We report an update on obstetric patient safety efforts and results in the nation’s largest obstetric health care delivery system. The application of principles advocated by the Institute of Medicine a decade ago has resulted in reduced adverse outcomes, as reflected by claims experience. Particular progress has been made in standardization and documentation of critical processes, establishment of national quality benchmarks, reduction in elective deliveries <39 weeks’ gestation, and reduction in fatal postcesarean pulmonary embolism. Our experience provides a useful blueprint for similar progress in other health care systems.

Key words: checklists, litigation, patient safety

T he Hospital Corporation of America is the largest obstetrical health care delivery system in the United States. Currently, approximately 220,000 babies are delivered annually in 114 patient facilities across 21 states. These facilities range from small, rural access facilities to large, urban university centers. Because of its demographic and geographic diversity, several previous publications have suggested that this system is representative of the United States as a whole.\(^1,2\) In addition, we do not employ our physicians, nor do we have a captive health insurance arm. Thus any efforts at change within our system must come in the form of pure leadership on a national and local level; we are not assisted by the ability to terminate the employment or insurance participation of physicians who do not respond favorably to quality and safety improvement efforts. In this respect as well, the Hospital Corporation of America mirrors the situation in most US hospitals.

In 2008, we published the results of a comprehensive, multiyear effort to improve perinatal outcomes throughout our system.\(^4\) In addition to a precipitous decline in adverse perinatal outcomes, litigation related to obstetric care fell markedly during this time. We report here an update on these efforts. Our experience demonstrates the long-term sustainability of our initial results and methods and also outlines persistent areas of concern in the quest to achieve high reliability status in the area of perinatal patient safety.

Our approach has been based on 5 basic principles, discussed in more detail in a previous publication.\(^4\)

1. In any complex endeavor involving the performance of multiple individuals, uniformity of process will generally yield improved results.\(^4,6\) Obstetrics is a prime example of such an endeavor.
2. Each member of the team involved in these processes must speak the same language, and be empowered to stop any process deemed unsafe through a clearly defined chain of command.\(^4,7\)
3. Cesarean delivery rate functions poorly as an independent metric of quality of obstetric care. Sustainable reductions in cesarean rate cannot be approached directly, but will naturally flow from optimization of care processes that lead to cesarean delivery.\(^4,8\)
4. Attempts to reduce medical malpractice loss through the promulgation of ambiguous, nondirective guidelines have served our specialty poorly in the past. Continued emphasis on such guidelines is likely to serve us just as well in the future. In contrast, it has been clearly demonstrated that malpractice loss may be effectively reduced by focusing efforts toward a reduction in adverse outcomes, and by adherence to practice protocols that clearly define one way in which the standard of care may be met.\(^4,9-11\) As stated by the Institute of Medicine regarding patient safety efforts, “We are confident that this higher level of care cannot be achieved by further stressing current systems of care. The current care system cannot do the job. Trying harder will not work. Changing systems of care will.”\(^12\)
5. Peer review is an essential part of patient safety improvement. However, its effectiveness is currently limited by forces both internal and external to medicine.\(^4,13\)

The initial approach outlined in 2008 has been expanded and modified since that time to include several important components not originally addressed. These additions include the following:

1. Expansion of our online provider education/communication program. Our original efforts focused on the development of an online, interactive fetal heart rate monitoring course. Our purpose was not only educational, but also intended to ensure common terminology and thus avoid potentially hazardous miscommunication between providers. This course has been both well accepted within our own system, and widely adopted by facilities and organizations external to the Hospital Corporation of America. Since that time, we have added similar courses dealing with operative vaginal delivery, shoulder dystocia, ...
and postpartum hemorrhage. Completion of these courses as well as shorter updates are mandatory for all nursing staff in our facilities. We also strongly encourage course completion for all physicians. While we cannot mandate such efforts be adopted by the nonemployed, independent medical staffs at our facilities, many departments of obstetrics and gynecology continue to make completion of these courses a requirement for staff privileging. Participation in such educational programs is encouraged by the provision of malpractice premium credit by our hospital insurance carrier to system facilities that achieve targeted levels of staff physician completion. In a number of cases, premium reductions are also offered to individual physicians by private malpractice carriers based on satisfactory course completion. All of these courses have been made available publicly and can be accessed at www.healthstream.com.

