Institutional Liability for Birth Injuries, Revisited

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I. INTRODUCTION

Hospitals are dangerous places. For over 40 years, study after study has confirmed the existence of a medical malpractice epidemic in the United States. Current research demonstrates that 440,000 people die every year in hospitals as a result of preventable medical mistakes.[1] Moreover, the estimate for "serious harm" from preventable medical errors is 10-20 fold more common than "lethal harm".[2] Putting these numbers in perspective: it takes about one month for preventable errors in U.S. hospitals to kill more people than died in combat during the Vietnam conflict! It takes one and a half months to seriously injure as many total American soldiers that have died in combat in the history of our country![3] This is not simply as a result of medical and nursing mistakes. Instead, it stems from institutional systems failures that predominate at many hospitals throughout the country. To be sure, we need to focus on doctor and nursing negligence as well as the institutional failures that are the root causes of

[1] James, John T., PhD., *"A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care,"* J Patient Saf, Vol. 9, Number 3 (September 2013). See also, *HealthGrades, Patient Safety In American Hospitals* 1 (July 2004), available at http://www.Healthgrades.com (last visited February 2, 2006); *see also, Health: Study: Hospital errors cause 195,000 deaths*. July 28, 2004, available at http://cnn.com.2004/HEALTH/07/28/health.mistakes.reut/index.html; *see also, HealthGrades, HealthGrades Quality Study: Third Annual Patient Safety in American Hospitals Study* (April 2006). *See also,* Healthgrades, Healthgrades Quality Study; Fourth Annual Patient Safety in American Hospitals Study (April 2007).

[2] Kohn, Linda T., *et al, To Err is Human: Building a Safer Health System* Washington D.C.: National Academy Press, 2000 at 1 *citing* Centers for Disease Control and Prevention (National Center for Health Statistics). "Births and Deaths: Preliminary Data for 1998." NATIONAL VITAL STATISTICS REPORTS. 47 (1999): 27. *See also*, Andrews, Lori B., *et al*, "An alternative strategy for studying adverse events in medical care." 349 THE LANCET 309-313 (1997); Chaundry, Sarwat I., M.D., *et al*, "Detection of Errors by Attending Physicians on a General Medicine Service' 18 J GEN INTERN MED 595-600 (2003), Schimmel, Elihu M., M.D., "The Hazards of Hospitalization" 60, No. 1 ANNALS OF INTERNAL MEDICINE 100-110 (1964).

[3] American Revolution (4,435); War of 1812 (2,260); Indian Wars (1,000); Mexican War (1,733); Civil War (214,938); Spanish-American War (385); World War I (53,402); World War II (291,557); Korean War (33,741); Viet Nam War (47,410); Gulf War (147); Iraq (2,543 as of February 19, 2007) equals 653,651. *See,* http://www.infoplease.com/ipa/a0004615.html and http://www.antiwar.com/casualties/index.php

much of the tragic and unnecessary harm suffered from preventable mistakes.

The American College of Healthcare Executives ("ACHE") is the professional society for those managing the very hospitals in which preventable errors take place. Many hospital executives are members, fellows and even chairpersons in ACHE and the organization actually has an abundance of patient safety literature available to its members. For example, one book available to all ACHE members is Matthew Lambert's "Leading a Patient – Safe Organization." In this book, Lambert explains the role of system failures in preventable harm. He writes:

> Thinking systematically about medical error is recognizing that relatively few mistakes can be attributed solely to individual actions.
>
> When focusing on reducing medical error, the entire organization should be viewed as a system that operates and interacts in complex ways. It includes physicians, nurses, employees, equipment, policies, procedures, physical plant, and many other components.[4]

Lambert makes it clear that when analyzing the cause of any severe injury, it is imperative to note the systems in place, their interaction, and how the systems failures lead to the injury at hand.

As a related inquiry, the obstetrical units, like other areas of the hospital, are governed by a variety of federal, state, and other regulations in an effort to keep patients out of harm's way. Everyone has heard the absurd argument that policies and procedures are "only guidelines;" however, evidence suggests otherwise. In order to effectively ensure safe care, physicians, nurses, and administrators must be intimately familiar with the standards set forth by the federal, state, and other regulations that govern patient safety. And in order to protect the rights of those injured by bad medical care, trial lawyers must be intimately familiar with the established regulatory framework that delineates and governs these standards.

Recent press suggests that three important factors conspire to produce a bad outcome in the face of a healthcare system disaster:

(1) Failure of training (i.e. competence);
(2) Failure of protocol (i.e. policies, procedures, guidelines); and
(3) Failure of communication (i.e., competence, policies, procedures, and guidelines).

From a viewpoint of institutional framework these general failures are likely all present in the case of virtually any preventable adverse outcome. These systemic failures almost always represent a failure to adhere to the duties set forth by the regulations mentioned above. Two things must be kept in mind when exploring these issues. First, obviously, the regulations themselves are critical. Second, most adverse outcomes are the result of failures that occur at virtually every level within the hospital organization. This is a systemic problem at the hospital and not simply the matter of a "bad apple" nurse who does not have his/her eye on the ball. We must focus on the system failures.

II. HOSPITAL ARE DANGEROUS PLACES

The following studies are largely historical, but important to keep in mind. Consider asking who at the hospital is responsible for understanding the patient safety problem in depositions. Likely, the L&D nurse, the Nurse Manager of L&D, the Nursing Director of Women's Services, the CNO and the hospital CEO- will admit to a shared duty to keep the patients (mother and baby) out of harm's way. This is reason patients go to the hospital to deliver, instead of a Holiday Inn Express. Some will admit to having heard of the 440,000 deaths per year figure. More will have heard of

[4] Lambert, III, Matthew J. *Leading a Patient –Safe Organization,* Health Administration Press (2003)

"To Err is Human". Consider asking who at the hospital has the responsibility to keep up with the patient safety literature. Of course, such focus may lead to the depositions of nurse educators, the Chief Safety Officer (if there is one), the Chief Medical Officer and others, in addition to the Administrative Chain of Command. Establish the hospitals organizational structure early and plan depositions accordingly.

A. California Medical Insurance Feasibility Study

The Medical Insurance Feasibility Study was one of the first large hospital records studies looking at hospital errors, was done in the 1970s[5]. The study was sponsored by the California Hospital Association and the California Medical Association in an effort to support their tort reform efforts. At the time, California was in the midst of a perceived medical malpractice insurance crisis. The idea behind the study was to test the feasibility of going to a no-fault system of compensation for injuries and death as a result of medical malpractice. The expectation was that the frequency and severity of malpractice would be shown to be a minor problem. They further expected to be able to show that the cost of a no-fault system would be substantially less than the premiums the doctors and hospitals were paying for medical malpractice insurance.[6]

The study revealed quite the opposite and the results were striking. The Medical Insurance Feasibility Study found that doctors and hospitals injured one out of every twenty hospitalized patients. Of those, one out of ten patients died from the injury. Extrapolated, that meant that in California in 1974 some 140,000 patients were injured, 14,000 of whom died as a result. The study also concluded that one out of every six of the medical injuries, over 23,000 cases, was the result of malpractice. The authors found that there was a positive correlation between the severity of the injury and malpractice. Four-fifths of the most seriously injured patients were injured by medical malpractice.[7]

The California Hospital Association and California Medical Association correctly concluded that a no-fault system was not the way to lower their malpractice insurance premiums. They shelved the study and moved their legislative initiatives in a different direction.[8] In 1975 the California legislature passed the Medical Injury Compensation Reform Act ("MICRA"). MICRA capped non-economic damages for pain and suffering at $250,000. There is no evidence to suggest that MICRA did anything to decrease the frequency or severity of medical injuries or medical malpractice in the state of California. Nor did it decrease the medical malpractice premiums for doctors and hospitals. Indeed, over the next 13 years the premiums continued to increase until California voters took matters into their own hands and passed Proposition 103, which changed the state's insurance laws. The insurance reform froze premiums, forced insurance companies to open their books and justify future increases. California voters got the right to elect their state insurance commissioner. After Proposition 103 passed, medical malpractice premiums began to decrease and stabilize.[9]

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[5] Mills, Don Harper, M.D., J.D.. "Medical Insurance Feasibility Study," 128 WEST J MED 360-365 (1978).

[6] Baker, Tom. *The Malpractice Myth*, Chicago: University of Chicago Press, 2005 at 25-27, *see generally*, Medical Insurance Feasibility Study, *supra* note 5.

[7] *Id.*

[8] *Id.*

[9] In fact, after the MICRA caps and until Proposition 103, thirteen years later, malpractice insurance premiums for California doctors increased by 450%. "Insurance reform required medical malpractice insurers to directly refund more that $135 million to policy holders." *See, How Insurance Reform Lowered Doctors' Medical Malpractice Rates in California and How Malpractice Caps failed* (2003) available at http://www.consumerwatchdog.org/mal-practice/rp/1008.pdf (last visited February 6, 2006).

B. The Harvard Medical Practice Study

The next major study based upon hospital records of medical injuries caused by medical malpractice was the Harvard Medical Practice Study.[10] This study was conducted in the mid 1980's during another medical malpractice insurance crisis. The Harvard Medical Practice Study was commissioned by the state of New York to evaluate medical injuries and also methods of compensating injured patients. The results of the study were published in three parts in the *New England Journal of Medicine* under special article status.[11]

The methodology of the Harvard Medical Practice Study is impressive. The Harvard researchers used a two-stage sampling process to create a weighted sample of 31,000 randomly selected records of hospitalized patients from a population of 2,671,863 non-psychiatric patients discharged from non-federal acute care hospitals in 1984. Each medical record was initially screened by two people consisting of trained nurses or medical records administrators, using eighteen screening criteria. If the screeners agreed that a record met any of the criteria, then it was reviewed independently by two physicians, almost all of whom were board certified internists or surgeons. The physicians identified adverse events and were tasked with describing each adverse event and its relation to the medical care. Additionally, they estimated the degree of disability that resulted. The reviewers were also asked to indicate whether each adverse event had been caused by a reasonably avoidable error. If yes, they classified the error and then indicated the specific type of error within the class. Finally, the physician reviewers were asked to determine if there was negligence.[12]

Part One of the Harvard Medical Practice Study "estimated the incidence of adverse events, defined as injuries caused by medical management, and the sub-group of such injuries that resulted from negligent or substandard care."[13] The results showed that adverse events occurred in 3.7 percent of the hospitalizations. 27.6 percent of the adverse events were due to negligence. The researchers found that 70.5 percent of the adverse events gave rise to a disability lasting less than six months. 2.6 percent caused permanent disability, 13.6 percent caused death. Like the California Medical Insurance Feasibility Study, the study also established that the percentage of adverse events attributable to negligence increased as the severity of the injury increased. The Harvard study concluded that of 2,671,863 patients, there were 98,609 adverse events, of which 27,179 involved negligence.[14]

Part Two of the Harvard Medical Practice Study analyzed the adverse events and their relation to error, negligence and disability. The authors found that drug complications were the most common type of adverse event (19%); wound infections were second (14%); and technical complications, third (13%). Forty-eight percent of the adverse events were associated with an operative procedure. However, adverse events during surgery were less likely to be caused by negligence (17%) than in non-surgical events (37%). The proportion of adverse events caused by negligence was highest for non-

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[10] Harvard Medical Practice Study. *Patients, doctors, and lawyers: Medical Injury, Malpractice Litigation and Patient Compensation in New York: The report of the Harvard Medical Practice Study to The State of New York*. Cambridge: Harvard University, 1990.

