to financial stability. Obstetricians have long considered themselves champions of women’s and children’s health. Embracing a culture of safety will help them to maintain that status.

**REFERENCES**