2. Ongoing process standardization. Our efforts at process standardization originated with the development of checklist-based protocols governing the administration and monitoring of 3 high-risk medications: oxytocin, misoprostol, and magnesium sulfate.4,14 These mandatory protocols remain in place at our facilities and have been freely provided and widely adopted or adapted by numerous outside entities at the facility, hospital system, or state levels. We have subsequently introduced similar, checklist-based protocols directing the administration of magnesium sulfate for neuroprophylaxis of preterm infants, management of hypertensive crisis, and management of postpartum hemorrhage. Two large studies involving approximately a quarter million parturients over 1 year have also identified specific areas of concern regarding the timing and content of postpartum care. Since the vast majority of serious puerperal morbidity occurs in the first 2 weeks postpartum, the traditional scheduling of a single visit 6 weeks postpartum affords little opportunity to detect and prevent developing problems. Specific checklist-based instruction and patient feedback mechanisms focused on the first 2 weeks following discharge are currently being introduced to address these issues and reduce postpartum readmission and emergency department visits.15,16

3. The development of national quality metrics. In 2007, the Hospital Corporation of America sponsored an initiative of the National Quality Forum to develop, for the first time, a set of specific national perinatal quality metrics. Through the established process of quality measure sponsorship and approval, several new perinatal and neonatal metrics were developed by committees of the National Quality Forum. Several of these have been adopted by the Joint Commission. A complete list of quality metrics and definitions from these organizations is now available.17,18 These metrics will facilitate benchmarking, which should drive focused patient safety efforts in individual facilities and systems.

4. Elective early term delivery. In conjunction with the American College of Obstetricians and Gynecologists and the March of Dimes, we spearheaded an effort to define more precisely neonatal morbidity associated with the practice of elective delivery <39 completed weeks of gestation.19 Such data, along with subsequent efforts by other investigators, have led to a concerted effort by concerned national and regional organizations to sharply curtail or abolish this practice.20-22 A subsequent study examined the relative effectiveness of various approaches to eliminate this practice, and provides a blueprint for action by interested groups.23 Based on these efforts, it is now suggested that “early term” be appended to descriptions of pregnancies at 37 and 38 weeks’ gestation to emphasize the additional morbidity associated with elective delivery at these gestational ages.24

5. Prevention of postcesarean venous thromboembolism. In a comprehensive review of maternal deaths within our system during the years 2000 through 2006, we concluded that the single major cause of maternal death most amenable to reduction by systems-of-care improvement was postcesarean thromboembolism.2 We observed that the use of either medical or mechanical perioperative thromboprophylaxis has been shown to reduce the risk of postoperative thromboembolism by approximately 70% in most other forms of major surgery, and demonstrated that a similar reduction in maternal deaths from thromboembolic disease would eliminate the statistical difference between maternal death attributed causally to cesarean, as opposed to vaginal delivery.2 Based on these data, and the availability of an effective method of prophylaxis with negligible risks (pneumatic compression device), we instituted a policy of universal perioperative pneumatic compression device use in all patients undergoing cesarean delivery. During the years 2000 through 2006, the rate of postcesarean death due to pulmonary embolism (without the use of prophylaxis) was 7/458,097 (1.5/100,000 cesareans). Our policy was implemented during 2007. During the years 2008 through 2010, we observed just 1 death from pulmonary embolism following cesarean (1/214,260 or 0.5/100,000 cesareans). This represents a two-thirds reduction in postcesarean deaths from thromboembolism. Due to the low absolute rate of death, this change did not reach statistical significance using the Fisher’s exact test (P = .45). However, this observation is consistent with an approximate 70% reduction in postoperative thromboembolism seen with most other forms of major surgery.2,25 Given the above disease prevalence, randomization of approximately 2 million patients undergoing cesarean would be necessary to demonstrate statistical significance of the expected degree of change using the Fisher’s exact test. Thus, while our data are not perfect, they are likely to be the best available in the foreseeable future. We believe these data support our position that women undergoing
major surgery who would otherwise qualify for either mechanical or medical thromboprophylaxis should not receive a lower level of care simply because they have an additional major risk factor (pregnancy) while we await the perfect study that, as indicated above, will never realistically be performed.26,27 As in many areas of medicine, no decision is also a decision. This is particularly the case given the availability of an effective method of prophylaxis without significant risks (the short-term use of pneumatic compression devices) that has been shown in previous work to be cost-effective for cesarean delivery under a wide range of circumstances.25

