

OBSTETRICS

Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety

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The Hospital Corporation of America (HCA) is the nation's largest private health care delivery system, providing approximately 220,000 deliveries annually in 120 facilities in 21 states. Representing approximately 5% of all births in the United States, we describe here our assessment and approaches to 4 major challenges in contemporary obstetric practice and the initial results of these initiatives. Notably, and as part of a concerted effort to incorporate the features of high-reliability organizations into HCA's obstetrical services, these interventions have been associated with improved perinatal outcomes, a reduced primary cesarean delivery rate, and lower maternal and fetal injury, with reduced litigation, as measured by halving of the number of claims and a nearly 5-fold reduction in the cost of claims.

The problems

1. Despite spending more of our gross domestic product on health care than any other industrialized country, the United States currently ranks 17th in the world in perinatal mortality rate, outcomes that, according to the World Health Organization, are largely due to obstetric causes.¹ While there are certainly demographic differences between the United States and some of the world's countries with better perinatal outcomes, we have found it increasingly difficult to ac-

In a health care delivery system with an annual delivery rate of approximately 220,000, a comprehensive redesign of patient safety process was undertaken based on the following principles: (1) uniform processes and procedure result in an improved quality; (2) every member of the obstetric team should be required to halt any process that is deemed to be dangerous; (3) cesarean delivery is best viewed as a process alternative, not an outcome or quality endpoint; (4) malpractice loss is best avoided by reduction in adverse outcomes and the development of unambiguous practice guidelines; and (5) effective peer review is essential to quality medical practice yet may be impossible to achieve at a local level in some departments. Since the inception of this program, we have seen improvements in patient outcomes, a dramatic decline in litigation claims, and a reduction in the primary cesarean delivery rate.

Key words: litigation, patient outcomes, patient safety, quality medical practice

Cite this article as: Clark SL, Belfort MA, Byrum SL, et al. Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety. *Am J Obstet Gynecol* 2008;199:105.e1-105.e7.

cept such differences as the sole explanation for our performance in this area.

2. For the past several decades, the rate of cesarean delivery in the United States has continually increased.² This trend was briefly interrupted by a plateau in the 1990s because of the widespread acceptance of vaginal birth after cesarean. However, subsequent reports of adverse outcomes among women undergoing trial of labor after a cesarean delivery resulted in a progressive decline in the number of women choosing this option for birth.^{3,4} Indeed, with the recent acceptance of primary cesarean on demand, reversal of this trend seems unlikely.⁵ Given the safety of cesarean delivery in the United States, a high rate of such operative delivery per se would not be of concern if it resulted in improved perinatal outcomes; however, evidence of such a link is lacking.⁶ This increasing cesarean delivery rate has been amply decried, but as yet effective solutions to reverse this

trend have not been readily forthcoming.^{7,8}

3. Despite the frequent misconception that cesarean delivery is a panacea for cerebral palsy and other adverse obstetric outcomes, obstetric malpractice claims have actually risen in parallel association with the rise in the cesarean delivery rate. Concerted efforts by organized medicine to remedy this situation through encouraging evidence-based practice have not been uniformly successful. There are no data that support the contention that cesarean delivery on the basis of any single or combination of fetal heart rate patterns reduces the rate of cerebral palsy.⁹ Thus, the continued presentation of claims that cerebral palsy would have been prevented by an earlier cesarean delivery are clear evidence that the policy of judicial policing of junk science has not been as effective as had been hoped.^{10,11} Furthermore, recent attempts at a federal tort reform by a government in which both executive and legislative

From the Hospital Corporation of America, Nashville, TN.

Received Oct. 16, 2007; revised Nov. 26, 2007; accepted Feb. 14, 2008.

Reprints not available from the authors.

0002-9378/\$34.00

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doi: 10.1016/j.ajog.2008.02.031

branches were dominated by the sponsoring political party were unsuccessful. These observations suggest that neither better science nor legislative relief is likely to be the sole answer to the current malpractice crisis.