[11] Brennan, Troyen A., M.P.H., M.D., J.D., *et al*, "Incidence of Adverse Events and Negligence In Hospitalized Patients: Results of the Harvard Medical Practice Study I," 324 N. ENGL. J. MED. 370-376 (1991); Leape, Lucian L., M.D., *et al.,* "The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II," 324 N. ENGL. J. MED. 377-384 (1991); Localio, Russell, J.D., M.P.H., M.S., *et al.,* "Relation Between Malpractice Claims and Adverse Events Due To Negligence, 325 N. ENGL. J. MED. 245-251 (1991).

[12] Leape, *supra*, at 245-6.

[13] Brennan, *supra* note 12, at 370.

[14] *Id*.

invasive therapeutic mishaps (77%); diagnostic mishaps (75%); and mishaps in the emergency room (70%).[15]

Part Three of the Harvard study looked at the other side of the equation. The Harvard researchers identified patients who had filed claims against healthcare providers in their sample. They compared those results with their findings based on their review of those records. The researchers then matched their results with statewide data on medical malpractice lawsuits. The Harvard study concluded that the vast majority of patients injured by medical negligence did not make a claim.[16]

C. The Utah and Colorado Study

The Harvard Medical Practice Study stirred debate in at least some circles. As early as 1993, some healthcare safety experts extrapolated from the Harvard study to suggest that 180,000 people per year die in the United States as a result of an iatrogenic (healthcare provider caused) injury.[17] Questions were raised as to whether the findings from the Harvard Medical Practice Study might be inappropriate because they were limited to one year and to New York. And while the findings were consistent with the California feasibility study, the Harvard Medical Practice Study had not been replicated in a large-scale study in the United States. Additionally, a population based study from Australia that used the Harvard Medical Practice Study methods and a study from a Chicago teaching hospital that used observational methods found considerably higher rates of preventable medical injury than the Harvard Medical Practice Study.[18] Accordingly, the Utah and Colorado study was designed to determine whether the Harvard study findings were similar to those of other states in different time periods.

The Utah and Colorado study used methods similar to the Harvard Medical Practice Study in order to estimate the incidence and types of adverse events and negligent adverse events in Utah and Colorado in 1992. The researchers selected a representative sample of hospitals from Utah and Colorado and randomly sampled 15,000 non-psychiatric 1992 discharges. Each record was reviewed by a nurse using eighteen criteria associated with adverse events. If one of the criteria was met, the record was then reviewed by a physician to determine whether an adverse event or a negligent adverse event occurred and to classify the type of adverse event. After completion of all reviews, two investigators independently reviewed each adverse event and negligent adverse event to ensure that all events fulfilled the definition set forth in the study.[19]

The study concluded that the incidence and types of adverse events found in Utah and Colorado in 1992 were similar to those found by the Harvard Medical Practice Study from New York in 1984. Adverse events occurred in 2.9 percent of the hospitalizations in each state. In Utah, 32.6 percent of the adverse events were due to negligence. In Colorado, 27.4 percent were due to negligence. Death occurred in 8.8 percent of the negligent adverse events.[20]

D. Institute of Medicine Report

The National Academy of Sciences is a private, non-profit society of distinguished scholars engaged in scientific and engineering research. Upon the authority of the charter granted to it by the U.S. Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific matters. The National Academy of Sciences established the Institute of Medicine in 1970 to examine policy matters pertaining to the health

[15] Leape, *supra* note 12, at 377.

[16] Localio, *supra* note 12, at 245.

[17] Leape, Lucian L., M.D., *et al*., "Preventing Medical Injury." 19 QUAL. REV. BULL. 144-149 (1993).

[18] Thomas, Eric, M.D., M.P.H., *et al*., "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado," 38 MEDICAL CARE 261-271 (2000).

[19] *Id*. at 262-263.

[20] *Id*. at 261.

of the public and to advise the federal government.[21] The Institute of Medicine (IOM) initiated the Quality of Healthcare in America project in June of 1998. Its purpose was to develop a strategy to result in at least a threshold improvement in the quality of healthcare over the next ten years.[22] In 1999 the institute published its first report, entitled: *To Err is Human: Building a Safer Healthcare System*.[23] The IOM studied the literature on the frequency and cost of healthcare errors and the factors that contribute to their occurrence. In the report, an "error" is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning). An "adverse event" is defined as an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event." Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question).[24]

The IOM looked at four questions:

1. How frequently did the errors occur?
2. What factors contribute to errors?
3. What are the costs of errors?
4. Are public perceptions of safety in healthcare consistent with the evidence?[25]

The IOM concluded that between 44,000 and 98,000 Americans die in hospitals each year as a result of preventable medical errors.[26] Importantly, the IOM acknowledged that these extrapolations likely *under*estimate the occurrence of preventable adverse events. As to public perception, the IOM concluded:

> Although the risk of dying as a result of a medical error far surpasses the risk of dying in an airline accident, a good deal more public attention has been focused in improving safety in the airline industry than in the health care industry. The likelihood of dying per domestic jet flight is estimated to be one in eight million. Statistically, an average passenger would have to fly around the clock for more than 438 years before being involved in a fatal crash. The American public may be vaguely aware that healthcare is less safe than some other environments, but to date, it has made few demands on the healthcare industry to demonstrate improvement.[27]

The IOM found that licensing and accreditation processes of healthcare providers and organizations have focused only limited attention on the safety issue. Even these minimal efforts have met with resistance from healthcare organizations and providers. The researchers found that the decentralized and fragmented nature of the healthcare delivery system contributes to unsafe conditions. The IOM also found that the context in which healthcare is purchased in the United States further exacerbates the problem. Group purchasers have made few demands for improvement in safety. The IOM concluded that a comprehensive approach to improving patient safety is needed.[28] The Institute of Medicine made a series of recommendations to that end.[29]

The IOM report created a stir. President Clinton established the Quality Interagency Coordination Task Force. He directed the Task Force to evaluate the IOM's recommendation in *To Err is Human* and to respond with a strategy to identify prevalent threats to patient safety

[21] Kohn, Linda T., *et al*, *To Err is Human: Building a Safer Health System*, *supra* note 2, at iii.
[22] *Id*. at xi.
[23] *Id*.
[24] *Id*. at 28.
[25] *Id*. at 29.
[26] *Id*. at 31.
[27] *Id*. at 42.
[28] *Id*. at 3.
[29] *Id*. at 69, 87, 111, 133, and 156.

and to reduce medical errors.[30] In February, 2000 the Task Force presented its report: *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*.[31] The Task Force reported that medical errors were "[a] National Problem of Epidemic Proportion."[32] The report concluded that research documented that the rate of healthcare errors is far higher than the rate of error in other industries.[33] It looked at the epidemiology of medical errors and adverse events and medical products' use or misuse.[34] The Task Force also looked at current programs in place to prevent medical errors and found that they were insufficient.[35] The Task Force concluded that there was a "general lack of awareness" about the problem.

E. Healthgrades Quality Study

The Agency for Healthcare Research and Quality (AHRQ) became the lead agency for the federal government on quality in healthcare. In order to better track medical errors, the agency developed and released a computer program which included a set of Patient Safety Indicators ("PSI"). These were specifically designed for screening hospital administrative data for incidents of concern related to patient safety.[36] HealthGrades took the Agency's Patient Safety Indicators software and applied it to approximately 37 million Medicare discharges. In 2004, HealthGrades, Inc. released its study: *HealthGrades Quality Study: Patient Safety in American Hospitals*.[37] This was the first study to look at the potentially avoidable mortality and cost impact of patient safety incidents using the PSI's across all U.S. hospitals among the most concentrated at-risk patient population, Medicare patients.[38] The report was shocking. The authors concluded that their data clearly supported the Institute of Medicine's report and the findings from other studies which showed that medical errors and injuries from them are epidemic in the United States.[39] They found that even though there were "shocking and widely publicized" statistics on preventable deaths due to medical errors, there had not been improvements in patient safety since the publication of the Institute of Medicine's report five years earlier. Indeed, they found the previous studies had underestimated the number of deaths caused by preventable medical errors.

F. Recent news: "Medical error—the third leading cause of death in the US"

More recently, in a well-publicized article published in The BMJ, researchers from Johns Hopkins University analyzed prior studies on medical errors and concluded that there was a mean rate of death of 251,454 per year since the 1999 IOM report and that when read in conjunction with CDC rankings of cause of death, "medical error is the third most common cause of death in the US. Makary, M.A., et al., Medical Error-The Third Leading Cause of Death in The US, BMJ 2016; 353; i2139 (3 May 2016). The authors additionally stated that the 251,454 number actually understated the true incidence of death from medical error because the studies analyzed only included inpatient hospital deaths and did not account for reasons for death not associated with specific ICD codes. The authors concluded that recognizing

[30] Quality Interagency Coordination Task Force, *Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact*: Report to the President (Washington: QuIC Task Force, 2000).
[31] *Id*.
[32] *Id*. at 1.
[33] *Id*. at 34.
[34] *Id*. at 37.
[35] *Id*. at 41.
[36] *Patient Safety Indicators*, Version 2.1, Revision 1. March 2004. (Agency for Healthcare Research and Quality. Rockville, M.D.).

