



Solutions in Sight

Safety Initiatives Have Dramatically Reduced Harms
During Childbirth But Are Unevenly Implemented

Acknowledgments

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Executive Summary

The United States has a poor childbirth safety record, likely due in part to the failure of obstetrics practitioners to develop and adhere to standardized practices. In the past 15 years, methods to improve perinatal safety have been developed and adopted at certain organizations. These initiatives have been remarkably successful at reducing infant deaths and other adverse outcomes, according to the providers' reports. But this cause for celebration is tempered by experts' agreement that generally accepted best practices have not been comprehensively implemented across the country. This would appear to yield a conclusion that otherwise avoidable tragic events are likely continuing to occur where practices with demonstrated track records of reducing harms have not been put into place.

Childbirth Safety Outcomes in the United States Are Dismal Compared to Other Wealthy Nations

About 4 million babies are born in the United States every year and nearly 25,000 die during their first year of life. The CIA World Factbook ranked the U.S. infant mortality rate 56th among countries and territories in 2014, at 6.2 deaths per 1,000 births. That was nearly twice the rates of France, Italy and Spain (which each were at 3.3 per 1,000) and nearly three times the rate of Japan (2.1 per 1,000). Reducing the U.S. infant mortality rate to the levels of France, Italy and Spain would save more than 10,000 lives a year.

Meanwhile, the United States is one of the few countries in the world with a rising maternal mortality rate. In the past quarter century, the U.S. ranking in that indicator has fallen from 22nd in the world to 60th.

Several Findings Call the Quality of U.S. Obstetric Care Into Question

Although quality of care is not the only explanation for the dismal statistics on the safety of childbirth in the United States, evidence suggests that it is likely at least partially to blame.

For instance, outcomes vary greatly by provider. Even after accounting for demographic differences and other factors out of providers' control, deliveries at low-performing hospitals are two to five times more likely to involve unexpected medical complications as those at high-performing hospitals, a study published in *Health Affairs* in 2014 concluded.

"Our finding of a large gap in quality in obstetrical care between high- and low-performing hospitals has important policy implications for maternal health," the authors of the study wrote. "If this performance gap could be narrowed, it could lead to substantial improvements in obstetrical outcomes for large numbers of women."

Many experts have faulted the obstetrics profession for having inconsistent practice patterns. This has been illustrated in widely varying frequency in the use of cesarean section deliveries. A national study of a year's births published in *Health Affairs* in 2013 found that the cesarean rate varied by provider from 7.1 percent to 69.9 percent for all deliveries and from 2.4 percent to 36.5 percent for low-risk pregnancies. The fifteenfold

variation for low-risk pregnancies “indicated a wide range in obstetric care practice patterns across hospitals and signaled potential quality concerns,” the researchers wrote.

Concerns over obstetrics practitioners’ varying practice patterns are consistent with criticisms of the medical profession as a whole. In 1999, the prestigious Institute of Medicine shocked the nation by reporting that between 44,000 and 98,000 U.S. patients were dying every year because of avoidable medical errors. Among the IOM’s conclusions was that most medical errors were caused by “faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them.”

A Corpus of Practices Has Been Developed Over the Past 15 Years to Improve Childbirth Safety

In sync with the medical profession’s effort to heed the IOM’s call for improved systems and in response to concerns over medical malpractice litigation, obstetricians and other health care quality specialists have over the past 15 years developed several related practices aimed at reducing adverse outcomes in childbirth.

These practices, each of which has sought to foster standardization, fit into three broad categories:

1. Conducting training in communications and empowering all employees to speak up if they perceive an unsafe situation. Such training programs often incorporate simulations of emergency medical events. A study by the Joint Commission, which accredits hospitals to be eligible to receive Medicare payments, found that problems in communications figured in 65 percent of catastrophic events involving childbirth.
2. Implementing “bundles,” which are groups of essential practices that must be used in scenarios posing special risks, such as when inducing labor.
3. Reducing unnecessary cesarean section deliveries. Although recognized as medically necessary in certain instances, experts generally agree that the rate of cesarean deliveries in the United States is too high. Cesarean use has risen from 21 percent of deliveries in the mid-1990s to nearly 33 percent in recent years. A consensus exists that cesarean procedures pose health risks to mothers and babies, and should only be undertaken for medical reasons. Numerous studies have concluded that cesareans are sometimes initiated for nonmedical reasons, such as convenience for either the doctor or patient, or compensation for providers.

