PATIENT SAFETY SERIES
Perinatal high reliability

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The concept, theory, and attributes of high reliability organizations that operate highly complex and hazardous technologic systems, essentially without mistakes, was introduced to clinical obstetrics practice approximately 12 years ago.[1] The original description was based on an empiric observation that differentiated perinatal units that produce more or less harm to patients, with professional liability claims as a proxy for perinatal injury. In the original description, attributes of low-risk, harm-free, highly reliable perinatal units were identified: (1) safety is declared as the hallmark of organizational culture and is understood to be the responsibility and duty of every team member. All clinicians are considered competent with an obligation to speak up if the question of safety arises. (2) Patient safety is considered a team rather than individual property. Team interaction is noted to be collegial rather than hierarchic. (3) Respectful communication is highly valued and rewarded. Extensive, transparent communication is used to orient, plan, update, and adjust to the unexpected. Routine debriefing is practiced for unusual or unexpected events. (4) Emergencies are rehearsed and unexpected events are anticipated. (5) Paradoxically, successful operations (ie, absence of maternal, fetal, and neonatal injury) are viewed as potentially dangerous.

Perinatal high reliability is achievable with principles of high reliability organizations. Key organizational, leadership, and clinical characteristics that are essential for developing and sustaining a highly reliable perinatal unit are presented. Interdisciplinary collaboration and commitment to safe care that are founded on standardization are the hallmarks of perinatal high reliability.

Key words: evidence-based practice, high reliability organization, perinatal patient safety, standardization

As pointed out by Vaughn,[2] all work groups and teams are susceptible to "normalization of deviance," which is a degradation of professional, behavioral, and technical standards that increases the probability of a major accident or harm. Because large accidents or patient harm occur infrequently, clinical practice in the absence of professional standards and/or incorrect process (eg, work-a-rounds) may go undetected or deteriorate over long periods of time. For example, elective early term birth 39 completed weeks of pregnancy, a clear violation of professional guideline[3] and evidence-based practice[4] is often undertaken because in the experience of a single practitioner or obstetrics unit "we never had a problem." Normalization of deviance ("slide to failure") must be understood as unavoidable unless cumulative evidence and professional standards are actively used instead of individual experience, care processes are continuously monitored, and importantly, an absence of poor outcomes is not used as a indication that care is universally safe.

Since that time, the concept of "high reliability" has been refined and expanded and, in some instances, confused or misunderstood. Pronovost et al[5] framed the question most directly: "Exactly what does reliability mean in health care today, and how do we know if we are reliable?" The purpose of this article is to (1) update and reinforce the basic definition/concept of high reliability as culture ("the way we work around here"), (2) draw an important distinction between high reliability as a qualitative behavioral descriptor as opposed to simply quantitative measurement, (3) describe organizational tactics and strategy for moving toward high reliability, and (4) illustrate increased obstetric safety and quality where elements of high reliability have been incorporated into the culture and operations of obstetrics units.

Updated elements of a highly reliable (ie, safety) culture
Understanding updated and refined concepts of high reliability in the delivery of obstetrics care requires an understanding of what high reliability is not (ie, a quality improvement method focused on efficiency and productivity like Six Sigma, Total Quality Management, or LEAN). Rather, high reliability is a creation of a culture and processes that radically reduce system failures and effectively respond when failures do occur. As presently described and understood, core elements of high reliability organizations are 5 key concepts that are essential for any patient safety initiative to succeed.[6]

Sensitivity to operations
Preservation of constant awareness by leaders and clinicians of the current state of the systems and processes that affect patient care is essential. This awareness is key to noting risks and preventing "normalization of deviance,"[2] which is an insidious, but real, danger in obstetrics where most of what we do turns out normal despite flawed process or outdated practice patterns (ie, "the way we have always done it").[7]

Reluctance to simplify

Although standardization (eg, oxytocin administration) is essential for safety,[8] simplistic explanations for the reason that things work or fail are risky. Avoiding overly simple explanations of failure (eg, unqualified staff, inadequate training, did not follow protocol, communication failure) is essential to understanding the fundamental basis that patients are placed at risk (eg, an organizational failure to provide adequate staffing or resources in the face of ever-increasing production pressures).[9]

Preoccupation with failure

"Near-misses" (eg, successful resuscitation of a baby with a low Apgar score) are viewed as evidence that systems must be improved to reduce potential harm to patients. Rather than viewing near-misses as proof that the system has effective safeguards, the near-misses are viewed as symptomatic of areas that need more attention. Continuous and timely interdisciplinary case review is the hallmark of the use of actual clinical work for learning and improvement.