[37] *HealthGrades Patient Safety In American Hospitals*, *supra* note 1.
[38] *Id*. at 7.
[39] *Id*.

and reporting medical errors is essential in the process of improving healthcare and that data from the science of improving safety" should be standardized and shared. See id. Finally, the authors opined that strategies to reduce death from medical errors should be established and these strategies should include 3 steps: 1) "making errors more visible when they occur so their effects can be intercepted", 2) "having remedies at hand to rescue patients" and 3) "making errors less frequent by following principles that take human limitations into account." See id. Currently, the patient safety statistics are followed by a number of organizations. Most of the administrative personnel whom you depose will be familiar with Leapfrog.[40]

III. BIRTH INJURIES AND OBSTETRICAL COMPLICATIONS

Unfortunately, the potential to be swept up in the medical malpractice epidemic in hospitals is highest during the single human moment deserving of the most joy, childbirth. The most prevalent reason for hospitalization in the United States is Childbirth, accounting for nearly 1,195 per 100,000 hospitalizations.[41] Nearly one-third of all births in the US are cesarean sections, making cesarean section the most common surgical procedure in the United States.[42] In 2018, there were 3,788,500 births in the US.[43]

Not surprisingly, as is the case with medical care generally, the number of errors and complications associated with childbirth is astounding. The vast majority of stays for both vaginal delivery and C-section involve at least one complicating condition (91.3 percent of vaginal delivery stays; 99.9 percent of cesarean section stays).[44] Further, experts suggest that cerebral palsy results from 2–3 birth/thousand per year. While some may debate the cause of cerebral palsy and other neurologic injury manifesting at or about the time of birth, no one seriously disputes the enormity of the injury to the children and families involved, as well as to society in general.

According to ACOG, "more women die in the US from pregnancy-related complications than in any other developed country" and "between 2000 and 2014, there was a 26% increase in the maternal mortality rate."[45]

Furthermore, between 2006-2015, trends were identified showing an alarming increase in the rates of maternal mortality morbidity, specifically:

- The rate of severe maternal morbidity at delivery—as defined by 21 conditions and procedures–increased 45 percent from 2006 through 2015.
- Severe maternal morbidity was highest among women aged 40+ years and lowest for those aged 20-29 years.
- Compared with other deliveries, those involving severe maternal morbidity were more likely to be in the youngest and oldest

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[40] See www.leapfroggroup.org

[41] 2015 U.S. National Inpatient Stays, https://www.hcupus.ahrq.gov/faststats/NationalDiagnosesServlet

[42] Mistry, K. et al., *Variation in the Rate of Cesarean Section Across U.S. Hospitals, 2013.* HCUP Statistical Brief #211, AHRQ. Available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb211-Hospital-Variation-C-sections-2013.pdf

[43] Hamilton, B. et al, *Births: Provisions Data for 2018,* Vital Statistics Rapid Release #7 (May 2019), https://www.cdc.gov/nchs/data/vsrr/vsrr-007-508.pdf

[44] Moore A, Witt W, *Complicating Conditions Associated with Childbirth, by Delivery Method and Payer 2011*. HCUP Statistical Brief #173 May 2014, Agency for Healthcare Research and Quality Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb173-Childbirth-Delivery-Complications.pdf

[45] ACOG, https://www.acog.org/About-ACOG/ACOG-Departments/Government-Relations-and-Outreach/Federal-Legislative-Activities/Maternal-Mortality?IsMobileSet=false

age groups, paid by Medicaid, and from lower-income communities.

- Rates of acute renal failure, shock, ventilation and sepsis at delivery more than doubles between 2006 and 2015.
- Deliveries involving severe maternal morbidity also were more likely to occur at hospitals that typically have a mission to serve vulnerable populations and at hospitals in the Northeast and South, as compared with all other deliveries.
- Black women, Hispanic women, and women of other races/ethnicities were overrepresented among deliveries involving severe maternal morbidity, as compared with White women.
- Although deaths decreased for all races/ethnicities, in-hospital mortality was 3 times higher for Black women than for White women in 2015 (11 vs. 4 per 100,000 deliveries).[46]

Examples of conditions of maternal morbidity (defined as "unexpected outcomes of labor and delivery that result in significant short or long term consequences to a woman's health") include: need for blood transfusion, acute renal failure, shock, ventilation, aneurysm, adult respiratory distress syndrome, disseminated intravascular coagulation, hysterectomy, cardiac arrest/ventricular fibrillation, temporary tracheostomy, conversions of cardiac rhythm, amniotic fluid embolism, sickle cell disease with crisis, pulmonary edema/acute heart failure, air and thrombotic embolism, eclampsia, puerperal cerebrovascular disorders, acute myocardial infarction, severe anesthesia complications, heart failure/arrest during surgery.[47]

Ultimately, for us, the question is "what is being done at a system and institutional level to address these already well-known, well-publicized failures of the US healthcare system towards it women patients?"

IV. SYSTEMS FAILURE

As mentioned, the American College of Healthcare Executives views patient safety and preventable errors as systemic issues. This is consistent with the thinking behind the Joint Commission root cause analysis. It is also consistent with and overlaps the duties set forth by the CMS Conditions for Participation, Joint Commission Standards and the various states nurse practice act's. By focusing on a systems analysis, there are several potential benefits. First, the cause will focus on typically a large corporate entity, opposed to an individual nurse. Second, the analysis will move the relevant timeline back months or even years prior to the delivery at issue. Third, it will provide a legitimate basis to depose those involved with the administrative change of command, including the CEO.

The American College of Healthcare Executives has its own professional journal, *Healthcare Executive*. Indeed, it has additionally published "Leading a Culture of Safety: a Blueprint for Success". The organization has its own Code of Ethics. In fact, the American College has its own safety pledge which it encourages members to take:

> I pledge to lead for safety, to model the values and best practices to create and sustain a safety culture in my organization and to empower other leaders, within and outside my organization, to make safety leadership an imperative.

An article entitled: The Patient Safety Team: Healthcare Executives Embrace Their Role, the organization shows the importance of going up the administrative chain. It provides:

> The notion of the healthcare executive as a critical patient safety change agent was a rare concept not long ago. It was

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[46] Finger, K. et al., *Trends and Disparities in Delivery Hospitalizations Involving Severe Maternal Moribidy, 2006-2015*. HCUP Statistical Brief #243, AHRQ. Available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb243-Severe-Maternal-Morbidity-Delivery-Trends-Disparities.jsp

[47] Id.

primarily the clinical staff who worked to ensure safety and patient care administrative – clinical alignment was strengthened, however with the realization that C–suite carries as much accountability for patient safety as the clinical staff does. If you are a healthcare executive, you know that a patient's safety has become an integral part of your job.[48]

The publication, *Healthcare Executive* had a regular section entitled "Patient Safety" Additionally; the American College of Healthcare Executives also has a journal of Healthcare Management. An example of patient safety analysis from the current issue of that journal is an article entitled: "High Reliability Healthcare, Building Safer Systems Through Just Culture and Technology".[49] These resources are rich in information that establishes a duty of care on the part of healthcare executives to ensure patient safety and our very helpful in preparing for depositions of healthcare executives and administrators. From a more practical standpoint in a recent deposition a hospital CEO admitted that the following systems are required in order to protect patient safety:

1. Training and Orientation of the nursing staff.
2. Training and Orientation of the physician staff.
3. Putting into place appropriate policies and procedures.
4. Ensuring Physicians and nurses review policies and procedures.
5. Enforcement of policies and procedures.
6. Staffing: ensuring an appropriate number of staff with appropriate training are available.
7. Competency testing of physician and nursing staff.
8. Developing a plan for care for each patient.
9. Communication: having all systems work together/communicate with one another to protect the patient.
10. An established Chain of Command.

A systems analysis should always be included in your case analysis and in your deposition and trial preparation.

V. FRAMEWORK OF DUTIES

Healthcare is a heavily regulated industry. These regulations and standards have many sources. Some stem from federal law and from national accrediting organizations such as the Joint Commission. Others stem from national organizations such as AWHONN and state laws such as Nurse Practice Acts and other state rules and regulations governing healthcare. Care also is regulated by the policies and procedures in any given hospital.

Several states impose direct liability upon hospitals. For example in Pennsylvania, a hospital is directly liable under the doctrine of corporate negligence if it fails to uphold any *one* of the following four duties: "a duty to use reasonable care in the maintenance of safe and adequate facilities and equipment"; "a duty to select and retain only competent physicians"; "a duty to oversee all persons who practice medicine within its walls as to patient care"; and "a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients" *See Rauch v. Mike-Mayer,* 2001. Pa. Super 270, 783 A.2d 815, 826 (2001)(quoting *Thompson v. Nason Hospital*, 527 Pa. 330, 339-40, 591 A.2d 703, 707-08 (1991). *See, e.g., AirShields, Inc. v. Spears*, 590 S.W.2d 574 (Tex. Civ. App. – Waco 1979, writ ref'd n.r.e.)

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[48] Birk, S., "The Patient Safety Team: Healthcare Executives Embrace Their Role", *Healthcare Executive*, 13 Sept/Oct 2011

[49] Adelmam, J., "High Reliability Healthcare: Building Safer Systems Through Just Culture and Technology", *Journal of Health Management*, vol. 64, no. 3, 137-141 May/June 2019

The Texas Pattern Jury Charges defines negligence:

> "Negligence," when used with respect to the conduct of *[] Hospital*, means failure to use ordinary care, that is, failing to do that which a hospital of ordinary prudence would have done under the same or similar circumstances or doing that which a hospital of ordinary prudence would not have done under the same or similar circumstances.

and defines ordinary care:

> "Ordinary care", when used with respect to the conduct of *[] Hospital*, means that degree of care that a hospital of ordinary prudence would use under the same or similar circumstances.

In states with direct hospital liability, like Pennsylvania and Texas, a well-prepared attorney and his or her experts can use federal, state and other regulations, standards and policies to establish what a reasonable hospital should or should not have done. Even in states without direct corporate liability, many of these regulations can be used as evidence of the standard of care for medical staff members and nurses—or at least what the standard of care should have been. As discussed above, the breach of these regulations and standards can be found in almost every adverse outcome.

