Obstetrical safety and quality is an emerging and important topic not only as a result of the pressures of patient and regulatory expectations, but also because of the genuine interest of caregivers to reduce harm, improve outcomes, and optimize care. Although each seeks to improve care by using scientific approaches beyond human physiology and pathophysiology, patient safety methodologies seek to avoid preventable adverse events, whereas health care quality projects aim to achieve the best possible outcomes. It is well-documented that an increasingly complex medical system controlled by human workers is a circumstance subject to recurrent failure. A safety culture encourages a proactive approach to mitigate failure before, during, and after it occurs. This article highlights the key concepts in health care safety and quality and reviews the background of the quality improvement sciences with particular emphasis on obstetric outcomes and quality measures.

The primary aspiration of health care providers and systems is improving health. Regardless of best intentions, however, studies at the end of the 1990s illuminated the burden of harm related to medical errors, many of which were not the result of the mistake of an individual but to the confluence of systems-level factors. Certainly, many adverse health outcomes are an inevitable consequence of the disease process. However, there also is evidence that the health care system often contributes either to the failure of improvement or a preventable adverse outcome. When addressing issues of quality improvement and safety, therefore, the system providing care is the primary target for change.

Three factors make patient safety and quality improvement in obstetrics an important topic. First, because obstetric admissions are the leading reason for hospitalization in the United States, accounting for more than 4 million hospitalizations annually, the effects of obstetric quality improvement on the health care system as a whole are substantial. Second, obstetrics is a unique health care setting because in an overwhelming majority of cases, the expectations of families are for a healthy and joyous outcome. Failure to meet these expectations because of mishaps or missed opportunities creates considerable disappointment from families and health care providers alike. Finally, the medicolegal climate of obstetrics, with historically high rates of claims and monetary judgments against obstetricians, makes adverse outcomes economically costly to the system as well as emotionally costly to the parties involved.

It is estimated that 44,000–98,000 patients die each year in the United States as a result of medical errors, and perhaps 10% of patients are inadvertently harmed while receiving care in the hospital.1 Although investigators have attempted to estimate the rates of adverse obstetric outcomes, they have been limited in their ability to distinguish between preventable and inevitable events. For instance, adverse events are estimated to occur in up to 3–16% of deliveries in the United States, although the frequency that these events may have been preventable is harder to ascertain.2–4 Geller et al5 analyzed cases of adverse outcomes at their tertiary care center.
over a 7-year period and estimated the rate of preventability in maternal deaths, near-miss morbidities, and other severe morbidities as 40.5%, 45.5%, and 16.7%, respectively.

DEFINING SAFETY AND QUALITY

The 1996 Annenberg Conference on patient safety and medical errors was convened by leaders from the American Association for the Advancement of Science, the American Medical Association, and the Joint Commission on Accreditation of Healthcare Organizations (now The Joint Commission) in response to several well-publicized medical mishaps. This meeting sparked initiatives such as the Patient Safety Initiative of the Veterans Affairs Department, the Institute for Healthcare Improvement (now The Joint Commission) in response to several well-publicized medical mishaps. This attention is not unfounded; the number of annual deaths from patient safety events would rank medical error as the eighth leading cause of death in the United States, ahead of human immunodeficiency virus infection, motor vehicle accidents, and breast cancer.

Patient safety has been defined in numerous ways, although all definitions have common themes. The World Health Organization defines patient safety as “the prevention of errors and adverse events to patients associated with health care” and “the absence of preventable harm to a patient during the process of health care.” The IOM describes it as “freedom from accidental injury” and “prevention of harm to patients,” with the Agency for Healthcare Research and Quality using the same terms. Finally, the National Patient Safety Foundation states that patient safety is the “avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of care.” All of these definitions are built on a foundation that recognizes that human limitations and system complexities make error inevitable. Thus, a system with a strong patient safety culture works to prevent errors and harm, learns from errors that do occur, is built on a culture that prioritizes safety, and encompasses the entire health care team, from those at the front door to those in the administrative suites.