Related to items 2 and 3 above, a concerted campaign in recent years has sought to eliminate elective deliveries by inductions or cesareans prior to 39 weeks of gestation. The American Congress of Obstetricians and Gynecologists (ACOG), the primary professional association of obstetricians, has since 1979 recommended against initiating delivery before 39 weeks unless medically necessary. But many practitioners ignored this advice, and the rate of deliveries at 37 and 38 weeks (elective and otherwise) rose from 20 percent in 1990

to nearly 29 percent in 2006, before tapering off to just under 25 percent in recent years. Numerous studies have found that the risk of complications for babies born from normal pregnancies at 37 weeks is significantly greater than for those born at 39 weeks.

Spurred by lobbying efforts by the March of Dimes Foundation and accumulation of research evidence, nongovernmental organizations and Medicare have in the past half-decade begun requiring providers to report on their rates of early-elective deliveries. Meanwhile, several insurance companies and state governments have recently instituted policies of reducing or eliminating payments for these deliveries. This effort has achieved significant, but not complete, success. The Leapfrog Group reported that the rate of early-elective deliveries fell from 17 percent of all births in 2010 to less than 5 percent in 2013. Medicare reported a 64 percent drop from 2010 to 2013. But rates among states still vary from 2 percent to 22 percent, the National Quality Forum reported in 2014.

Results of Safety Initiatives at Select Institutions Show Remarkable Success

This report recounts initiatives to improve safety in childbirth at four health care organizations. These organizations' inclusion in this report does not mean that they are the only ones to institute obstetric safety programs. The initiatives enumerated here resulted in remarkable reductions in untoward outcomes for patients, according to the organizations' reports. For example:

Hospital Corporation of America, the largest obstetrical health delivery system in the United States, reported:

- Maternal fatalities from pulmonary embolism were reduced by 86 percent;
- Maternal deaths from hypertension were reduced by 77 percent;
- Overall maternal deaths, excluding patients who entered the hospital with terminal conditions, declined by 19 percent; and
- Obstetrics litigation claims were reduced by two-thirds.

New York Presbyterian Hospital-Weill Cornell Medical Center, which delivers about 5,000 babies a year, reported:

- Incidence of hypoxic-ischemic encephalopathy, a brain injury caused by oxygen deprivation, was 98 percent lower than the national average;
- Sentinel events, which refer to unexpected occurrences involving death or serious physical or psychological injury, were cut to zero during the final two years reported upon; and
- Obstetrics litigation costs were reduced by 99 percent.

Ascension Health, the third-largest health care network in the United States, reported:

- Reducing incidence of birth trauma at its safety program's pilot sites by 85 percent over the first three years and to zero in the fourth year. (Birth trauma refers to harm to a newborn that requires medical intervention.);

- Achieving a systemwide 33 percent reduction in its birth trauma rate in the first two years after broadening its initiative to each of its 43 hospitals; and
- Reducing neonatal fatalities (referring to death in the first 28 days of life) by nearly 50 percent in first two years of systemwide implementation of its safety program.

Premier Inc., a health care alliance, reported that a safety initiative encompassing 16 of its member institutions was successful in:

- Reducing birth trauma among full-term newborns by 74 percent;
- Reducing birth hypoxia and asphyxia, which are associated with causing brain damage, by 31 percent; and
- Achieving a 38 percent reduction in preventable neonatal intensive care unit admissions of full-term babies.

The Ascension and Premier initiatives were bolstered in 2010 when both were awarded \$3 million grants from the federal government's Agency for Healthcare Research and Quality (AHRQ) to continue and expand their safety programs. Results from those grant-funded research projects have not yet been released, except in anecdotes. However, numerous papers incorporating data from the projects are forthcoming, individuals familiar with the grants have told Public Citizen.

Meanwhile, AHRQ has issued a \$5.4 million grant to Research Triangle Institute (RTI) to use findings from the AHRQ grant-funded projects and other sources to create a perinatal safety program, then implement it in 50 hospitals.

Adoption of Standardized Practices Is Not Comprehensive

Measuring the degree of adoption of safety practices is challenging for various reasons, but experts agree that implementation of recommended safety practices is not comprehensive. The highly varying use of cesareans and the rise in the past two decades of early-elective deliveries support a conclusion that the obstetrics profession's adherence to standards has been inconsistent. In response to an inquiry from Public Citizen, ACOG described adoption of "updated and new best practices" as "variable."