A. Conditions of Participation for Hospitals

The Conditions of Participation for Hospitals are regulations that health care organizations must meet in order to participate in the Medicare and Medicaid programs. According to the Centers for Medicare and Medicaid Service ("CMS") the Conditions of Participation ("COP") are health and safety standards that are the foundation for improving quality and protecting the health and safety of Medicare and Medicaid beneficiaries. The COP pertaining to hospitals are delineated in Title 42, Chapter 4, Part 482 in the Code of Federal Regulations. The COP provides basic standards that govern many aspects of the administration, quality assurance and performance improvement as well as basic hospital functions of hospitals. In the context of a medical negligence case, the COP can be used by a well-prepared expert as evidence of what a reasonable hospital (or hospital employee) should have done to prevent avoidable harm. Below are several relevant examples of COP mandated hospital duties. Keep in mind there are COP for all categories of healthcare facilities, from Ambulatory Care Centers to Nursing Homes that are potentially relevant in those types of cases. As to birth injury cases, the following can form a basis for important questions for hospital personnel from the CEO to the floor nurse:

> **§ 482.12 Condition of participation: Governing body.**
>
> There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body. The governing body (or the persons legally responsible for the conduct of the hospital and carrying out the functions specified in this part that pertain to the governing body) must include a member, or members, of the hospital's medical staff.
>
> **Standard**: Medical staff. The governing body must:
> *Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;
> *Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;
> *Assure that the medical staff has bylaws;
> *Approve medical staff bylaws and other medical staff rules and regulations;
> *Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

*Ensure the criteria for selection are individual character, competence, training, experience, and judgment; ...

Standard: Chief executive officer. The governing body must appoint a chief executive officer who is responsible for managing the hospital.

Standard: Care of patients. In accordance with hospital policy, the governing body must ensure that the following requirements are met:
(1) Every Medicare patient is under the care of: (i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.); ...
(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. ...
(3) A doctor of medicine or osteopathy is on duty or on call at all times.
(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—
(i) Is present on admission or develops during hospitalization; and
(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, ...
(e) **Standard**: Contracted services. The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.
(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.
(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

These duties are important to keep in mind in cases involving impaired physicians and other providers, residents, absent physicians, contracted nurses and hospital policies and procedures in general. They are also important to keep in mind in cases in which resuscitation and NICU care are contractual through a neonatal group!

§482.13 Condition of participation: Patient's rights.

A hospital must protect and promote each patient's rights. ...
(a) **Standard**: Exercise of rights.
(1) The patient has the right to participate in the development and implementation of his or her plan of care.
(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

These duties establish the hospital's obligation to ensure that meaningful informed consent takes place. In most states, consent is a physician's responsibility. However, the COP lays out a broader framework to make sure that the process actually happens in the pan of care. This is true whether a given case involves Pitocin, an operative vaginal delivery or indeed even, a "normal" course of labor.

§482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain and effective, ongoing, hospital-wide,

data driven quality-assessment and performance-improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) **Standard**: Program scope.

(1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events and other aspects of performance that assess processes of care, hospital services and operations. …

(e) **Standard**: Executive responsibilities.

The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

These duties go beyond the "peer review" that is protected in most States, placing a direct duty on hospitals to reduce risk to patients and to improve safety. Even in peer review privilege states, asking administrators what has been done to comply with COP in this regard is fair game. In many hospitals and in many Labor and Delivery units, these duties are largely ignored.

§482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) **Standard**: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) **Standard**: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient

(4) The hospital must ensure that the nursing staff develops, and keeps current, a

nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.
(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.
(6) Non-employees licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

This section has many critical duties often ignored in hospitals even with large Labor and Delivery departments. For example, a written plan of care should obviously include the plan, potential complications, the patient's response and changes to the plan throughout care to protect and promote the patient's health and safety. An appropriate plan of care for an induction should include something about the expected progress of labor and potential complications. The plan should be updated based on the patient's response throughout labor. When questioned about the written plan of care in these types of cases, three seemingly unacceptable responses seem to prevail. First, shockingly, some labor and delivery nurses will simply testify, "Oh, we don't do that here." Second, some will say that the written plan of care is reflected in their nursing notes. Careful examination will usually show the absurdity of that position. Third, with the advent of electronic records, many hospitals have a drop down entry for a plan of care in labor and delivery. In many hospitals this "plan of care" is identical for every labor and delivery and is never updated to reflect the patient's response to the plan. Not only is this in violation of federal law, it is plainly dangerous.

B. Joint Commission

The Joint Commission is an independent, not-for-profit organization that accredits and certifies more than 20,500 health care organizations and programs in the United States.(*See generally* www.jointcommission.org.) The Joint Commission accredits about 77 percent of the nation's hospitals, and while it is not the only accreditation organization in the United States, The Joint Commission accredits approximately 90 percent of the nation's accredited hospitals. Accreditation is important financially to hospitals in that many states require accreditation for participation in Medicaid programs and the Social Security Act Sections 1881 and 1865(a) permit for "deemed status" of accredited hospitals. This means that hospitals that are accredited by The Joint Commission are deemed to have met all of the Medicare Conditions of Participation. It is also important because The Joint Commission sets accreditation standards. In the context of medical negligence, a hospitals failure to follow the standards can be powerful evidence of institutional negligence.

In a Texas medical-malpractice action, the plaintiff must prove: (1) the applicable standard of care; (2) that the medical provider failed to act in accordance with that standard; and (3) that such failure was a proximate cause of the plaintiff's injuries. *Webb v. Bouton*, 350 Ark. 254, 264, 85 S.W.3d 885, 891 (2002). While The Joint Commission standards are not identical to the standard of care in Texas cases, they are instructive and may be used as bases of expert opinion of the standards – along with the hospital's own policies and bylaws. See for example *Denton Regional Medical Center v. LaCroix*, 947 S.W.2d 941, 951 (Tex.App.-Fort Worth 1997, pet. denied), citing *Hicks v. Canessa*, 825 S.W.2d 542, 544 (Tex.App.-El Paso 1992, no writ); *Hilzendager v. Methodist Hosp.*, 596 S.W.2d 284, 286 (Tex.Civ.App.-Houston [1st Dist.] 1980, no writ); *Foley v. Bishop Clarkson Mem. Hosp.*, 185 Neb. 89, 173 N.W.2d 881, 884 (1970); *Darling v. Charleston Community Mem.*

Hosp., 33 Ill.2d 326, 211 N.E.2d 253, 257 (1965), cert. denied, 383 U.S. 946, 86 S.Ct. 1204, 16 L.Ed.2d 209 (1966). In Oklahoma, The Joint Commission guidelines "provide evidence of the appropriate standard of care even at facilities which are not accredited by [the Joint Commission]." *Gaines v. Comanche County Medical Hosp.*, 143 P.3d 203, 213 (Okla. 2006). In Michigan, The Joint Commission guidelines may be used to establish the duty of care. *Zdrojewski v. Murphy*, 254 Mich.App. 50, 63, 657 N.W.2d 721, 730 (Mich.App. 2002). As with the Conditions of Participation described above, the Joint Commission standards are useful bases of expert opinion and helpful to the jury when describing the applicable standards of care.

Keep in mind that most (ie, the L&D nurse, the Nurse Manager of L&D, the Nurse Director of Women's Services, the CNO and the CEO) will admit:

*They have a duty to follow the standards.
*One of the reasons for the standard is to protect patient safety.
*If the standards are not followed, it could unnecessarily put the patient at risk for permanent injury or death.

Joint Commission Standards

The Joint Commission publishes "Standards" that define the performance expectations and/or processes that "must be in place" for a hospital to "provide safe, quality care, treatment, and services." *See, e.g.* 2104 *Hospital Accreditation Standards (HAS), The Joint Commission 2104,* at Intro-1. The Standards are the prerequisites for accreditation and cover the function and administration of the hospital in all areas, including but not limited to: Infection Prevention and Control; Medication Management, Provision of Care, Treatment, and Services; Rights and Responsibilities of the Individual; Human Resources; Information Management; Leadership; Medical Staff; Nursing; Performance Improvement, and Record of Care, Treatment and Services. The Standards are published in the yearly *Comprehensive Accreditation Manual for Hospitals (CAMH)* and the *Hospital Accreditation Standards (HAS)*. Each Standard is broken down into Elements of Performance (EP's) that "detail the specific performance expectations and/or structures or processes that must be in place in order for a hospital to provide quality care, treatment and services" *See Hospital Accreditation Standards (HAS), The Joint Commission,* published every year by the Joint Commission. They change slightly every year. Be sure to have the year applicable to your case!

Since just about every area of the hospital is covered, the Standards and EP's are tremendously useful in the proving medical negligence in birth injury cases. Here are some examples of Standards and Elements of Performance:

1. Leadership

The responsibility for patient safety does not just adhere to the staff nurse caring for the patient. It extends throughout the chain of command. In fact, it originates with the hospital leadership and must be established and enforced from the top down. This is made clear in the Leadership Standards and EP's.

Standard LD.03.01.01

Standard LD.03.01.01 requires that "[l]eaders create and maintain a culture of safety and quality throughout the hospital." See *2019 CAMH, at LD-14*.

Elements of Performance for Standard LD.03.01.01

The Elements of Performance for Standard LD.03.01.01 mandate the following specific obligations on hospital leadership:

1. Leaders regularly evaluate the culture of safety and quality using valid and reliable tools.
2. Leaders prioritize and implement changes identified by the evaluation.
3. Leaders provide opportunities for all individuals who work in the hospital to participate in safety and quality initiatives.

4. Leaders develop a code of conduct that defines acceptable behavior and behaviors that undermine a culture of safety.
5. Leaders create and implement a process for managing behaviors that undermine a culture of safety.

<u>Standard LD.03.03.01</u>
Standard LD.03.03.01 requires that "Leaders use hospital wide planning to establish structures and processes that focus on safety and quality." See *2014 CAMH, at LD-15*.
<u>Elements of Performance for LD.03.03.01</u>
The Elements of Performance for LD.03.03.01 mandates hospital leadership to have:
1. Planning activities focus on improving patient safety and health care quality, [and] adapting to changes in the environment.
2. Planning is hospitalwide, systematic, and involves designated individuals and information sources.
3. Leaders evaluate the effectiveness of planning activities.

<u>Standard LD.03.04.01</u>
Standard LD.03.04.01 requires that the "hospital communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties". See *201 CAMH, at LD-16*.
<u>Elements of Performance for LD.03.04.01</u>
The Elements of Performance for LD.03.04.01 mandate the following:
1. Communication processes are effective in doing the following:
*Fostering the safety of the patient and his or her quality f of care.
*Supporting safety and quality throughout the hospital.
*Meeting the needs of internal and external users.
*Informing those who work in the hospital of changes in the environment.
2. Leaders evaluate the effectiveness of communication methods.