Quality as a health care concept preceded the patient safety movement by nearly 25 years. In the early 1970s, a series of articles highlighted substandard care delivery, and this was followed by the creation of regulatory and accreditation organizations, hospital quality assurance programs, the Institute for Healthcare Improvement, and the concept of providing higher quality health care products. Discussions of quality currently are ubiquitous in medical practice, especially in the discussions of reducing costs and improving care.

Safety and quality are closely intertwined and often aligned in purpose. In fact, the IOM recognizes patient safety as “indistinguishable from the delivery of quality health care.” However, there are nuances that hint at important differences. From a health care perspective, quality is the achievement of the best possible outcomes and experiences across multiple domains (eg, health outcomes, patient satisfaction, access, equity). Safety, on the other hand, is the prevention of inadvertent adverse outcomes. Thus, the difference is that quality work aims for the achievement of maximal positive results, whereas safety enterprises attempt to minimize the negative. For example, a program enhancing timely and correct dosing of preoperative antibiotics is a quality improvement endeavor, whereas a simulation program designed to teach responses during a shoulder dystocia would be a safety project. What quality and safety projects have in common is that they both work for improved health through means that are beyond the physiology and pathophysiology of the medical event and attempt to optimize medical care often through nonmedical measures such as social tools, systems engineering, and electronic technologies.

THREATS TO QUALITY AND SAFETY

During the 20th century, medicine became exponentially more powerful, complex, and effective; at the same time, however, these properties have made it more dangerous. Still, health care continues to rely at nearly every step on tasks executed by humans and those who are limited by fallibility and imperfection. This combination of complex systems controlled by flawed humans is the foundation of the patient safety problem: even the most well-designed systems with the most well-intentioned personnel can fail.

This situation is not unlike that of aviation, which as an industry has been a leader in safety improvement and thus provides a reasonable model for medicine. It should be acknowledged that the analogy is flawed in many ways—for instance, the pilot’s safety is always at risk in an aviation event, whereas most often only the patient is at risk in a medical event—but the three basic assumptions of aviation safety still may be used as a good model for medicine. First, aviation safety begins
by assuming that the risk of failure is inherent. Complex systems controlled by fallible human workers create ongoing opportunities for error. Second, these failures cannot always be anticipated, so recognizing and managing failure is a critical activity. Third, teamwork strategies that de-emphasize traditional hierarchies are emphasized, given that a majority of accidents are based on the confluence of multiple errors and unanticipated occurrences. Thus, although error is considered inevitable, harm is considered preventable through human and technological systems that can mitigate breakdowns. This is the concept of the high reliability organization, a system in which attention and vigilance are directed to the next potential mistake, to the point of creating a preoccupation with failure built on foundations of collaboration, standardization, resilience, and self-evaluation.14

The 2004 Joint Commission Sentinel Event Alert on preventing neonatal death and injury during delivery highlighted some of the important factors contributing to safety lapses in obstetrics.15 This report summarized the investigation of 47 perinatal deaths and categorized the frequency of root causes (Table 1). It is apparent from the table that nonmedical factors, in particular communication and organizational culture, contributed significantly to poor perinatal outcomes. This Sentinel Event Alert was critical for shedding light on the important safety threats in obstetrics and the risk reduction strategies that should be targeted as any unit begins a patient safety program.

THE SCIENCE OF QUALITY AND SAFETY

Although quality and safety initiatives often seek to solve problems using tools peripheral to human physiology and pathophysiology, these initiatives still have a scientific basis. In general, the quality improvement sciences are younger than most of the other medical sciences. They are also less understood because they are not widely taught in medical, nursing, and other postgraduate schools and the research articles focused on these initiatives often are in journals less commonly read by clinicians. Furthermore, some have the perspective that the work is more problematic—if not downright messy—because of challenges in finding proper controls or comparator groups or in designing interventions that can be assessed without deeply embedded bias or confounding.

Two pioneers in the science of quality improvement were Walter Shewhart and W. Edward Deming. A mathematician, Shewhart developed methods of statistical quality control, focusing on stabilizing processes and reducing variation in industrial production. Deming, an engineer, expanded on Shewhart’s work and is credited with refining and promoting the Plan-Do-Study-Act cycle method of project implantation and evaluation. Neither ever worked in health care, but the adaptation of their processes and analyses from industrial to health care applications is the foundation of quality improvement interventions in medicine.