Conclusion

The extraordinary progress of some institutions in reducing adverse outcomes in childbirth is cause for celebration. However, indications that methods with demonstrated records of success have not been comprehensively implemented suggest that otherwise avoidable tragic events are likely continuing to occur at non-adopting hospitals.

Some experts credit the obstetrics profession in recent years with improving its adherence to standardized practices, such as in reducing early-elective deliveries. They attribute much of this progress to reporting requirements and changes to payment policies. The success of these methods should serve as a model for stakeholders to compel adherence to other proven safety practices.

Introduction

Childbirth is the most common reason that patients are admitted to a hospital, accounting for about one-in-four admissions.¹ The job of facilitating childbirth is indisputably among the most hallowed and high-stakes tasks performed by medical professionals. Along with millions of trouble-free deliveries every year in the United States, the birthing process also results in hundreds of thousands of cases involving medical complications, sometimes resulting in death to mothers or infants or rendering infants in need of lifelong care.²

The safety record in the United States relating to childbirth is not impressive. The U.S. infant mortality rate (referring to deaths of infants prior to reaching one year of age) ranked last among the 17 peer wealthy nations studied by the Institute of Medicine in 2013.³ The CIA World Factbook ranked the U.S. infant mortality rate 56th among countries and territories in 2014, at 6.2 deaths per 1,000 births. That was nearly twice the rate of France, Italy and Spain (which each were at 3.3 per 1,000) and nearly three times the rate of Japan (2.1 per 1,000).⁴

About 4 million babies are born in the United States every year and nearly 25,000 die during their first year of life.⁵ Reducing the U.S. infant mortality rate to the levels of France, Italy and Spain would save more than 10,000 lives a year.⁶

Meanwhile, the U.S. maternal mortality rate, referring to mothers dying due to pregnancy-related causes while pregnant or within one year of giving birth, is also dismal compared to peer countries, and appears to be on the rise. The U.S. maternal mortality rate was nearly 2.5 times higher in 2011 than in 1987, according to data provided by the Centers for Disease Control and Prevention (CDC).⁷

¹ See, e.g., Laurent G. Glance, Andrew W. Dick, J. Christopher Glantz, Richard N. Wissler, Feng Qian, Bridget M. Marroquin, Dana B. Mukamel and Arthur L. Kellermann, *Rates of Major Obstetrical Complications Vary Almost Fivefold Among U.S. Hospitals*, HEALTH AFFAIRS (August 2014), at 1330.

² *Id.*

³ STEVEN H. WOOLF AND LAUDAN ARON, U.S. HEALTH IN INTERNATIONAL PERSPECTIVE: SHORTER LIVES, POORER HEALTH, NATIONAL RESEARCH COUNCIL AND INSTITUTE OF MEDICINE (2013), at 65 (Figure 2-1).

⁴ The CIA World Factbook, *Infant Mortality Rate* (2014 data) CENTRAL INTELLIGENCE AGENCY (viewed on Feb. 23, 2015), <http://1.usa.gov/1za0lMW>.

⁵ *Births: Final Data for 2013*, CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL VITAL STATISTICS REPORTS (Jan. 15, 2015), <http://1.usa.gov/17NYubT>. (A total of 3,932,181 births were registered in the United States in 2013, down less than 1% from 2012); and *Infant Mortality*, CENTERS FOR DISEASE CONTROL AND PREVENTION (viewed on Feb. 23, 2015), <http://1.usa.gov/1Det8Xc>.

⁶ Based on a calculation of 4 million annual U.S. births and infant mortality rates of 6.2 per 1,000 births in the United States and 3.3 per 1,000 in France, Italy and Spain. A difference of 2.9 deaths per 1,000 births would translate to 11,600 deaths per 4 million births.

⁷ *Pregnancy Mortality Surveillance System*, CENTERS FOR DISEASE CONTROL AND PREVENTION (page last updated Dec. 23, 2014), <http://1.usa.gov/1CgMFG5>.