2. Nursing

The Nursing Standard governs the duties of the nurse executive in the provision of nursing services. The Joint Commission expressly states that "[n]urses make up the front line of patient care; they are directly and intimately involved in the care, treatment, and services patients receive and are likely to be the most visible face of health care for patients who enter the hospital." See *2019 CAMH, at NR-3, Rationale for NR.01.01.01*.

<u>Standard NR.02.02.01</u>
Standard NR.02.02.01 places the duty on nurse executives for the establishment of "guidelines for the delivery of nursing care, treatment, and services." See *2019 CAMH, at NR-4*. <u>Elements of Performances for NR.02.02.01</u>The Elements of Performances for NR.02.02.01 mandate the following:
2. The nurse executive coordinates the following:
*The development of hospitalwide programs, policies and procedures that address how nursing care needs of the patient population are assessed, met, and evaluated.
* The development of an effective, ongoing program to measure, analyze, and improve the quality of nursing care, treatment, and services.
4. The nurse executive directs the following**:**
*The implementation of hospitalwide plans to provide nursing care, treatment, and services.
*The implementation of hospitalwide programs, policies, and procedures that address how nursing care needs of the patient population are assessed, met, and evaluated.
*The implementation of an effective, ongoing program to measure, analyze, and improve the quality of nursing care, treatment, and services.

3. Human Resources

The human resources standards set forth the hospital's obligation to ensure the competency of hospital personnel. The hospital has a duty to test, train and retest its nursing and other staff. Two things should be kept in mind when addressing human resources issues: first, most hospitals keep a separate education file for its nurses in addition to the personnel file.

Request both. Second, the standards applied to all hospital personnel, including managers, directors and others further up the administrative chain.

Standard HR .01.05.03

Standard HR .01.05.03 requires that "staff participate in ongoing education and training." This is after the standards require that the hospital defined staff qualifications, verify the employees qualifications, determines how the employee functions within the organization and provides orientation. *2019 CAMH at HR-8.*

Standard HR .0 1.0 6.01

Standard HR .01.06.01 requires the hospital to ensure that " staff are competent to perform their responsibilities." *2019 CAMH at HR-11.*

Elements of performance for HR .01.06.01

The elements of performance for HR .01.06.01 require the hospital to

1. The hospital defines the competencies it requires of its staff who provide patient care, treatment, or services. ...
3. An individual with the educational background, experience, or knowledge related to the skills being reviewed assesses competence. ...
5. Staff competence is initially assessed and documented as part of orientation.
6. Staff competence is assessed and documented once every three years, or more frequently as required by hospital policy or in accordance with law and regulation.

4. Medication Management

The use of medication within the hospital, the prescribing and ordering of medication, and the hospital response to adverse medication events are all discussed in the medication management standards. These standards should be reviewed when pursuing a case where Pitocin mismanagement is an issue.

Standard MM.04.01.01

Standard MM.04.01.01 requires that "medication orders are clear and accurate." See *2019 CAMH at MM-12.*

Elements of Performance for MM.04.01.01

Elements of Performance for MM.04.01.01 mandate the following:

1. The hospital has a written policy that identifies the specific types of medication orders that it deems acceptable for use. ...

The hospital follows a written policy that defines the following:

2. The required elements of complete medication order.
3. When indication for use is required on a medication order.
4. The precautions for ordering medications with look-alike or sound-alike names.
5. Actions to take when medication orders are incomplete, illegible, or unclear.
6. The hospital minimizes the use of verbal and telephone medication orders. ...
9. The diagnosis, condition, or indication for use exists for each medication ordered. ...
15. For hospitals that use Joint Commission accreditation for deemed status purposes: Processes for the use of pre-printed and electronic standing orders, order sets, and protocols for medication orders include the following:

*Review and approval of standing orders and protocols by medical staff and the hospital's nursing and pharmacy leadership.
*Evaluation of established standing orders and protocols for consistency with nationally recognized and evidenced-based guidelines.
*Regular review of such standing orders and protocols by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the standing orders and protocols.
*Dating, timing, and authenticating of standing orders and protocols by the ordering practitioner or another practitioner responsible for the patient's care in accordance with professional standards of practice; law and regulation; hospital policies; and medical staff bylaws, rules and regulations.

Standard MM.07.01.03

Standard MM.07.01.03 requires that the "hospital responds to actual or potential adverse drug events, significant adverse drug reactions, and medication errors." See *2019 CAMH, at MM-22.*

Elements of Performance for MM.07.01.03

The Elements of Performance for MM.07.01.03 mandate the following:
1, The hospital follows a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
2, The hospital has a written process addressing prescriber notification in the event of an adverse drug events, significant adverse drug reaction, or medication error.
3. The hospital complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors.
…
6. For hospitals that use Joint Commission accreditation for deemed status purposes: Medication administration errors, adverse drug reactions, and medication incompatibilities as defined by the hospital are immediately reported to the attending physician ….

5. Medical Staff

Standards for credentialing and the granting of privileges are delineated in the Medical Staff (MS) standards. The Joint Commission demands that the medical staff provide "oversight of the quality of care, treatment, and services delivered by practitioners who are credentialed and privileged through the medical staff process." See *2019 CAMH, at MS-1*.

Standard MS.03.01.03

Standard MS.03.01.03 provides that the "management and coordination of each patient's care, treatment, and services is the responsibility of a practitioner with appropriate privileges." See *2019 CAMH, at MS-18*.

Elements of Performance for MS.03.01.03

The Elements of Performance for MS.03.01.03 mandate the following:
1. Physicians… with appropriate privileges manage and coordinate the patient's care, treatment, and services.
3. A patient's general medical condition is managed and coordinated by a doctor of medicine or osteopathy. …
12. For hospitals that used joint commission accreditation for team status purposes: a doctor of medicine or osteopathy is on duty or on call at all times.

Standard MS.06.01.03

Standard MS.06.01.03 requires that a "hospital collects information regarding each practitioner's current license status, training, experience, competence, and ability to perform the required privilege." See, *2019 CAMH, at MS-27*.

Elements of Performance for MS.06.01.03

The Elements of Performance for MS.06.01.03 mandate the following:
1. The hospital credentials applicants using a clearly defined process.
2. The credentialing process is based on recommendations by the organized medical staff.
3. The credentialing process is approved by the governing body.

Standard MS.06.01.07

Standard MS.06.01.07 requires that an "organized medical staff reviews and analyzes all relevant information regarding each requesting practitioners current licensure status, training, experience, current competence, and ability to perform the requested privilege." See *2019 CAMH, at MS-31*.

Elements of Performance for M.S.06.01.07

The Elements of Performance for M.S.06.01.07 mandate the following:
1. The information review and analysis process is clearly defined.
2. The hospital, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny and requested privilege. …
6. Decisions on membership and granting of privileges include criteria that are directly related to the quality of healthcare, treatment, and services.
7. If privileging criteria are used that are unrelated to quality of care, treatment, and services or professional competence, evidence exists that the impact of resulting decisions on the quality of care, treatment, and services is evaluated.

6. Provision of Care, Treatment And Services

Standard PC.01.02.01

Standard PC.01.02.01 requires that "[t]he hospital assesses and reassesses its patients." See *2019 CAMH, at PC-5*.

Elements of Performance for PC.01.02.01

The Elements of Performance for PC.01.02.01 mandate the following:

1. The hospital defines, in writing, the scope and content of screening, assessment, and reassessment information it collects. Patient information is collected according to time requirements.
2. The hospital defines, in writing, criteria that identify when additional specialized, or more in-depth assessments are performed.

Standard PC.01.02.03

Standard PC.01.02.03 requires that "[t]he hospital assesses and reassesses the patient and his or her condition according to defined time frames." See *2019 HAS, at PC-7*.

Elements of Performance for PC.01.02.03

The Elements of Performance for PC.01.02.03 mandate the following:

1. The hospital conducts the patient's initial assessment in accordance with the written time frames it defines and law and regulation. ...
3. Each patient is reassessed as necessary based on his or her plan for care or changes in his or her condition.
4. The patient receives a medical history and physical examination no more than 30 days prior to, or within 24 hours after, registration or inpatient mission, but prior to surgery or a procedure requiring anesthesia services.
5. For medical history and physical examination that was completed within 30 days prior to registration or inpatient admission, an update documenting any changes in the patient's conditions is completed within 24 hours after egistration or inpatient admission, but prior to surgery or a procedure requiring anesthesia services.
6. A registered nurse completes a nursing assessment within 24 hours after the patient's inpatient admission.

7. Rights and Responsibilities

Standard PC.01.03.01

Standard PC.01.03.01 requires that "[t]he hospital plans the patient's care." See *2019 CAMH, at PC-18.*

Elements of Performance for PC.01.03.01

The Elements of Performance for PC.01.03.01 mandate the following:

1. The hospital plans the patient's care, treatment, and services based on needs identified by the patient's assessment, reassessment, and results of diagnostic testing. ...
5. The written plan of care is based on the patient's goals in the time frames, settings and services required to meet those goals. ...
22. Based on the goals established in the patient's plan of care, staff evaluates the patient's progress.
23. The hospital revises plans and goals for care, treatment, and services based on the patient's needs. ...

Standard PC.02.01.19

Standard PC.02.01.19 requires that the "hospital recognizes and responds to changes in patient's condition." See *2019 CAMH, at PC-24*.

Elements of Performance for PC.02.01.19

The Elements of Performance for PC.02.01.19 mandate the following:

1. The hospital has a process for recognizing and responding as soon as a patient's condition appears to be worsening.
2. The hospital develops written criteria describing early warning signs of a change or deterioration in a patient's condition and when to seek further assistance.

Standard RI.01.02.01

Standard RI.01.02.01 requires that the "hospital respects the patients right to participate in decision about his or her care, treatment, and services." See *2019 CAMH, at RI-7*.

Elements of Performance for RI.01.02.01

The Elements of Performance for RI.01.02.01 mandates the following:

1. The hospital involves the patient in making decisions about his or her care, treatment, and services, including the right to have his or her own physician promptly notified of his or her admission to the hospital. ...