Safety and quality projects can be designed as classical biomedical studies such as randomized controlled trials or observational studies. The 15-hospital cluster-randomized trial evaluating the effect of crew resource management on perinatal outcomes is a good example of the former.16 Far more studies are observational in nature and involve comparing conditions in a particular setting before and after an intervention. Examples of these are the comprehensive obstetric safety program at Yale and the team training program at Brown’s Women and Infants Hospital,17 which both demonstrated improvements in adverse obstetric outcomes, or the shoulder dystocia simulation program at Northwestern18 that showed improved management and reduced neonatal brachial plexus palsies after training, despite unchanged shoulder dystocia rates. Although these studies can suggest the effect of a large-scale intervention, causality between the intervention and the change in outcomes can be challenged by the potential for confounding and bias.

For many quality improvement projects, however, traditional study design is impractical as a result of large sample size requirements, the time required to complete the project, and the many sources of bias that may impair interpretation of results. The quasiexperimental Plan-Do-Study-Act cycle, however, is a commonly used approach that allows the exploration of

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Frequency (%)</th>
</tr>
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<tbody>
<tr>
<td>Communication</td>
<td>72</td>
</tr>
<tr>
<td>Organizational culture</td>
<td>55</td>
</tr>
<tr>
<td>Staff competency</td>
<td>47</td>
</tr>
<tr>
<td>Orientation and training</td>
<td>40</td>
</tr>
<tr>
<td>Inadequate fetal monitoring</td>
<td>34</td>
</tr>
<tr>
<td>Unavailable equipment and medication</td>
<td>30</td>
</tr>
<tr>
<td>Credentialing, supervision, and privileging</td>
<td>30</td>
</tr>
<tr>
<td>Staffing</td>
<td>25</td>
</tr>
<tr>
<td>Health care provider unavailable or delayed</td>
<td>19</td>
</tr>
<tr>
<td>Unavailability of prenatal records</td>
<td>11</td>
</tr>
</tbody>
</table>

change in less-controlled, real-world settings. When this approach is chosen, the stakeholders begin by forming a team, setting aims and objectives, and determining how and what to measure. They then proceed through an iterative process of instituting changes into the system (Fig. 1), learning from each cycle and correcting as needed for the next. The attempt of the Ohio Perinatal Quality Collaborative, a statewide initiative of 20 maternity hospitals to reduce early-term deliveries without medical indications, is an example of an obstetric Plan-Do-Study-Act project. Beginning with a 25% rate of “inappropriate scheduled births” between 36 0/7 and 38 6/7 weeks of gestation (inclusive), this collaborative group established an initial plan of action and set of interventions. Each month, each site received local and overall data regarding the frequency of early-term deliveries. Conference calls, webinars, and formal learning sessions allowed teams to respond and create new interventions. Over a short period of time, improvements were seen in rates of elective early delivery, but these rates improved even more over a longer period of time as the teams learned from their own as well as the sites’ collective experience (Fig. 2). Although the Plan-Do-Study-Act cycle is a common study design in quality improvement, it is probably underutilized in obstetrics with very few publications to date that are founded on this approach.

Analysis of quality improvement data can be performed using traditional methods (eg, descriptive statistics, bivariate statistics, and multivariable regressions) or methods specific to quality improvement. For instance, process control (ie, Shewhart) charts can be used to demonstrate change and improvement in two ways. First, a mean or frequency can be charted and tracked over time. Improvements in outcome or process measures could be seen, for example, in changes in the frequency of an event over time. Additionally, changes in the system (eg, the institution of an intervention) can be suggested by data points that are outside of the upper and lower control limits (ie, the dotted lines in Fig. 2). The control chart in Figure 2 is the chart generated by the Ohio Collaborative to demonstrate how their efforts were associated with a reduction in early elective delivery. Another example of a study in which control charts were used is the work of Einerson et al, who demonstrated how a postpartum hemorrhage patient safety program could improve both processes and outcomes associated with obstetric hemorrhage.