4. Once an obstetrician/gynecologist has completed the board certification process, few standard processes exist that will ever again adequately scrutinize the quality of that physician's clinical care outside the local hospital peer review committee process. Although some superb, effective local peer review committees exist, those seeking to establish such processes face significant challenges, given current medical staff and hospital board structures.

In short, our specialty is faced with unsatisfactory perinatal outcomes and an ongoing malpractice crisis despite increased costs and more cesarean deliveries. In too many cases, meaningful postboard certification oversight of physician practice that includes clinical outcomes assessment and review is absent and may contribute to these problems. In the face of such concerning trends, alternative approaches must be considered. This review reports on interventions that have been effective in our organization in addressing challenges to the following: (1) reduce perinatal morbidity and mortality; (2) reduce unwarranted cesarean sections; (3) reduce malpractice loss; and (4) assure safe, highly reliable individual practice. Statistical analysis was performed using χ^2 with Yates continuity correction.

Our approach

Beginning in the year 2000 and continuing to the present date, HCA has evolved and implemented a unique, integrated approach to these issues, in conjunction with a clinical advisory board and work group consisting of practicing physicians and nurses at our facilities. This approach is based on the following 5 principles:

1. Uniform processes and procedure result in an improved quality, in-

cluding medical care. As a corollary, process variation generally leads to poor quality.

2. Every member of the obstetric team should be not only empowered but also required to intervene and halt any process that is deemed to be dangerous.
3. In the current environment, cesarean delivery is best viewed as a process alternative, not an outcome or quality endpoint.
4. Malpractice loss is best avoided by reduction in adverse outcomes and the development of unambiguous practice guidelines, rather than by attempting to make unusual care more "defensible" through the use of nonspecific guidelines.
5. Effective peer review is essential to quality medical practice yet may be impossible to achieve at a local level in some departments.

In most areas of human endeavor, process or procedure variation is typically associated with a poorer outcome or product, and uniformity of process is generally associated with improvement of these measures.^{2,12-14} This principle has been demonstrated to be valid in both mechanical and biological systems ranging from manufacturing to evolution and professional baseball.¹⁵ Furthermore, such standardization is central to any profession or enterprise seeking consideration as a high-reliability organization.^{16,17}

An example of a highly reliable industry, aviation has achieved an enviable record of safety, largely through standardization of process, unflinching use of checklist-driven protocols to govern behavior in high-risk situations, and crew resource management.^{18,19} The latter represents an approach in which all crew members are not only encouraged but also obligated to intervene when they perceive potential pilot error. This approach is similar to that pioneered by Toyota Motor Co in which every worker is both empowered and obligated to stop the production line if he or she identifies a potential production or process error.²⁰

These concepts are the antithesis of a medical model in which the attending

physician functions as the unchallenged captain of the ship, and the protection of physician autonomy is promulgated as a desirable goal. We suggest that both ideas are antiquated and counterproductive. There is no highly reliable organization that develops guidelines for use in critical situations that are even remotely affected by concerns for preservation of pilot or operator autonomy. In fact, in both military and civilian aeronautics, situations not uncommonly arise in which the actions of every team member are tightly regulated down to the level of the words that may be spoken. All communications are clear, timely, and solution driven. In any highly reliable organization, deviations from critical protocols are permitted only in extreme and uncommon circumstances and are invariably subjected to uncompromising and critical peer review.

In recent years, examination of the internal HCA data system has allowed the identification of several clinical situations that place patients at an increased risk for adverse outcome and place physicians at an increased risk for litigation. These include the use of 3 specific drugs, oxytocin, misoprostol, and magnesium sulfate; the performance of operative vaginal delivery; and the management of shoulder dystocia and abnormal fetal heart rate tracings. Following discussions with a large panel of HCA physicians and nurses, highly specific, checklist-driven protocols, procedure documentation templates, and/or mandatory online educational modules have been developed and implemented.

The protocol for oxytocin administration has previously been described.¹⁴ Checklist-based protocols for the administration of misoprostol and magnesium sulfate and a standardized delivery note addendum for patients with shoulder dystocia are described in [Figures 1-3](#). Online educational modules may be accessed at www.healthstream.com. A physician may override any such protocol but only after a personal evaluation of the patient and a written note clearly articulating the rationale for such variation.