8. Sentinel Event Alert, Issue 30: Prevention Of Infant Death And Injury During Delivery

As part of its accreditation activities, the Joint Commission reviews organizations' activities in response to sentinel events. "A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function." Periodically, the Joint Commission issues alerts discussing its findings. Of relevance to birth injury cases, the Joint Commission issued *Sentinel Event Alert, Issue 30: Preventing infant death and injury during delivery* on July 21, 2004 in which it reviewed 47 cases of "perinatal death or major permanent loss of function unrelated to a congenital condition in an infant having a birth weight greater than 2,500 grams." The Joint Commission reviewed the root cause of each case and found an institutional or systems cause in each and every one. According to the Joint Commission, the root causes included the following: 1) communication issues, with more than one-half of the organizations citing organization culture as a barrier to effective communication and teamwork, i.e., hierarchy and intimidation, failure to function as a team, and failure to follow the chain-of-communication; 2) staff competency; 3) orientation and training process; 4) inadequate fetal monitoring; 5) unavailable monitoring equipment and/or drugs, 6) credentialing/privileging/supervision issues for physicians and nurse midwives, 7) staffing issues, and 8) physician unavailable or delayed, and unavailability of prenatal information.

The Joint Commission in Sentinel Event 30 fully acknowledged that error prevention requires direct hospital involvement. After reviewing both the root causes and hospital action plans, the Joint Commission issued specific recommendation to organizations to prevent these injuries, including the following:

1. Conduct team training in perinatal areas to teach staff to work together and communicate more effectively.
2. For high-risk events, such as shoulder dystocia, emergency Cesarean delivery, maternal hemorrhage and neonatal resuscitation, conduct clinical drills to help staff prepare for when such events actually occur, and conduct debriefings to evaluate team performance and identify areas for improvement.
3. Review and apply the ACOG VBAC Practice Bulletin, Vaginal Birth after Cesarean Delivery; the Standards & Guidelines for Professional Nursing Practice in the Care of Women and Newborn from the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN); and the AAP and ACOG guidelines for perinatal care, including those to:
   a. Develop clear guidelines for fetal monitoring of potential high-risk patients, including nursing protocols for the interpretation of fetal heart rate tracings (pages 127, 133-134).
   b. Educate nurses, residents, nurse midwives, and physicians to use standardized terminology to communicate abnormal fetal heart rate tracings (pages 127, 133-134).
   c. Review organizational policies regarding the availability of key personnel for emergency interventions (page 19).
   d. Ensure that designated neonatal resuscitation areas are fully equipped and functioning (page 188).

e. Develop guidelines for the transfer of patients to a higher level of care when indicated, if essential services cannot be readily provided per ACOG guidelines (Chapter 3, pages 57-71).

f. Use a standardized maternal fetal record form for each admission.

In addition to the Joint Commission Standards and the Sentinel Event Alerts, the Joint Commission publishes a number of books and other materials to show specifically how to comply with the Standards. These include, for example, *Nursing The Front Line of Defense and Competency Testing*. The same administrative personnel who will admit to the existence of the standards will likely say that they have never seen or heard of these texts. The obvious follow up questions could be: "Then who in your organization would be responsible for implementing the concepts in these sources?" An enlightening set of questions to administrative personnel would include "What have you personally done in the 5 years before this delivery to develop clear guidelines for fetal monitoring of potential high-risk patients, including nursing protocols, for the interpretation of fetal heart rate tracings (etc.)?" Often the answer is "nothing". This can be followed by an inquiry as to "who in the organization would have responsibility for such efforts?"

C. The Association for Women's Health, Obstetrics and Neonatal Nurses (AWHONN)

The Association for Women's Health, Obstetric and Neonatal Nurses (AWHONN) is a national organization of nurses "committed to the health of women and newborns."[50] The organization has 24,000 members and is arguably "the foremost nursing authority" in women's health. According to its mission statement, AWHONN's mission is to "improve and promote the health of women and newborns and to strengthen the nursing profession through the delivery of superior advocacy, research, education and other professional and clinical resources to nurses and other health care professionals." Through its education materials and publications, AWHONN is an excellent resource for standards of nursing care in the obstetrical case. Every hospital should require its obstetrical nurses to be members and to utilize and be familiar with AWHONN's published standards. Otherwise, a credible argument can be made that the hospital is not committed to the health of its women and newborn patients. As is the case with the other materials, AWHONN's publication can be strong evidence of the standard of care in the hands of a well-prepared expert or a knowledgeable plaintiffs' attorney.

1. The Standards For Professional Nursing Practice in the Care of Women and Newborns (7th Ed.)

The Standards For Professional Nursing Practice in the Care of Women and Newborns (7th Ed.), for example, delineates specific standards that describe the responsibilities for which nurses are accountable. The "standards of practice" describe a "competent level of nursing care" in six areas: assessment, diagnosis, outcome identification, planning, implementation and evaluation. The "standards of professional performance" cover "professional behavior" in the areas of quality of practice, education, professional practice evaluation, ethics, collegiality, collaboration and communication, research, resource and technology, and leadership. See *The Standards For Professional Nursing Practice in the Care of Women and Newborns* (7th Ed), at p. 1. For each standard, measurement criteria are included which are key indicators used to measure performance. Below are some examples that are particularly relevant to the obstetrical negligence case:

[50] See https://www.awhonn.org.

Standard I. Assessment:

The registered nurse collects health data about women and newborns in the context of woman-centered and family-centered care.

Measurement Criteria

The registered nurse:

1. Prioritizes data collection based on the immediate condition of the woman or newborn and their needs for health promotion, maintenance or restoration.
2. Collects data using appropriate evidence-based assessment techniques.
3. Involves the woman and newborn and when appropriate, the family, significant others, and members of the health care team during data collection.
4. Collects data with respect for individual cultural needs in an age-appropriate manner.
5. Analyzes data in a systematic and ongoing manner.
6. Synthesizes available data to identify trends and variances.
7. Documents data in a retrievable form with appropriate protection of patient confidentiality.

Standard II. Diagnosis:

The registered nurse formulates nursing diagnoses by analyzing assessment data to identify and differentiate normal physiologic and developmental transitions from pathophysiologic variations and other clinical issues in the context of woman centered and family- centered care.

Measurement Criteria

The registered nurse:

1. Develops and prioritizes diagnoses based on synthesis of the assessment data. Individualizes and validates diagnoses with the woman or with parents of the newborn and when appropriate, with family members, significant others, and members of the health care team.
2. Documents diagnoses in a retrievable form that facilitates the determination of expected outcomes and plan of care with appropriate protection of patient confidentiality.

Standard III. Planning:

The registered nurse develops a plan of care that includes interventions and alternatives to attain expected outcomes for women and newborns in the context of woman- centered and family- centered care.

Measurement Criteria

The registered nurse:

1. Individualizes and prioritizes the plan to support the health promotion, maintenance or restoration needs of women and newborns.
2, Formulates a plan of care that is age- and developmentally appropriate as well as culturally and environmentally sensitive.
3. Develops a plan that is based on principles of woman- centered and family-centered maternity, neonatal or women's health care.
4. Develops a plan with the woman or with parents of the newborn and when appropriate, with family members, significant others and members of the health care team.
5. Utilizes current evidence-based practice, accepted guidelines for care, statutes, rules, and regulations when developing the plan.
6. Develops a plan with consideration for continuity of care and including a timeline for implementation.
7. Considers economic and environmental influences on the plan of care.
8. Documents the plan using standardized language or recognized terminology in a retrievable form accessible to other members of the health care team, with appropriate protection of patient confidentiality.

Standard IV. Implementation:

The registered nurse implements the interventions identified in the woman's or newborn's plan of care in the context of woman-centered and family- centered care.

Measurement Criteria

The registered nurse:

1. Utilizes interventions that are consistent with the established plan of care in a safe and timely manner, incorporating community resources and systems as appropriate.
2. Utilizes interventions that are consistent with evidence-based nursing practice and with accepted guidelines for care, statutes, rules and regulations.
3. Collaborates with nursing colleagues and other members of the health care team, and refers to community resources and systems as appropriate to implement the plan of care.
4. Integrates principles of safety and quality into interventions.
5. Documents implementation and modifications of the identified plan.
6. Documents interventions in a retrievable form accessible to other health care providers with appropriate protection of patient confidentiality.

Standard V(a) Coordination of Care

The registered nurse coordinates care delivery to women and newborns in the context of woman-centered and family centered care and within her/his scope of practice.

Measurement Criteria

The registered nurse:

1. Coordinates implementation of the plan.
2. Documents the coordination of the care in a retrievable form accessible to other health care providers with appropriate protections of patient confidentiality.

Standard VI. Evaluation

The registered nurse evaluates the progress of women and newborns toward attainment of expected outcomes in the context of woman-centered and family- centered care.

Measurement Criteria

The registered nurse:

1. Conducts an evaluation that is systematic, ongoing and criterion-based, relative to the elements of patient care and indicated time lines.
2. Evaluates the effectiveness of the planned strategies in relation to patient responses and the attainment of the expected outcomes.
3. Utilizes ongoing assessment data to revise diagnoses, problem lists, plans of care, interventions, and outcomes, as needed.
4. Involves the woman or the parents of the newborn and when appropriate, family members, significant others, and other health care providers in the evaluation process, in accordance with state and federal laws and regulations.
5. Documents the revisions in diagnoses, problem lists, plans of care and evaluation of outcomes in a retrievable form accessible to other health care providers with appropriate protection of patient confidentiality.

Standard VII. Quality of Practice

The registered nurse systematically evaluates and implements measures to improve the quality, safety and effectiveness of nursing practice for women and newborns.

Measurement Criteria

The registered nurse:

1. Participates in the evaluation of quality of practice activities as appropriate to her or his position, education, and practice environment. Such activities may include:
   *Identification of aspects of practice important for quality monitoring
   *Identification of aspects of practice important for quality monitoring
   *Identification of indicators used to monitor quality, safety and effectiveness of nursing practice

*Integration of best available evidence into quality, safety and effectiveness indicators, as appropriate
*Development, regular review and revision of evidence-based practice guidelines and organizational policies and procedures
*Collection of data to monitor quality, safety, and effectiveness of nursing practice
*Analysis of quality data to identify opportunities for improving nursing practice
*Development, implementation, and evaluation of policies, procedures and/or practice guidelines to improve quality of care
*Formulation of recommendations to improve nursing practice and patient outcomes
*Participation on inter-professional teams that evaluate clinical practice and safety related to provision of health services
*Analysis of barriers to quality of practice within the organizational systems
*Implementation of strategies designed to minimize or remove barriers to quality of practice within organizational systems
*Participation in efforts to minimize costs and unnecessary duplication without compromising quality of practice

2. Uses the results of quality of care activities to initiate and implement changes in practice with the goal of enhancing quality, safety, and effectiveness of nursing practice and the healthcare system, as appropriate.
3. Protects the privacy of patient information used to evaluate the quality of care as is consistent with institutional, state, provincial, and federal law.