In the same way that there are reporting guidelines for randomized controlled trials (Consolidated Standards of Reporting Trials [CONSORT]), observational studies (STrengthening the Reporting of OBServational studies in Epidemiology [STROBE]), meta-analyses and systematic reviews (Meta-Analyses and Systematic Reviews of Observational Studies [MOOSE] and Preferred Reporting Items for Systematic reviews and Meta-Analyses [PRISMA]), and studies of diagnostic accuracy (STandards for the Reporting of Diagnostic accuracy studies [STARD]), the Standards for Quality Improvement Reporting Excellence (SQUIRE) publication guidelines help authors, editors, and reviewers report quality improvement work coherently and to the standards of expert consensus. As publications of quality and safety work in obstetrics become more prevalent, the tools for designing, studying, and publishing strong projects will become more integrated into common language and practice.
and can be engaged and changed by the system distributing the care (actionable and modifiable). Delivery before 39 weeks of gestation without a medical indication is an example of a sound quality metric. These deliveries are easily identifiable in medical record review, and the numerator and denominator for the rate are clearly defined. Reductions in nonindicated deliveries before 39 weeks of gestation are associated with improvements in neonatal outcomes. Furthermore, health care providers can control the processes that contribute to unnecessary early deliveries. Finally, this measure is comparable across health care providers and institutions. Some metrics might be appropriate to track at a local level over time but not across institutions. For instance, it might be desirable to compare the rate of third- and fourth-degree lacerations at an institution over time as interventions designed to reduce their occurrence are instituted, although the metric of third- and fourth-degree lacerations as a national comparative measure to demonstrate quality is more problematic for a variety of reasons. In 2002, The Joint Commission proposed quality measures for obstetrics, which were replaced in April 2010 by the Perinatal Care core measure set. The Perinatal Care core measures comprise five metrics (Table 2) with sufficient evidence that better outcomes are clinically important and are possible with system and process improvement. These core measures were chosen from a broader set from the National Quality Forum by a technical advisory panel of experts in perinatal care. The benefit of the core measures is that they provide a national, standardized set of quality metrics that hospitals can use. Since 2013, the Centers for Medicare and Medicaid Services have required hospitals to report Perinatal Care-01 as part of the Hospital Inpatient Quality Reporting Program, affecting hospital payments under its “pay-for-performance” initiative beginning fiscal year 2015. Since January 1, 2014, The Joint Commission, in alignment with the Centers for Medicare and Medicaid Services, has required hospitals with greater than 1,100 annual births to publicly report Perinatal Care core measures. In 2013, according to The Joint Commission, only 5.6% of hospitals achieved compliance rates in the composite index (calculated from Perinatal Care-01, Perinatal Care-03, and Perinatal Care-05a).
above 95%, mostly as a result of underperformance on Perinatal Care-05, even when only including patients who choose to breastfeed (Perinatal Care-05a). This low performance rate certainly points out room for improvement, but also may suggest further improvement may be necessary in how these outcomes are tracked and classified. The Perinatal Care core measures are far from a perfect encapsulation of obstetric quality. For example, a purely elective delivery (for convenience) of a woman with well-controlled gestational diabetes at 38 weeks of gestation would not be considered a numerator case and would be allowable for Perinatal Care-01, because diabetes is a diagnosis on the list of codes possibly justifying delivery before 39 weeks of gestation. On the other hand, a cesarean delivery for a patient with active genital herpes simplex virus infection would not be excluded from the numerator of Perinatal Care-02. A neonate presenting with hypoglycemia shortly after birth and who therefore required a bottle-feed would be considered a missed opportunity for exclusive breastfeeding for Perinatal Care-05. In the last two examples, one could imagine misplaced anxiety among health care providers for failing to meet quality goals despite the fact that they were trying to provide appropriate and important therapies.