Deference to expertise

Organizational leadership must be willing to listen and respond to the insights of professionals at the bedside who know and understand the risks that patients really face and the "work-arounds" that are forced on them by relentless production pressure. Just as important is the elimination of hierarchy that is created by traditional physician/nurse roles and licensing. Teams, not individuals, create safety at the bedside.

Resilience

Leaders and clinicians must be educated and prepared to know how to respond when system failures do occur (transparency and "aftermath analysis"). Preventable death of a baby or mother during the perinatal period is one of the most difficult and devastating failures in health care and one of the most difficult for all concerned to recover from effectively.

Is defining high reliability quantitatively and by measurement a useful construct?

In contrast to culture, an alternative, quantitative-based definition of high reliability has been proposed (ie, the inverse of the system's failure or defect rate).[5] A defect rate represents the number of defects per opportunity for that defect. In health care, an opportunity for a defect usually translates to a population of patients (pregnant women) who are at risk for a medical error or adverse event (eg, maternal death or still-born infant).[8] In this context, it has been suggested that high reliability represents failure-free operation over time. The Institute for Healthcare Improvement further suggests that reliability is the number of actions that achieve the intended result, divided by the total number of actions that are taken.[10] However, in organizations where provider autonomy is highly valued, intended results may or may not be coincidental with professional standard of care, current evidence, or patient desire. A consequence of high reliability thus defined may be doing the wrong thing consistently.

Pronovost et al[5] suggest that this potential problem may be resolved in health care by the application of high reliability only when valid rate-based measures are used. A fundamental principle in measuring reliability should be focusing only on defects that can be measured validly as rates, which is not possible for most patient safety defects. Most safety parameters, such as information from patient safety reporting systems, are difficult, if not impossible, to capture in the form of a valid rate. Such safety parameters are still useful but are not interpretable as rates, which creates a conundrum when one is attempting to define high reliability solely in a quantitative manner. The proposed solution of Pronovost et al[5] is to acknowledge that high reliability organizations have established that the context in which care is delivered (ie, organizational culture) has important influences on patient safety. Further, valid measures of "safety climate" (ie, perceptions of the organization's com-

mitment to safety) can be measured reliably with questionnaires.[11]

In sum, as was proposed 10 years ago, obstetric high reliability may continue to be viewed primarily as a function of culture rather than quantitative measurement. Valid, reliable, and desirable quantitative outcomes are the result rather than the definition of a high reliability organization.

Organizational strategy for moving toward a high reliability (safety) culture[6,12]

The Chief Executive Officer and Board of Directors must take ownership for setting the climate and focusing the perinatal work. This is especially true and difficult in obstetrics because, in the executive offices of many health care organizations, obstetrics has been seen as a "money loser" at worst and "loss leader" at best that has not gained the respect and attention of more profitable service lines. Clarity of purpose, a demonstration of confidence, and acceptance of ultimate accountability from the Chief Executive Officer is necessary to transform and sustain a high reliability obstetric and organizational culture.

Safety must be the overarching value and strategy. Only if safety is the starting point, can the balance between safety, efficiency, and effectiveness remain positive and supportive of high reliability. Safety must be the strategy that is used as a basis for the achievement of efficiency and effectiveness. If the inverse of this relationship exists, the likelihood of unsafe yet highly efficient processes increases ("production trumps safety"). Retaining this focus is especially difficult in obstetrics where adverse outcomes occur only infrequently, thereby allowing work-a-rounds to supplant safe operations on a regular basis.

Trust, transparency, and teamwork are the basis and sustainability of a highly reliable culture. An unwillingness to face and share the hard facts is an indicator of denial; denial is not compatible with a safe environment. A culture that is characterized by fear and self-protection will not lend itself to openness, learning, and improvement. Hierarchy creates unstable and therefore unsafe conditions. Be-

cause much of the work of inpatient obstetrics is done by 1 physician, or 1 midwife, and 1 nurse taking care of a single patient in the relative privacy of the labor room, the potential for hierarchy and lack of trust and transparency remains an ongoing issue.

Physician leadership and active participation in the department is necessary, cannot be assumed, and is easy to avoid. Frequently, obstetricians indicate that while they know how they personally practice ("I never perform elective inductions"), they are not aware of the practice patterns of their colleagues, partners, or department ("I had no idea we were doing that"). Physician engagement in departmental learning or improvement is difficult due to a lack of incentives or perceived benefit ("I want to come, do my deliveries, and get back to the office"; "I can't block out my office time for these types of meetings"). Process or culture changes that are perceived as creating less efficiency are particularly resisted. It is important to provide organizational resources and expertise that will allow physicians to help lead improvement in collaborative efforts and to drive the transformational goals that have been established.