That disparity may be exaggerated due to improved identification of pregnancy-related causes of death, the CDC cautions, but other data support the conclusion that maternal mortality is growing worse in the United States. A study published in *The Lancet* in 2014 reported that the maternal mortality rate in the United States increased 49 percent between 1990 and 2013. The United States was one of only eight countries out of 188 measured in the study to experience an increase in maternal mortality over the preceding decade. The U.S. ranking fell from 22nd in the world in 1990 to 60th in 2013, among the worst among developed countries.⁸

Not all of these grim results are due to subpar care in the delivery room. Poor health status of U.S. mothers and substandard access to medical care prior to giving birth also are likely hindering outcomes. But evidence suggests that more consistent care could prevent many harms that occur during childbirth in the United States.

For example, the quality of outcomes varies markedly among U.S. hospitals. Even after accounting for demographic differences and other factors out of providers' control, deliveries at low-performing hospitals are two to five times more likely to involve unexpected medical complications as those at high-performing hospitals, authors Laurent G. Glance *et al.* reported in a study published in *Health Affairs* in August 2014.⁹

"Our finding of a large gap in quality in obstetrical care between high- and low-performing hospitals has important policy implications for maternal health," Glance *et al.* wrote. "If this performance gap could be narrowed, it could lead to substantial improvements in obstetrical outcomes for large numbers of women."¹⁰

The disparity in outcomes likely owes at least in part to wide variations in practice patterns. For instance, in 2009, the frequency of cesarean section deliveries in U.S. hospitals for low-risk pregnancies varied fifteenfold from provider to provider, according to a study by Kozhimannil, *et al.* that was published in *Health Affairs* in 2013.¹¹ Cesarean deliveries are

⁸ Nicholas J. Kassebaum, *et al.*, GLOBAL, REGIONAL, AND NATIONAL LEVELS AND CAUSES OF MATERNAL MORTALITY DURING 1990–2013: A SYSTEMATIC ANALYSIS FOR THE GLOBAL BURDEN OF DISEASE STUDY 2013, 384 *THE LANCET* 980-1004 (Table 1) (Sept. 13, 2014), <http://bit.ly/1KISTT6>. See also, Carol Morello, *Maternal Deaths in Childbirth Rise in the U.S.*, *THE WASHINGTON POST* (May 2, 2014), <http://wapo.st/1vEFyrB> and Anna Almendrala, *The U.S. Is the Only Developed Nation With a Rising Maternal Mortality Rate*, *THE HUFFINGTON POST* (May 19, 2014), <http://huff.to/1ITsDIb>.

⁹ Laurent G. Glance, Andrew W. Dick, J. Christopher Glantz, Richard N. Wissler, Feng Qian, Bridget M. Marroquin, Dana B. Mukamel and Arthur L. Kellermann, *Rates of Major Obstetrical Complications Vary Almost Fivefold Among U.S. Hospitals*, *HEALTH AFFAIRS* (August 2014), at 1330-1331. (Authors "controlled for differences in patient case-mix by adjusting for patients' demographic characteristics (age and race or ethnicity), payer status, elective status, transfer from another hospital, prior cesarean delivery, weekend admission, and comorbid conditions.")

¹⁰ *Id.*, at 1334.

¹¹ Katy Backes Kozhimannil, Michael R. Law, and Beth A. Virnig, *Cesarean Delivery Rates Vary Tenfold Among US Hospitals; Reducing Variation May Address Quality and Cost Issues*, *HEALTH AFFAIRS* (March 2013), at 527.

associated with multiple health risks and should not be performed unless medically necessary.¹²

“The variation in hospital cesarean delivery rates ... indicated a wide range in obstetric care practice patterns across hospitals and signaled potential quality concerns,” Kozhimannil, *et al.* wrote.¹³

Inconsistencies in obstetricians’ practice patterns have historically extended well beyond decisions concerning cesareans, and may even be due to a deficiency in guidance on appropriate practices, critics have charged. “We find it regrettable that when an obstetrician encounters a clinical situation likely to result in a suboptimal outcome ... and sincerely desires to ‘do it by the book,’ there is often no such ‘book’ to which to turn,” Steven L. Clark, *et al.* wrote in 2008.¹⁴

The absence of such a book might have been intentional, historically. The obstetrics profession has traditionally favored “purposefully ambiguous guidelines to assist in legal defenses of medical malpractice cases in which judgment played a key role,” Clark told Public Citizen.¹⁵

But Clark, who was medical director of women’s and children’s services at Hospital Corporation of America (HCA) from 2004 to 2014 and oversaw several quality-improvement initiatives there, criticizes ambiguous guidelines as anathema to achieving high-quality results. “One of the most fundamental principles in quality assessment and control is that unwarranted variation in a product or process generally equates to poor quality. Conversely, as quality improves, variation will diminish,” Clark *et al.* wrote in 2007.¹⁶