Numerous other adverse outcome measures have also been proposed. The obstetric adverse outcome index was proposed by Mann and colleagues and constitutes a set of events or indicators determined by consensus (Box 1). The index is calculated as the number of mothers affected by one or more indicators divided by the total number of mothers delivered over the time period of measurement. Multiple quality improvement projects have used this to track change. It should be pointed out the adverse outcome index is imperfect. Perineal lacerations are typically much more common than the other indicators, and thus performance according to the adverse outcome index might be dominated by this single measure at some institutions. Another important weakness of the adverse outcome index is that it has strong internal validity for comparison within a hospital, but it is difficult to use to compare across health systems with different patient populations, levels of acuity, and health care provider types. The Assessment of Perinatal Excellence study, a Maternal-Fetal Medicine Unit Network program, tracked five primary outcome measures (venous thromboembolism, postpartum hemorrhage, peripartum infection, severe perineal lacerations, and a composite neonatal outcome in term neonates) with the aim of evaluating how to risk-adjust for patient characteristics. Two publications from this group have demonstrated that risk-adjustment models, at least for these outcomes, may be necessary, because hospital performance on these measures may be materially affected by the case-mix of patients for whom they care. Moreover, this study as well as a study by Howell et al demonstrated that outcomes were not clearly related to process measures that had been proposed.

### Table 2. Perinatal Core Measures

<table>
<thead>
<tr>
<th>Core Measure</th>
<th>Name</th>
<th>Description</th>
<th>National Rate: 2012 (%)</th>
<th>National Rate: 2013 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perinatal Care-01</td>
<td>Elective delivery</td>
<td>Rate of deliveries 37 0/7–38 6/7 weeks of gestation without labor or a medical indication</td>
<td>8.2</td>
<td>4.3</td>
</tr>
<tr>
<td>Perinatal Care-02</td>
<td>Cesarean delivery</td>
<td>Cesarean delivery rate in nulliparous, singleton patients with cephalic presentation without contraindication to vaginal delivery</td>
<td>26.3</td>
<td>25.9</td>
</tr>
<tr>
<td>Perinatal Care-03</td>
<td>Antenatal steroids</td>
<td>Rate of steroid initiation in patients delivering 24 0/7–31 6/7 weeks of gestation</td>
<td>81.8</td>
<td>89.7</td>
</tr>
<tr>
<td>Perinatal Care-04</td>
<td>Health care-associated bloodstream infections in newborns</td>
<td>Percentage of newborns with septicemia or bacteremia</td>
<td>0.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Perinatal Care-05</td>
<td>Exclusive breast milk feeding</td>
<td>Percentage of newborns that are fed breast milk only since birth (Perinatal Care-05a is exclusive breast milk-feeding considering the mother’s choice)</td>
<td>50.8</td>
<td>53.6</td>
</tr>
<tr>
<td>Composite</td>
<td>Composite</td>
<td>Perinatal Care-01, Perinatal Care-03, Perinatal Care-05a</td>
<td>57.6</td>
<td>74.1</td>
</tr>
</tbody>
</table>

Average number of hospitals reporting data is 167.
An alternate method of measuring safety is not by the number of events that occur over a certain period of time, but rather by the period of time between adverse events. For the most part, serious safety events are infrequent. This method should be used for types of events that are infrequent and grave, like sentinel and serious safety events. Improvement would be demonstrated with an increase in the time between serious safety events.

Sentinel events are adverse medical events requiring immediate investigation and corrective action. The definition of a sentinel event, revised in January 2015, is “any patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm.” Specifically related to obstetrics and perinatology, The Joint Commission further specifies that sentinel events would also include—among other events—any intrapartum maternal death or severe maternal morbidity, unanticipated death of a full-term neonate, discharge of a neonate to the wrong family, abduction of any patient receiving care, wrong-site surgery, unintended retention of a foreign object in a patient after an invasive procedure, hemolytic transfusion reaction, and severe neonatal hyperbilirubinemia. Sentinel events frequently require in-depth structured reviews such as root cause analysis and failure and event modes analysis, which typically result in the conveyance of formal corrective action plans to regulatory agencies like The Joint Commission or the state’s public health department.

The definition of severe maternal morbidity with reference to sentinel events is based on a consensus statement from the American College of Obstetricians and Gynecologists (the College), the Society for Maternal-Fetal Medicine, and the Centers for Disease Control and Prevention and is defined as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hours), that requires the transfusion of four or more units of packed red blood cells, admission to the intensive care unit, or both. Experts have recommended a formalized and structured event review system for each severe maternal morbidity.