In this process, we did not anticipate that our specific practice protocols

would be uniquely effective; in most cases, alternative tools could certainly be developed that yield equivalent outcomes.¹⁴ Rather, our actions are guided by the belief that process standardization itself yields improved outcomes. At a minimum, such uniform guidelines create an improvement platform to understand the relationship between the standardized process (the independent variable) and the clinical outcomes (the dependent variables).

A common initial objection to this process involved the lack of fully evidence-based recommendations underlying some of these protocols. Clearly the practice of evidence-based medicine should be an overriding goal of any responsible clinician. However, the practice of evidence-based medicine does not mean that in the absence of multiple prospective, randomized, double-blinded, placebo-controlled, cross-over trials, clinicians may properly engage in clinical anarchy. Obstetrics today is a team process, requiring the coordinated, integrated involvement of physicians, midwives, nurses, technicians, laboratory support personnel, and the mother. The recommendations developed are consensus driven based on the best interpretation of the scientific-based evidence that does exist.

Obstetrics in the United States is also unique in that the traditional captain of the team is often not present during important parts of the labor process. Process standardization ensures that each team member invariably knows what the physician team leader is expecting and what the other delivery team members will be doing. This process provides multiple shields against error and eliminates much of the speculation that the delivery team may experience in the absence of standard processes. Any team member can, in effect, stop the assembly line (or at least slow it down somewhat) when that person detects error, or potential error, in the process. Thus, the standard protocols serve as a “forcing function” for both the desired clinical process and the ability to analyze any unanticipated concerns.

It should be emphasized that where evidence-based medicine exists, it is ac-

FIGURE 1
Checklist-based protocol for administration of misoprostol in viable term fetuses



**RECOMMENDED
PRE AND IN-USE CHECKLIST
MISOPROSTOL**

“This check Pre and In Use Misoprostol Checklist represents a guideline for care: however, individualized medical care is directed by the physician.”

Notes: for repeat doses of misoprostol, begin with #11
Adequate variability may be substituted in #13 for repeat doses.

Date and time completed _____

1. Physician or Midwife Order on chart
2. Physician with cesarean section privileges is aware and readily available
3. Patient understands risk (1-2%) of hyperstimulation
4. Prenatal record and history and physical on chart
5. Pelvis documented to be clinically adequate by the physician (should be on prenatal record)
6. Estimated fetal weight within past week (clinical or ultrasound) less than 4500grams, or less than 4250grams if diabetic
7. Gestational age documented
8. Indication for ripening/induction _____
9. No contraindications present
10. Fetus is vertex
11. Patient is not having regular contractions with cervical change since last dose (if applicable)
12. A minimum of 30 minutes of monitoring has been completed
13. At least 2 accelerations of 15 bpm x 15 sec in 30 minutes or Biophysical profile of 8 of 10 is present within the past 4 hours or variability is adequate.
14. No late decelerations are present
15. No more than 2 variable decelerations exceeding 60 seconds in duration and decreasing 60 bpm from baseline within the previous 30 minutes prior to misoprostol insertion.

This checklist must be completed prior to the administration of each dose.

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tively incorporated into our clinical care tools. When such evidence is not available, we rely on the collective wisdom and experience of a team composed of active clinicians from our institutions for protocol development. We anticipate standardization of additional processes because our internal data demonstrate the need for such to address adverse patient outcomes.

Our approach to the cesarean delivery rate has also been unique: we ignore it as an outcomes goal and view it instead as an acceptable alternative process. In doing so, we proceed with the assumption that the appropriate cesarean delivery

rate can be approached only secondarily through primary improvement in practice quality.