Professional behavior
In a high reliability perinatal unit, there exists an expectation that all professionals will conduct themselves in a professional and respectful manner at all times.[7,13] Expectations for professional behavior are outlined explicitly in institutional policies for good citizenship and are reaffirmed by leaders and each team member on an annual basis during contract renewal and performance reviews. Respectful, collegial interactions between nurses, midwives, physicians, and health care professionals and patients are the bedrock of the unit culture. The different but equal contribution of nurses to the care process and ultimate clinical outcomes is recognized and valued. Throwing instruments, temper tantrums, or demeaning comments are not tolerated by any member of the interdisciplinary team. Exceptions are not made because "he or she is a good doctor or nurse otherwise," "we need their patient

volume," or "he/she is one of the few who are always willing to work overtime." Respectful collegial professional behavior is valued equally as competent clinical practice and patient volume. Processes for reporting inappropriate behavior are disseminated widely, and their use is encouraged and supported actively by the leadership team. There is accountability for individual actions and meaningful follow-up procedures with clear actionable implications when inappropriate behavior occurs. Each instance of inappropriate behavior is addressed in a timely manner rather than delaying interventions until "trends" are apparent. Competent clinical practice is a basic expectation and is not substituted for taking responsibility for inappropriate, dysfunctional and/or abusive behavior.

Staffing
There are consistently adequate numbers of registered nurses and ancillary personnel to meet the production and safety needs of the service.[14,15] Core staffing is based on the unit's history of average daily census and on acuity, types of patients, and complexity of clinical situations. Both fetus and newborn infant are counted as patients when considering registered nurse-to-patient ratios. Pregnant women with high-risk conditions routinely are provided 1-to-1 nursing care.[14,15] Charge nurses do not have a patient assignment so that they can act fully in their supervisory role and maintain the ability to oversee clinical and unit operations.[14] Minimal staffing consists of at least 2 nurses with obstetric triage, fetal assessment, and labor and birth skills and is maintained even when there are temporarily no perinatal patients on the unit.[14]

Educational infrastructure
Continuous learning is fundamental for patient safety and therefore should be budgeted for and scheduled on a routine basis. At least 1 person should be designated as responsible for unit education. Educational programs should not be limited to nurses; keeping current is a product of the entire perinatal team. In addition to obstetricians, midwives, and

resident physicians, anesthesia and neonatal colleagues should be invited and expected to participate. Interdisciplinary team training in perinatal units is recommended to educate clinicians to work together and communicate more effectively.[16] Clinical drills for high-risk events, such as shoulder dystocia, emergent cesarean birth, maternal hemorrhage and neonatal resuscitation, are recommended to help clinicians to prepare for such events when they actually occur.[16-18] Debriefings after drills, near-miss events, and events that involve patient harm should be held routinely to evaluate team performance and identify areas for clinical and operational improvement.[16] Interdisciplinary fetal monitoring education and competence validation should be offered on a regular basis.[16]

Specific clinical requirements and tactics
Fetal assessment
Fetal safety during labor is based on assessment with common language for fetal heart rate (FHR) patterns, knowledge, an understanding of fetal physiology, and uniform expectations for interventions when the FHR pattern suggests fetal compromise.[16,19] The team routinely participates in regularly scheduled case reviews and offers suggestions for future care improvement. Communication between team members regarding indeterminate or abnormal FHR patterns includes specific details, the clinical context, pattern evolution, efforts to resolve the pattern, and the fetal response. There are common expectations for intrauterine resuscitation that are based on the FHR pattern.[20,21] There is an agreement among team members concerning which type of FHR patterns require bedside evaluation by the primary care provider and the timeframe involved.[19] Timely and appropriate interventions for indeterminate or abnormal fetal status, which includes emergent cesarean birth, are routine. Neonatal resuscitation is based on the Neonatal Resuscitation Program[17] that all members of the team have completed.