One concern with the definition of severe maternal morbidity is that incidents where massive transfusions or intensive care unit care were probable (such as delivery of a patient with placenta accreta or the care of a patient with a history of primary pulmonary hypertension) could be classified as events and trigger review. Indeed, within the event review system suggested for severe maternal morbidity, these cases would be examined. However, under the definition of a sentinel event per The Joint Commission, they would not get classified and would not reflect on the overall sentinel event rate because events that occur as a direct result of an underlying condition of the patient can be excluded. There is concern that the severe maternal morbidity classification system may penalize appropriate care and that medical teams may be hesitant to transfuse or transfer a patient as appropriate for fear of triggering a review. This points out the importance of creating the mature culture of safety characteristic of a high reliability organization, where a nonjudgmental and nonpunitive approach to event review can provide lessons and opportunities for improvement. Additionally, this concern should be tempered by the fact that if patients should but do not receive appropriate transfusion or intensive care unit admission, it is quite possible that they may experience another adverse event that will still indicate a potential quality problem.

**INTERVENTIONS TO IMPROVE SAFETY AND QUALITY**

Reducing harm, preventing error, and improving quality are aims that typically require multidimensional solutions. The threats to a single patient safety issue are often overlapping; most instances of potential harm, harm, or reduced quality involve multiple gaps and faults within a system. For this reason, it is often impossible to recommend a single solution for any one problem. This is why most quality improvement projects often require multiple Plan-Do-Study-Act

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**Box 1. Obstetric Adverse Outcome Index Indicators**

- Apgar score less than 7 at 5 minutes
- Blood transfusion
- Fetal traumatic birth injury
- Intrapartum or neonatal death greater than 2,500 g
- Maternal death
- Maternal ICU admission
- Maternal return to OR or Labor and Delivery
- Unexpected admission to neonatal ICU greater than 2,500 g and for more than 24 h
- Uterine rupture

ICU, intensive care unit; OR, operating room.

cycles and changes in approach before finding success. It is also the reason why some interventions, studied in isolation, may fail to yield the expected results or why a single intervention, tested at two different institutions, might have different outcomes at each site. Most safety interventions require multiple types of change, including education and training of individual caregivers, work to improve coordination and communication of teams, and organization of administrative and structural processes. For this reason, interventions should not be viewed as independent solutions, but rather as pieces of a matrix. Furthermore, sensitivity to context is important when planning a safety or quality project. An effective solution to a problem in one health care setting may not be the right approach to the same problem in a setting with different patient populations, clinical strengths, or administrative challenges. This concept is why some approaches that have worked in one setting (e.g., critical care, general surgery, anesthesiology) might not be as effective in obstetrics.

Rather than attempt an exhaustive review of all of the possible safety and quality interventions for our field, it seems most efficient to focus on a few concrete examples of the important approaches, organizing the strategies into a classification that accounts for the top five root causes of perinatal adverse events from The Joint Commission Sentinel Event Alert: communication, organizational culture, staff competency, orientation and training, and fetal monitoring.\(^1^5\)

**Communication**

Caregivers are expected to work in health care teams, but the concept of teamwork is rarely reviewed or practiced in medical education or training. Crew resource management (or “team training”) is one type of approach that aims to improve communication and coordination of health care team members. The topics covered in crew resource management programs like TeamSTEPPS and MedTeams address four main skills: leadership, situational monitoring, mutual support, and communication. Structured tools and techniques for collaboration (team huddles and briefings), clarification (“check-backs”), handoffs (“SBAR”), and conflict resolution (chain of command, two-challenge rule) are typically reviewed and practiced. Crew resource management is advocated by the IOM, the Institute for Healthcare Improvement, the Agency for Healthcare Research and Quality, the Department of Defense, the College, and The Joint Commission. The Joint Commission has issued the most direct recommendation regarding the importance of communication in the 2004 Sentinel Event Alert to “conduct team training in perinatal areas to teach staff to work together and communicate more effectively.”