The ideal cesarean delivery rate will naturally follow the achievement of ideal overall care and can be effectively approached in no other way. We believe that difficult vaginal delivery is not appropriate when an easy cesarean delivery is an option. We maintain that the mark of a good obstetrician, and safe, highly reliable care, is the ability to send home a healthy mother/baby pair, not the ability to “tough out” a difficult delivery, and we are unwilling to tolerate any avoidable adverse outcomes in the pursuit of

FIGURE 2
Checklist-based protocol for magnesium sulfate infusion



HCA

HCA Perinatal Safety Initiative

Recommended

Magnesium Sulfate In-Use Checklist

“This Magnesium Sulfate In-Use Checklist represents a guideline for care: however, individualized medical care is directed by the physician”

To be completed every 4 hours, with the exception of the oxygen saturation monitoring, which must be continuous, and assessed and documented every 30 minutes. For patients being treated for preterm labor without hypertensive disease in whom the dose has not been changed for 24 hours, hourly documentation of continuous oxygen saturations measurements is acceptable. If the checklist cannot be completed, Magnesium Sulfate is to be discontinued, a stat magnesium level ordered and the physician notified.

Date and time completed _____

- Deep tendon reflexes present**
- Respiratory rate greater than 12/minute**
- O2 saturation is within 5% of the baseline level.**
- Total urine output equal to or greater than 120mL during the last 4-hour period.**
- Medication, pump, safety tubing, and infusion rate verified by the RN every 4 hours.**
- Medication, pump, safety tubing, and infusion rate verified by 2 RN's with each change of medication bag or infusion rate.**

In addition, mixing restrictions assure that a lethal dose can never be hung.

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an arbitrary cesarean delivery rate. Thus, although we wish to avoid unnecessary cesarean deliveries, we urge and encourage our physicians to use cesarean liberally for individual cases of labor arrest and abnormal fetal heart rate tracings. In isolation, such a policy might be expected to increase the rate of cesarean delivery; as part of an integrated approach to patient safety and process standardization, the results have been surprising (see the following text.)

In attempting to avoid litigation, we have noted the existence of 2 distinct schools of thought. One traditional approach involves the production of guidelines that give a general sense of clinical direction but at the same time are purposefully ambiguous. This ambiguity is

often a result both of a lack of solid, evidence-based medicine on which to base practice recommendations and the thought that such ambiguity may assist in the defense of a wide variety of clinical actions taken in specific situations. The current state of malpractice litigation in the United States, and HCA's successful reduction in both the number and value of claims for care occurring in our hospitals using the approaches described, suggests that there may be room for improvement of these strategies.

As with the safety and quality issues outlined above, guidelines with substantial ambiguity are not the approach to litigation avoidance taken by other highly reliable/high-risk organizations. Any current commentary on commer-

cial airline litigation is difficult, given that fact that entire years go by in which no person is killed in a commercial airline accident worldwide. However, when such issues do arise, the focus is typically simple: did the pilot or crew follow the specific protocols and checklists governing the situation? In obstetrics, a field in which such specific protocols generally do not exist, the question of standard of practice must be left up to the vagaries of expert witness opinion and jury sympathy.

We find it regrettable that when an obstetrician encounters a clinical situation likely to result in a suboptimal outcome, regardless of her or his actions, and sincerely desires to “do it by the book,” there is often no such “book” to which to turn. Indeed, an analysis of the variation in cesarean delivery rates throughout the United States suggests that lack of such guidelines contributes to decision making regarding operative delivery that is virtually random.² In terms of practice guidelines, we believe that specificity, not ambiguity, is 1 answer to both patient safety and litigation.

Some of HCA's protocols are much more explicit and restrictive than would currently be mandated by standard of care. For example, with respect to vaginal birth after cesarean delivery in our facilities, we have defined the mandatory response time from the nurse's recognition of a problem to the physician arriving at the bedside as 5 minutes. When this is not possible, we feel that this procedure should not be offered in that facility. We recognize that such a policy significantly restricts the availability of vaginal birth after cesarean. Furthermore, we do not claim that this approach defines the standard of care in the United States.