6. Perinatal/neonatal collaboration. We have also been active in attempts to foster a closer relationship between obstetric and neonatal providers as we focus not only on obstetric antecedents to neonatal morbidity and mortality, but also on important areas of neonatal care. A large study involving >1 million neonates demonstrated the ability of health care providers to eliminate degrees of hyperbilirubinemia that have been associated with bilirubin encephalopathy in normal, term newborns through a simple and relatively inexpensive universal screening program now in place in all our facilities.3 A similar project involving the avoidance of ventilator-associated pneumonia in premature neonates has demonstrated significant improvement in outcomes for these infants.

Our efforts continue to be justified by continued outstanding results in perinatal outcomes and reductions in litigation, as reflected by reported claims (Figure). This trend contrasts with that seen nationally, in which claims have demonstrated a 15% increase since 2004.28 Currently, the national obstetric claims experience (claims/10,000 births) averaged over the past 3 years is approximately 20% higher than that seen in our system.28 In 2009, perinatal loss (in dollars) within our system remained below that seen in the category of “accidents on hospital grounds” and is rapidly approaching the level of loss seen in the category “occupational therapy.” Documentation remains a critical part of our malpractice loss prevention program; since its initial promulgation in 2006, we have yet to incur any malpractice payment for allegations of mishandling of shoulder dystocia when proper care was documented with this form. In addition, our systemwide primary cesarean delivery rate has plateaued in the range of 20-21% for the past 3 years. This has been achieved not as part of a concerted effort to reduce cesarean deliveries, but occurred naturally in response to improvements in individual components of intrapartum care.4

Despite these encouraging trends, several areas of concern remain. First, we are absolutely confident that adoption of our approach on a national level could, within 5 years, both dramatically reduce adverse perinatal outcomes and to a large extent eliminate the current national obstetric malpractice crisis. In reality, a relatively small number of repeated errors lead to most preventable adverse outcomes, and may be reduced by the approaches outlined above.4,29 While it is gratifying to see the adoption of these practices by disparate local and regional organizations, there currently exists no organization exerting an effective national leadership role in these areas. Thus, the benefits that accrue to our patients and to those of other interested health care systems are not available to the general population of women and babies. We are reminded of the warning expressed by the Institute of Medicine, “Leaders must ensure that their organization has the ability to change. Yet many leaders now view their role as shielding and protecting the organization from environmental pressures that may require them to change.”9 While countless individual physicians, hospitals, hospital departments, and state perinatal organizations have enthusiastically embraced the concept of patient safety–based practice, we remain concerned at the persistence of an alternative culture in which physician autonomy and anecdotal experience trump available data and the recommendations of the Institute of Medicine, contributing to a “normalization of deviance” at odds with a safety-based culture.
Despite these persistent problems, we are encouraged that patient safety is rapidly becoming a rallying cry for an increasing number of professional organizations. While the experience of the Hospital Corporation of America does not provide all the answers for all facilities in the United States, we are confident that it does provide some.

REFERENCES