As described earlier, the value of crew resource management has been tested in obstetrics in a randomized trial.\(^1^6\) This cluster-randomized trial involved didactic sessions introducing crew resource management principles to a multidisciplinary audience of nurses, obstetricians, and anesthesiologists. This study did not show an effect on outcomes, as tracked by the adverse outcomes index, although there was a significant improvement in decision-to-incision time for urgent cesarean deliveries (21.2 compared with 33.3 minutes) for centers with crew resource management compared with controls. An important limitation of this study is that observations were only made for 5 months after crew resource management implementation, which perhaps was not enough time to see maturity of the skills of team training. Furthermore, it may be argued that crew resource management implemented in isolation, without the structure of other safety and quality interventions, may not have a full effect. On the other hand, both the Yale and the Brown comprehensive obstetric safety programs used crew resource management as a major strategy and, using observational study designs, were able to demonstrate not only improvements in adverse outcomes, but also in patient safety climate and culture after implementation of their programs.\(^1^7,^3^5\)

**Organizational Culture**

Safety culture is defined as the integration of safety thinking and practices into clinical activities. Organizational safety culture refers to a shift from a traditional culture of hierarchy and blame to a “just culture,” a system built on a fair and nonjudgmental approach to adverse outcome and event reviews (debriefings, root cause analyses, failure modes, and effects analyses) to uncover the systems leading to unsafe activities or adverse outcomes.\(^3^6\) “Safety climate” is the description of the attitudes, perceptions, and values of the safety culture and can be measured through surveys. Climate surveys not only can be useful as measurement tools, which assess strengths and weaknesses of an organization, but also can be thought of as an intervention, because they increase employee awareness of the importance of safety and can be used to strategize about possible gaps and weaknesses that should be targets for intervention. The Safety Attitudes Questionnaire is an assessment tool of employee perception of safety and teamwork, validated in both the aviation and health care industries.\(^3^7\) The Safety Attitudes Questionnaire is the only safety climate survey to demonstrate
an association between improvements in safety culture and patient outcomes, both in general medicine and obstetrics.\textsuperscript{35,36} However, far more ubiquitous, and available for free in the public domain, is the Hospital Survey on Patient Safety Culture supported by the Agency for Healthcare Research and Quality (http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/hospital/). The public accessibility of the database allows units to access comparative data.

**Staff Competency**

Competency refers to the ability to do something successfully and proficiently. We expect nurses and doctors who have achieved certain levels of education, training, and credentialing to have general competency in their work, yet one should not assume that all caregivers have the same experience and levels of training. Furthermore, it would be imprudent to expect those workers to have expert competency across all tasks they might face in the day, particularly given today’s pace of developing information and standards. Developing structured protocols, guidelines, bundles, and checklists is one way of creating a structure to deal with heterogeneous competency. These tools—typically produced from an interdisciplinary process involving nursing, physicians, and administration working together—enable implementation of evidence-based standards and also create a shared mental model for how care should be given across all tasks they might face in the day, particularly given today’s pace of developing information and standards. Developing structured protocols, guidelines, bundles, and checklists is one way of creating a structure to deal with heterogeneous competency.

Implementing a policy for postcesarean thromboprophylaxis and a protocol for acute antihypertensive therapy at the Hospital Corporation of America (more than 110 maternal–newborn facilities in the United States) was associated with a reduction in deaths related to thromboembolic disease, intracranial hemorrhage, and preeclampsia.\textsuperscript{39} Shields et al and Einerson et al have demonstrated that detailed postpartum hemorrhage protocols were associated with enhanced management and improved outcomes of obstetric hemorrhage.\textsuperscript{40,41} The College has developed Patient Safety Checklists for induction of labor, planned cesarean delivery, documenting shoulder dystocia, magnesium sulfate, trial of labor after cesarean delivery, and postpartum hemorrhage (http://www.acog.org/Resources-And-Publications/Patient-Safety-Checklists-List). These serve as good templates and starting points for any program, but may need to be adapted specifically to the qualities of local settings. The Council on Patient Safety in Women’s Health Care (http://www.safehealthcareforeverywoman.org/index.html) is an interdisciplinary group that includes, among others, the College, the American Board of Obstetrics & Gynecology, and the Society for Maternal-Fetal Medicine, and aims, among other things, to have bundles for obstetric hemorrhage, severe hypertension, and venous thromboembolism implemented across all birthing centers in the United States over 3 years.