However, we have found that in practice, individual interpretation of the highly appropriate but nonspecific “immediately available” language incorporated into current practice guidelines all too often would permit being in the middle of an office procedure 20 minutes away from the hospital, assuming no traffic, an interpretation certainly not intended by the drafters of these guidelines.²¹ Although restrictive, we feel that

in practice there is no other way to consistently achieve the event to delivery interval documented in the literature to be associated with the absence of birth asphyxia in cases of uterine rupture.²² Thus, we suggest from our experience with 5% of all deliveries nationally that the best way to avoid litigation is to avoid adverse outcomes rather than attempt to defend various interpretations of the word “immediately.”

This approach extends to our conservative use of oxytocin and other high-risk medications as well as to procedures such as operative vaginal delivery. In a similar manner, we strongly encourage and support the establishment of 24 hour in-hospital obstetric coverage programs in our facilities. Such coverage does not represent the current standard of care and may never be feasible in smaller facilities. However, a review of almost 200 closed malpractice claims demonstrated that 40% of adverse outcomes related to intrapartum fetal hypoxia, and their associated malpractice claims, may have been avoided had such coverage been available.²³

Clearly, such protocols are not the sole answer to current litigation issues. Asch et al²⁴ recently demonstrated that physician compliance with protocols that are available is far from ideal. A review of the specific data regarding obstetric practice presented in these authors’ paper reveals that poor practice is also a significant contributor to the current malpractice crisis in our specialty.

Finally, the experience in transforming the reliability of delivery in HCA suggest that large-scale quality improvement measures such as those outlined here are incomplete without effective peer review. Unfortunately, it is difficult in practice to organize and carry out such local peer review, particularly when most reviewers find themselves either the partners or economic competitors of the individual being reviewed.

To assist local peer review committees, we have established a national peer review committee for review of select adverse obstetric outcomes: maternal death, term intrapartum or neonatal death or seizures, brachial plexus injury, uterine rupture, and term intracranial

FIGURE 3
Checklist-based delivery note supplement for cases of shoulder dystocia



HCA Shoulder Dystocia Delivery Note addendum

Time head delivered _____ Time body delivered _____

Initial Traction:

Gentle attempt at traction, assisted by maternal expulsive forces

Explain if above box not checked _____

Any/all maneuvers that apply and the order in which they were utilized. The order is not specified by the standard of care

Maneuvers utilized	In which order (circle)	By whom
<input type="checkbox"/> McRoberts	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Suprapubic pressure	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Episiotomy	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Episiotomy extension	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Posterior arm release	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Rubin’s Maneuver	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Woods maneuver	1 2 3 4 5 6 7	_____
<input type="checkbox"/> Other (list) _____	1 2 3 4 5 6 7	_____

Verify that fundal pressure was not applied after the head delivered:

_____ Not Applied

_____ Applied

If applied, by whom: _____

If applied, reason: _____

The arm under the symphysis at the point the head was delivered was: Right Left

List other items of note _____

 Primary Care Provider*

 Registered Nurse*

 Other Care Providers in attendance*

 Other Care Providers in attendance*

We encourage all health care providers present to sign and verify the events that did and did not occur.

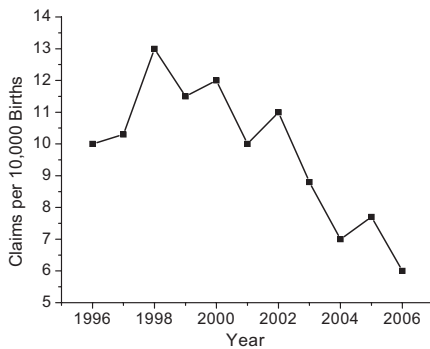
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hemorrhage. This committee is composed of 14 obstetricians and maternal fetal medicine specialists as well as 3 neonatologists and 3 obstetric nurses. Committee members include physicians practicing at our own facilities as well as outside experts. This committee is in-

tended to supplement rather than replace local peer review processes.

Logistical concerns prevent the national committee from addressing any but the most serious cases of adverse outcome. In 2006, 403 such cases were reviewed by this committee. When sub-

FIGURE 4
Trends in obstetrical malpractice claims



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standard care was identified, concrete recommendations were transmitted to the facility for action, as appropriate, by the local medical staff structure. The purpose of this committee was to provide local medical staffs with a consensus opinion regarding the outcome, unaffected by personal interest or practice bias. Perhaps counterintuitively, the committee's findings were unanimous in 97% of cases, suggesting that there is broad consensus among practicing obstetricians regarding standard of care in these areas. Also encouraging is the existence of numerous well-run, effective local peer review committees.