Standard VIII. Education

The registered nurse acquires and maintains knowledge and competencies that reflect current evidence-based nursing practice for women and newborns

Measurement Criteria

The registered nurse:

1. Acquires knowledge and experiences that reflect current evidence-based practice in order to maintain skills and competence appropriate for his or her specialty area, role, and practice setting.
2. Participates in and maintains professional records of educational activities required to provide evidence of competency.
3. Maintains licensure and certification as mandated by state licensing boards, health care facilities, and accrediting agencies.
4. Maintains certification within the specialty area of practice when appropriate, as a mechanism to demonstrate special knowledge.
5. Participates in lifelong learning, including educational activities related to evidence-based practice, knowledge acquisition, safety and professional issues.
6. Has knowledge of relevant practice parameters and guidelines of other organizations that focus on the delivery of health care services to women and newborns.

Standard XIV. Resources and Technology

The registered nurse considers factors related to safety, effectiveness, technological advances, and cost in planning and delivering care to women and newborns.

Measurement Criteria

The registered nurse:

1. Evaluates factors such as safety, effectiveness, availability, cost and benefits, efficiencies, and impact on practice options and resources.
2. Incorporates the most current technology in providing care and safety documentation and communication, whenever possible.
3. Assists the woman and her family in identifying and securing appropriate and available services to address health-related needs.
4. Assigns or delegates tasks based on evaluation of the needs and condition of the woman or newborn, potential for harm,

stability of the patient's condition, complexity of the task, predictability of the outcome and the knowledge, skill, and scope of practice of the provider.
5. Assists the woman and her family in becoming informed consumers about the options, costs, risks and benefits of treatment and care.

Again, these are merely examples of the some of the standards. If nothing else, The Standards For Professional Nursing Practice in the Care of Women and Newborns (7th Ed.) can be used to effectively rebut any claim by the defendants and their counsel that nurses are present merely to take doctors' orders. To the contrary, they have a clear, independent duty to assess, to evaluate, to develop and implement written plans of care and to coordinate care amongst healthcare providers. In addition, they must perform these tasks as professionals while taking measure to improve the quality, safety, and efficacy of their practice. Consider deposing nurse-executives and nurse-educators and questioning them on their familiarity with the above standards, their training budgets, and the efforts they take to ensure their staff nurses are meeting the above-standards. You are likely to find that they have no idea that these standards even exist.

2. Guidelines for Professional Registered Nurse Staffing for Perinatal Units

Another example of AWHONN guidelines is the Guidelines for Professional Registered Nurse Staffing for Perinatal Units (2010)("Staffing Guidelines") which were developed by the AWHONN Staffing Task Force. The AWHONN staffing task force was charged with "reviewing perinatal nurse staffing issues, identifying areas of most concern, and making recommendation about perinatal nurse staffing." See Guidelines for Professional Registered Nurse Staffing for Perinatal Units (AWHONN 2010), at p. i. The Staffing Guidelines state that "adequate staffing is critical to providing safe nursing care to mothers and babies. " Interestingly, it acknowledges that "budgeting for nurse staffing of perinatal units should include "nonproductive time" for a thorough orientation to the units, and regularly scheduled continuing education. According to the Staffing Guidelines, "[o]ngoing learning is fundamental to patient safety and therefore should be budgeted for and scheduled routinely." The Staffing Guidelines also provide specific nurse-patient ratio recommendations for specific events during antepartum, intrapartum, and post-partum care. For example, for obstetric triage, the Staffing Guidelines offer the following recommendations:

*The initial triage process (10-20 minutes) requires 1 nurse to 1 woman presenting for care. This ratio may change to 1 nurse to 2-3 women as maternal-fetal status is determined to be stable, until patient disposition.
*Fetal status assessment should be included in the initial triage assessment before determining the level and immediacy of care required.
*1 nurse to 2-3 women during nonstress testing.

During labor of women receiving oxytocin, the Staffing Guidelines recommend:
*Patient assignment for women receiving oxytocin for labor induction or augmentation should be 1 nurse to 1 woman to be able to assess maternal and fetal status every 15 minutes, consistent with safe care.
*If a nurse cannot clinically evaluate the effects of medication at least every 15 minutes, the oxytocin infusion should be discontinued until that level of maternal and fetal care can be provided.
*Elective procedures should be deferred until there are adequate nurses to safely meet the needs of patients and services.

During labor of women with medical or obstetric complications, the Staffing Guidelines provide:

*1 nurse to 1 woman with labor complication.
*Women in labor who are receiving magnesium sulfate should have 1 nurse in continuous bedside attendance for the first hour of administration and 1 nurse to 1 woman thereafter.

The Staffing Guidelines recognize that the definition of "medical and obstetric complications" varies but offers diabetes, pulmonary or cardiac disease and morbid obesity as examples of "medical complications" and preeclampsia, multiple gestations, fetal demise, indeterminate or abnormal FHR pattern and VBAC as examples of "obstetrical complications".

Other recommendations include: 1-to-1 staffing for a women whose fetus is being monitored via intermittent auscultation; 1-to-1 continuous bedside nursing attendance during initiation of regional anesthesia until condition is stable (at least for the first 30 minutes after initial dose); and 1-to-1 continuous bedside nursing attendance to women during the active pushing phase of second-stage labor. See id. at p. 37. In that poor staffing is potentially the issue in any failure of care, the plaintiff's lawyer should be well versed in the Staffing Guidelines applicable the issues presented in his or her case.

Additionally, AHWONN provides positions statements on many topics on its website that provide specific direction to hospitals and nurses. In the position statement on Nursing Support of Laboring Women (AWHONN, June, 2011), AWHONN explains that the support expected of a registered nurse during labor and delivery includes:

*Assessment and management of the physiologic and psychological processes of labor
*Facilitation of normal physiologic processes, such as the women's desire for movement in labor
*Provision of physical comfort measures, emotional and informational support and advocacy
*Evaluation of fetal well-being during labor
*Instruction regarding the labor process
*Role modeling to facilitate family participation during labor and birth
*Direct collaboration with other members of the health care team to coordinate patient care.

In AWHONN's position statement on Fetal Monitoring (AWHONN Nov. 2008, *currently under revision*), AWHONN provides very specific guidelines on the frequency of monitoring with both auscultation and electronic fetal monitoring:

Frequency of Fetal Assessment with Electronic Fetal Monitoring In the absence of risk factors:
Determine and evaluate the FHR every 30 minutes during the active phase of the first stage of labor and every 15 minutes during the (active pushing phase) of the second stage of labor (AAP & ACOG, 2007). In Canada, the FHR is evaluated every 5 minutes in the active phase of the second stage of labor (SOGC, 2007).

When risk factors are present, continuous EFM is recommended:
During the active phase of the first stage of labor, the FHR should be determined and evaluated every 15 minutes (AAP & ACOG, 2007). During the active pushing phase of the second stage of labor, the FHR should be determined and evaluated at least every 5 minutes (AWHONN, 2008). During oxytocin induction or augmentation, the FHR should be determined and evaluated every 15 minutes during the active phase of the first stage of labor and every 5 minutes during the (active pushing phase) of the second stage of labor (AAP & ACOG, 2007; AWHONN 2008).
When EFM is used to record FHR data permanently, periodic documentation can be used to summarize evaluation of fetal status at the frequencies recommended by AAP and ACOG (2007) as outlined by institutional protocols. Thus, while evaluation of the FHR may be occurring every 15 minutes, a summary note including findings of fetal status may be

> documented in the medical record less frequently. During oxytocin induction or augmentation, the FHR should be evaluated and documented before each dose increase. During the active pushing phase of the second stage of labor, summary documentation of fetal status approximately every 30 minutes indicating there was continuous nursing bedside attendance and evaluation seems reasonable.

See Fetal Monitoring (AWHONN 2008).

In addition to the standards and guidelines discussed above, AWHONN provides a wealth of other publications and resources that are useful in the obstetrical case. Here are a few examples of publications that we have used and in which we have found relevant standards and/or strong evidence of the standard of care:

"Strategies for Successful Communication." AWHONN 2013.
"The Women's Health Nurse Practitioner Guidelines for Practice and Education." NPWH 6th ed. 2008.
"Fetal Heart Monitoring: Principles and Practices." 4th ed. Washington: Kendall Hunt Publishing Company. AWHONN 2009.

D. Nurse Practice Act And Rules & Regulations

Every state has a Nurse Practice Act. Virtually all have separate Administrative Rules and Regulations of the Board of Nursing. Most have Board of Nursing Position Statements or other such mandates which set forth exquisitely the details of the nursing process. These can be found on the Board of Nursing Websites for each state. These are important, if not critical, to every case. First, these regulations are mandatory. It is a rare CEO, DON, Manager of Labor and Delivery or floor nurse that will deny that they have a duty to following these "rules" and to ensure that others do as well. (If they do, treat it as a gift). In fact, most have an absolute duty to report violations. Second, most will likewise admit that regulations have patient safety as their overriding purpose. This is especially true in light of the considerable body of literature referenced earlier about hospital errors. (Indeed, find out who at the hospital has that duty to keep up with such literature.) Third, these "rules" are usually defined in terms of professional conduct and standards of care. Conversely, most also specifically define "unprofessional" or "unethical" conduct. Finally, these mandatory rules often provide a basic outline for examination of all hospital personnel and can set the theme for your entire case. Some examples from Georgia follow:

> TITLE 43. PROFESSIONS AND BUSINESSES
> CHAPTER 26. NURSES
> ARTICLE 1. GEORGIA REGISTERED PROFESSIONAL NURSE PRACTICE ACT
> ....
> **§ 43-26-2. Legislative intent**
> The purpose of this article is to protect, promote, and preserve the public health, safety, and welfare through legislative regulation and control of registered professional nursing education and practice. This article ensures that any person practicing or offering to practice nursing or using the title registered professional nurse, as defined in this article, within the State of Georgia, shall be licensed as provided in this article.
> ...
>
> **§ 43-26-3. Definitions**
> As used in this article, the term: ...
> (6) "Practice nursing" or "practice of nursing" means to perform for compensation or the performance for compensation of any act in the care and counsel of the ill, injured, or infirm, and in the promotion and maintenance of health with individuals, groups, or both throughout the life span. It requires substantial specialized knowledge of the humanities, natural sciences, social sciences, and nursing theory as a basis for assessment, nursing diagnosis, planning, intervention, and evaluation. It includes, but is not limited to, provision of nursing care; administration, supervision, evaluation, or

any combination thereof, of nursing practice; teaching; counseling; the administration of medications and treatments as prescribed by a physician practicing medicine in accordance with Article 2 of Chapter 34 of this title, or a dentist practicing dentistry in accordance with Chapter 11 of this title, or a podiatrist practicing podiatry in accordance with Chapter 35 of this title. …

(8) "Practice nursing as a registered professional nurse" means to practice nursing by performing for compensation any of the following: …

(B) Establishing a nursing diagnosis;
(C) Establishing nursing goals to meet identified health care needs;
(D) Planning, implementing, and evaluating nursing care;
(E) Providing for safe and effective nursing care rendered directly or indirectly;
(F) Managing and supervising the practice of nursing;
(G) Collaborating with other members of the health care team in the management of care;
(H) Administering, ordering, and dispensing medications, diagnostic studies, and medical treatments authorized by protocol, when such acts are authorized by other general laws and such acts are in conformity with those laws;
(I) Administering medications and treatments as prescribed by a physician practicing medicine in accordance with Article 2 of Chapter 34 of this title, a dentist practicing dentistry in accordance with Chapter 11 of this title, or a podiatrist practicing podiatry in accordance with Chapter 35 of this title; or
(J) Performing any other nursing act in the care and counsel of the ill, injured, or infirm, and in the promotion and maintenance of health with individuals, groups, or both throughout the life span.