**Orientation and Training**

Medical simulation is the technique of recreating an experience that did or could happen in an atmosphere that replicates the actual setting or context. Simulation allows teams to reconstruct or practice events in a safe environment that allows for mistakes and removes the potential for harm to patients. Simulation is typically used to enhance practical skills and train for rare events, but it also can be used as a technique for building communication skills in the setting of team training exercises. Simulation is also an effective way of looking at the environmental design of an existing or a new obstetric unit, assisting with the implementation of new technologies, or optimizing a plan.

In obstetrics, simulation has been tested both as an educational tool and also as an intervention to enhance clinical outcomes. A great many studies have documented improvements in knowledge and skills of trainees in obstetric-specific simulation scenarios such as operative delivery, eclampsia, and postpartum hemorrhage. However, simulation can probably affect clinical outcomes as well. The Brown program that demonstrated reductions in the adverse outcomes index and improved safety culture used simulation as the core component to teach team training.\textsuperscript{42} Draycott et al\textsuperscript{43} found that the incidence of low Apgar scores at 5 minutes and neonatal encephalopathy were reduced after a required 1-day course of simulation in obstetric emergencies. A later study from the same group looking specifically at mandatory shoulder dystocia training showed that this training was associated with improved clinical management, through use of the appropriate maneuvers, and a fourfold reduction in the frequency of neonatal nerve palsy.\textsuperscript{43}

**Fetal Monitoring**

Fetal monitoring is used during labor management for 85–90% of pregnant women in the United States. Recent advances in standardized terminology and structured management approaches have aimed to improve the education of and consistency in use of language for intrapartum fetal monitoring. Previously, competency in fetal monitoring was gained through observation—if not trial and error—during real-life experiences and recognized only by the satisfactory
completion of an orientation or training period. Such informal training and credentialing is arguably inadequate for a tool used so ubiquitously. Improving competency, and thus utilization and efficacy, is one rationale for advocating for formalized fetal monitoring credentialing.44 The Perinatal Quality Foundation’s fetal monitoring credentialing examination uses script concordance testing questions that require judgment and decision-making proficiency on top of fundamental knowledge and interpretation skills. That said, there is very little direct evidence of the effect of fetal monitoring credentialing on outcomes, although it was an important and required component of the Yale comprehensive safety program.4

OUTPATIENT SAFETY AND QUALITY
The major focus of safety and quality, in general, has been on inpatient care. This is well-founded, given that the hospital setting has a more vulnerable patient population, can involve potentially more dangerous medications and technologies, and typically involves more human workers and complex systems. However, although adverse events are likely more serious in hospitals, they are probably more common in office practices. The outpatient setting may be more vulnerable to inadequate handoffs, poorly monitored and standardized practices, high workload, and distractions. Coordination of inpatient and outpatient care is critical: most pregnant ambulatory patients will have a hospitalization for childbirth and an error or gap in quality at the outpatient level has an opportunity to manifest at the inpatient level. In truth, the true scale of the outpatient or ambulatory safety and quality problem is unknown and approaches to safety and quality in the office setting are new and evolving. The College’s Safety Certification in Outpatient Practice Excellence program is a voluntary program that provides reviews of ambulatory practices for the implementation and use of patient safety concepts and techniques (http://www.scopeforwomenshealth.org/). The program involves a detailed application and questionnaire along with a site visit, resulting in a detailed analysis and report and a 3-year certification when the standards are met.

DISCUSSION
The major aims of patient safety and quality improvement are reducing harm, improving outcomes, and optimizing care. Designing, implementing, and assessing quality improvement and safety programs involve multidisciplinary approaches across many layers of the system with multiple types of measures used. The complexity of medical systems can make these programs a challenge to carry out but even harder to study, and can make quality and safety difficult to measure. Nevertheless, familiarity with the core principles of and threats to quality and safety can assist in the development into a high reliability organization.

Obstetric quality and safety is a nascent field and as a result, we have an opportunity to shape the conversation. As quality measures initially proposed and supported gain validity and the field becomes more comfortable with the mechanics of quality measurement, the hard work of quality improvement will get easier. With each advance, however, the core principles underlying the quality and safety sciences should be emphasized. The obligation to support quality improvement activities lies in regulatory bodies, credentialing and professional organizations, research funding sources, and editorial bodies of our journals. However, the duty to carry them out is the responsibility of each individual member of the health care team.

REFERENCES