On the other hand, we were discouraged that in a few of the most egregious cases, the physician's care had been officially condoned by the local peer review committee. Fear of legal entanglements associated with criticism of an economic competitor featured prominently in some of these cases.

We are currently engaged in pilot projects involving multihospital and regional peer review to address such issues. Our experience suggests that the gap between actual and ideal care can be partially closed only by broad, national initiatives. If the remaining gap is to be narrowed, it must come through the actions of local peer review committees. Increased training of peer review leaders, accountability of such leaders to medical staff officers, legal protection of the privileged status of the peer review process,

and broader legal protection for those who participate in this process remain essential to quality care in the United States.

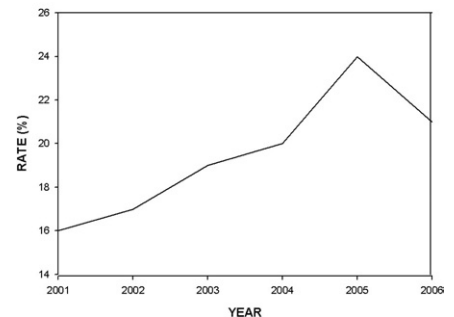
Despite these limitations, HCA's results have been dramatic and gratifying. Since the inception of this integrated effort focused on patient safety, based on the aforementioned principles, the obstetric malpractice claims and loss rates for our facilities has plummeted (Figure 4, $P < .001$). In this large health system with nearly 200 hospitals nationwide, obstetric malpractice claims currently rank behind "accidents on hospital grounds" in terms of litigation loss and cost. The achievement of fewer adverse perinatal outcomes leads to less litigation.

In addition, for the first time in many years, the primary cesarean delivery rate in our system in 2006 fell significantly (Figure 5, $P < .001$), despite the tolerance of a liberal general approach to operative delivery outlined in preceding text.¹⁴ This unanticipated and unique outcome appears to be attributable to fewer cesareans for oxytocin-induced fetal heart rate abnormalities associated with the universal implementation in 2006 of a uniform, checklist-based system for oxytocin administration.¹⁴ Again, process uniformity has resulted in process improvement. Although this course correction may well be overcome in future years as larger forces continue to drive the cesarean rate upward, in our large system, this translates annually into the avoidance of tens of thousands of primary and future repeat cesarean deliveries.

In analyzing the results of these programs, we certainly acknowledge the probable contribution of the Hawthorne effect: the simple knowledge that both practice patterns and outcomes are being scrutinized would be expected to lead to improved medical and nursing care. Furthermore, no quality improvement programs could be effective without the willingness of physicians and nurses in our institutions to become engaged in a culture of patient safety, founded on generally excellent physician and nursing practice.

FIGURE 5
Trends in primary cesarean delivery rate

PRIMARY CESAREAN DELIVERY RATE



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Our process has been generally well accepted; we receive far more requests from unaffiliated hospitals to adopt our protocols, checklists, and educational tools than we do complaints from physicians in our own system. However, this system is far from perfect. In a nonemployed, private practice setting, we cannot compel complete acceptance of our educational and documentation tools by every physician. We continue to see avoidable adverse outcomes and litigation, unnecessary cesarean deliveries, and vaginal births that ought to have been cesarean births. Although the use of such detailed and highly specified protocols, consistent with highly reliable processes, is perceived as a loss by some practitioners because of a reduction in independence and autonomy, it is unquestionably a win for patients and the quality of the health care system.

With an integrated, comprehensive patient safety program, the goals of improved patient outcomes, reduced litigation, and a lower primary cesarean rate appear to be achievable. These results are encouraging and suggest that our use of a different patient safety paradigm, based on the aforementioned principles, may be of value in addressing some of the most vexing problems in obstetrics and, more generally, in creating highly reliable health care. ■

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