Note that only the definitions section in the Georgia legislation provides the requirements for “Substantial Specialized Knowledge” – the requirement for establishing a nursing diagnosis and a consent outline of the nursing process.

410-11-.01 Standards of Registered Professional Nursing Practice. Amended.

(1) For purposes of O.C.G.A. Secs. 43-26-4 (a)(6)(B)(v) and 43-1-29(6), the Georgia Board of Nursing defines the minimal standards of acceptable and prevailing nursing practice as including, but not limited to the following enumerated standards of competent practice.

(2) The Georgia Board of Nursing recognizes that assessment, nursing diagnosis, planning, intervention, evaluation, teaching, and supervision are the major responsibilities of the registered nurse in the practice of nursing. The Standards of Registered Professional Nursing Practice delineate the quality of nursing care which a patient/client should receive regardless of whether it is provided solely by a registered nurse or by a registered nurse in collaboration with other licensed or unlicensed personnel. The Standards are based on the premise that the registered nurse is responsible for and accountable to the patient/client for the quality of nursing care rendered. The Standards of Registered Professional Nursing Practice shall establish a baseline for quality nursing care; be derived from the law governing nursing; apply to the registered nurse practicing in any setting; govern the practice of the licensee at all levels of competency.

(a) Standards related to the registered nurse's responsibility to apply the nursing process (adapted from American Nurses' Association *Code for Nurses and Standards of Practice*). The registered nurse shall:

1. Assess the patient/client in a systematic, organized manner;
2. Formulate a nursing diagnosis based on accessible, communicable and recorded data (which is collected in a systematic and continuous manner);
3. Plan care which includes goals and prioritized nursing approaches or measures derived from the nursing diagnoses;
4. Implement strategies to provide for patient/client participation in health promotion, maintenance and restoration;

5. Initiate nursing actions to assist the patient/client to maximize her/his health capabilities;
6. Evaluate with the patient/client the status of goal achievement as a basis for reassessment, reordering of priorities, new goal-setting and revision of the plan of nursing care;
7. Seek educational resources and create learning experiences to enhance and maintain current knowledge and skills appropriate to her/his area of practice.

(b) Standards related to the registered nurse's responsibilities as a member of the nursing profession. The registered nurse shall:

1. Function within the legal boundaries of nursing practice based upon knowledge of statutes and regulations governing nursing;
2. Accept responsibility for individual nursing actions and continued competence;
3. Communicate, collaborate and function with other members of the health team to provide optimum care;
4. Seek education and supervision as necessary when implementing nursing practice techniques;
5. Respect the dignity and rights of the patient/client, regardless of socioeconomic status, personal attributes or nature of health problems;
6. Delegate and supervise only those nursing measures which the nurse knows, or should know, that another person is prepared, qualified, or licensed to perform;
7. Retain professional accountability for nursing care when delegating nursing intervention;
8. Respect and safeguard the property of clients, family, significant others and the employer;
9. Notify the appropriate party of any unprofessional conduct which may jeopardize patient/client safety;
10. Participate in the periodic review and evaluation of the quality and appropriateness of nursing care.

Note that these statutory provisions are not set forth in terms of permissive guidelines. Instead, they are direct statutory mandates. They are required!

410-11-.02 Definition of Unprofessional Conduct. Amended.

Nursing behaviors (acts, knowledge, and practices) failing to meet the minimal standards of acceptable and prevailing nursing practice, which could jeopardize the health, safety, and welfare of the public, shall constitute unprofessional conduct. These behaviors shall include, but not be limited to, the following:

(a) Using inappropriate or unsafe judgment, technical skill or interpersonal behaviors in providing nursing care;
(b) Performing any nursing technique or procedure for which the nurse is unprepared by education or experience;
(c) Disregarding a patient/client's dignity, right to privacy or right to confidentiality;
(d) Failing to provide nursing care because of diagnosis, age, sex, race, creed or color;
(e) Abusing a patient/client verbally, physically, emotionally, or sexually;
(f) Falsifying, omitting or destroying documentation of nursing actions on the official patient/client record;
(g) Abandoning or knowingly neglecting patients/clients requiring nursing care;
(h) Delegating nursing care, functions, tasks or responsibility to others when the nurse knows or should know that such de legation is to the detriment of patient safety;
(m) Failing to notify the appropriate party of any unprofessional conduct which may jeopardize patient/client safety.

It is not hard to see how the landscape changes when a nurse's careless or uninformed conduct is shown for what it is, unprofessional violations of standards that mandate reporting by the Board. Given the dangers to babies in utero from a nurse's misuse of Pitocin, failure to recognize overstimulation of the uterus, failure to recognize changes in the fetal heart rate, failure to recognize abnormal progress of labor or failure to communicate, these terms are not

harsh. Instead, they are a realistic acknowledgment of the danger created by the uncaring or unqualified. These statutory proscriptions should not be ignored on behalf of the children we represent.

As stated, in addition to the statutory requirements, most Boards of Nursing specifically define the nursing process in addition to setting forth important policy statements. For example, consider the following from Georgia:

> **Medication Administration Policy Statement**
> The administration of medication is the process whereby a prescribed medication or a medication ordered under a nurse protocol, O.C.G.A. 43-34-26-1, is given to a patient/client by one of several routes to include but not be limited to, oral, inhalation, topical, rectal, or parenteral. The registered nurse verifies the medication order and the properly prescribed medication, gives the medication in accordance with current standards of practice and accepted principles and procedures as taught in nursing education. These include verification that the right medication is being given to the right patient/client in the right dose, by the right route at the right time as well as the assessment of the patient/client following administration of the medication for expected effects and possible untoward side effects. Administration of medication is a complex nursing responsibility which requires knowledge of anatomy, physiology, pathophysiology, and pharmacology. Registered nurses may administer medications prescribed by authorized health care providers which may include protocols as defined in O.C.G.A. 43-34-26.1.

One can easily see how these rules, regulations and policy statements can provide the basis for examination of hospital personnel in a misuse of Pitocin case, including examination about the pathophysical effects of over-stimulation on the fetal brain.

VI. INTEGRATING THESE RULES INTO DISCOVERY

Malpractice is typically not an isolated medical event. It is instead a culmination of errors –often directly from the failure to follow the regulations and standard discussed above--that occur at various levels throughout the hospital. It is necessary to understand the organizational structure and hierarchy at the hospital in order to determine who the appropriate defendants are and what standards apply. For example, at a large hospital, a typical arrangement is that the emergency department is staffed through a contract with an emergency room group of physicians, physician assistants who are employed by the physician group (or the hospital) and nurses and other ancillary personnel employed by the hospital. At a small rural hospital, the emergency department is typically staffed by physicians under contract with the hospital and nurses employed by the hospital.

Whether the hospital is a 40 bed rural hospital or part of a large chain, early discovery efforts should be undertaken to determine the organizational structure of the institution. For example, in a typical obstetrical case, this will include the obstetrical nurse, who may be an employee of the hospital, a pool nurse or agency nurse. It will include the charge nurse, the Nurse Manager of Labor and Delivery, the Nursing Director of Women's Services, the Director of Nursing, the Administrator and the board. It will include the Nursing Education Department. If the hospital is part of a chain, it may include national policies and procedures or reporting obligations to distant corporate entities. It is important to get a handle on the organizational structure early on. You can then begin to look for the various areas of breakdown, without which your client would not have been injured.

To determine the organization structure and also the various duties amongst the health care

providers, several references must be considered early on. Early discovery should include requests for institutional documents, including:

1. Organizational Chart;
2. Management Services Agreement;
3. Monthly Reporting to Board;
4. Annual Reports to Board;
5. Job Descriptions of everyone involved;
6. Medical staff bylaws;
7. Rules and regulations of medical staff;
8. Contract between physician group and hospital;
9. Contract between physician and hospital;
10. Contract between emergency department physician and emergency department group;
11. Physician personnel file;
12. Physician Assistant personnel file;
13. Nurse personnel file;
14. Nurse Education file;
15. Supervision agreements between physician and physician assistant;
16. Labor and Delivery policies and procedures;
17. Hospital policies and procedures;
18. Minutes from monthly Labor &delivery nursing staff meetings;
19. Owners' manuals and user's guide for fetal monitor and the electronic records;
20. Audit trails and metadata for all electronic records and also the card key access to the Labor & Delivery or NICU (even the parking garage in some cases); and
21. Relevant telephone and cell phone records.

Once you get this documentation, you can begin to evaluate where and at what levels, the regulations and standards discussed above were integrated into specific hospital policies. If they have not been integrated and are not being followed, the organizational chart should provide a nice outline for finding where the failures have occurred.

VII. CONCLUSION

As mentioned at the beginning, hospitals are dangerous places. The common law in virtually all states mandates that they act reasonably. But beyond that, there are numerous standards for hospital and nursing care that derive from the federal and state government, from accrediting organizations and from professional associations. The purpose for these standards at all levels of a hospital's operations is to promote safe care. Otherwise stated, they keep mothers and babies out of harm's way. When mothers and babies are injured because of disregard for (and of) these standards, the hospitals should be held institutionally accountable.