Labor induction

Labor induction includes appropriate candidates, timing, pharmacologic agents, dosing protocols, and recognition and treatment of complications as recommended by the American College of Obstetricians and Gynecologists[3] and the Association of Women's Health, Obstetric, and Neonatal Nurses.[22] Elective induction does not occur before 39 completed weeks of gestation, thus the complications of iatrogenic preterm birth are avoided.[3] Labor induction is initiated only when there are enough nurses to safely monitor the mother and fetus.[14,15,22] In a highly reliable unit, standard unit policies and corresponding provider order sets for each pharmacologic agent are used. There is acknowledgement that oxytocin is a high-alert medication.[23] A physiologic dosing regimen for oxytocin is used (ie, start at 1 mU/min and increase by 1-2 mU/min no more frequently than every 30 minutes until adequate progress of labor).[24] The definition of tachysystole is known by all members of the team, and treatment is not delayed until there is deterioration in the FHR pattern.[20,25] Nurses are empowered and encouraged to be assertive in their actions and communication with physician colleagues to advocate for patient safety if they feel pressured to increase oxytocin rates during tachysystole and/or when there are concerns regarding fetal status.

Second-stage labor care

The active phase of second-stage labor is the period of maximum stress for the fetus. High reliability units minimize that stress by shortening the active pushing phase and using appropriate pushing techniques. For women with epidural anesthesia who do not feel the urge to push when they are completely dilated, pushing may be delayed until the urge to push is felt, which is up to 2 hours for nulliparous women and up to 1 hour for multiparous women.[26,27] Tachysystole is avoided; if it occurs it is treated in a timely and appropriate manner. Similar to the first stage of labor, the FHR pattern is used continuously as an indicator of how well the fetus is tolerating second-stage labor. In the case of recurrent decelerations, the mother is encouraged to push with every other or every third contraction or temporarily to discontinue pushing to allow the fetus to recover.[28] Appropriate intrauterine resuscitation measures are initiated as well.

Results in organizations that incorporate elements of high reliability

Success at becoming and sustaining perinatal high reliability has been reported in large health care systems and individual hospitals that are both academic and community based. The Hospital Corporation of America implemented a comprehensive redesign of patient safety processes using the following principles: (1) standardized processes and procedures result in improved quality of care; (2) every member of the obstetric team should be required to stop any process that is deemed to be dangerous; (3) cesarean birth is best viewed as a process alternative, not an outcome or quality endpoint; (4) malpractice loss is best avoided by decreasing adverse outcomes and the development of unambiguous practice guidelines; and (5) effective peer review is critical to quality clinical practice yet may be impossible to achieve at a local level in some departments.[8] The Hospital Corporation of America program resulted in improvements in patient outcomes, a dramatic decline in litigation claims, and a decrease in the primary cesarean birth rate.

Catholic Healthcare Partners (CHP) launched a similar initiative with a focus on an agreement to provide care in the context of the best evidence and standards/guidelines from professional organizations.[29] Professional behavior, teamwork, and standardization of key clinical practices that include fetal assessment, labor induction, and second-stage labor care were critical aspects of the program. As a result, CHP realized a 96% decrease in birth trauma rates, a 65% decrease in potentially compensational events, and an approximate 50% decrease in average costs per obstetric claims and the number of new claims that were reported.[29] The Hospital Corporation of America and CHP experiences support the premise that a major factor in the reduction of patient harm, liability, and associated costs is to provide better care.[8,29,30]

The perinatal team at Yale New Haven Hospital perinatal patient safety program included outside expert review, protocol standardization, creation of a patient safety nurse position and patient safety committee, training in team skills and fetal monitoring interpretation.[31] The interventions significantly reduced adverse events as measured by the Adverse Outcome Index and resulted in clinically significant improvements in safety climate by validated safety attitude surveys. Likewise, the Seaton Family of Hospitals was able to reduce birth trauma rates virtually to zero through the implementation of a series of standardized practices and protocols that are related to cervical ripening, labor induction, fetal monitoring interpretation, and instrumented vaginal birth based on the principles of high reliability.[32]

Conclusion

High reliability does not occur by accident; rather, it is the result of a careful, planned strategy that involves all disciplines that contribute to care, with unwavering support from top administrative leaders. An acknowledgement that there may be some missteps along the way but that the team is in this for the long-term with mutual goals works well when the "going gets rough." Willingness to learn from previous mistakes and transparency in decision-making are critical aspects of high reliability. Ongoing monitoring of care processes is essential for quality maintenance and improvement. Patient safety must take precedence over convenience and productivity pressures. Hierarchic relationships and nonprofessional behavior are nonproductive and create unsafe clinical conditions. Teamwork is the foundation of safe care. Only when everyone is working together with the same goals (best outcomes for mothers and babies) can perinatal high reliability become reality. f

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