Criticisms of the medical profession’s failure to develop standardized systems are longstanding and not limited to obstetrics. In 1999, the prestigious Institute of Medicine shocked the nation by reporting that between 44,000 and 98,000 U.S. patients were dying

¹² See, e.g., ELLIOTT MAIN, CHRISTINE MORTON, DAVID HOPKINS GIOVANNA GIULIANI, KATHRYN MELSOP AND JEFFREY GOULD, CESAREAN DELIVERIES, CALIFORNIA MATERNITY QUALITY CARE COLLABORATIVE (CMQCC), OUTCOMES, AND OPPORTUNITIES FOR CHANGE IN CALIFORNIA: TOWARD A PUBLIC AGENDA FOR MATERNITY CARE SAFETY AND QUALITY (December 2011), <http://bit.ly/1qgQLVx>. [Hereinafter, *Main December 2011*]

¹³ *Id.*, at 533.

¹⁴ Steven L. Clark, Michael A. Belfort, Spencer L. Byrum, Janet A. Meyers, Jonathan B. Perlin, *Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety*, 199 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 105.e1, 105.e4 (August 2008).

¹⁵ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Steven L. Clark, M.D., professor Baylor College of Medicine/Texas Children’s Hospital (Feb. 19, 2015).

¹⁶ Steven L. Clark, Michael A. Belfort, Gary D. V. Hankins, Janet A. Meyers, Frank M. Houser, *Variation in the Rates of Operative Delivery in the United States*, 196 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 526.e1 (June 2007).

every year because of avoidable medical errors.¹⁷ Among the IOM's conclusions was that most medical errors were caused by "faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them."¹⁸

Since then, systems have been developed within many facets of medicine to reduce adverse events. But many believe the pace of implementation of such processes has been underwhelming.

"We need to stop relying on the heroism of our clinicians to ensure safety and start relying on well-designed systems, just as every other high-risk industry has done," Johns Hopkins physician and researcher Peter J. Pronovost testified to the U.S. Senate Committee on Health, Education, Labor and Pensions in July 2014, a decade and a half after the release of the IOM report.¹⁹

Pronovost in 2008 was awarded a MacArthur Fellowship, informally known as a "genius grant," for developing a checklist protocol that was credited with virtually eliminating often deadly infections resulting from the use of central line catheters.²⁰

Obstetrics practitioners and other quality specialists have over the past 15 years developed a number of approaches aimed at reducing adverse outcomes in childbirth. These efforts have occurred in sync with the medical profession's effort to heed the IOM's call for improved systems and in response to obstetricians' concerns about medical malpractice litigation. Litigation costs stemming from birth-related injuries have traditionally been among the most expensive in health care, in part because they can necessitate lifelong care.²¹

Quality improvement initiatives in obstetrics in some ways parallel efforts previously undertaken by the anesthesiology profession, which was under fire several decades ago over the high mortality rates of its patients. In the late 1970s, that profession instituted systemic reforms patterned after safeguards previously adopted by the aviation industry,

¹⁷ TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM, INSTITUTE OF MEDICINE, at 1 (1999), <http://bit.ly/18BsquJ>.

¹⁸ *To Err Is Human: Building a Safer Health Care System* (summary of report), INSTITUTE OF MEDICINE (November 1999), <http://bit.ly/1DGBVBm>.

¹⁹ Peter Pronovost testimony to U.S. Senate Committee on Health, Education Labor and Pensions, Patient Safety Hearing (July, 17, 2014), <http://1.usa.gov/1EJec3e>.

²⁰ *Peter J. Pronovost, MD, PhD, FCCM* (bio), JOHNS HOPKINS MEDICINE (viewed on Feb. 23, 2015), <http://bit.ly/1A1tVWU>.

²¹ See, e.g., Linda Wilson, *An Evidence-Based Approach Is Born; Hospitals, Physicians Use Protocols to Cut Costs From Avoidable OB/GYN Injuries*, MODERN HEALTHCARE (Dec. 20, 2010), <http://bit.ly/1LJKz5Q>.

and the number of fatalities of patients undergoing routine anesthesiology fell by twentyfold or more.²²

This report puts today's obstetrics safety reforms into three broad categories:

1. Implementing communications programs to minimize misunderstandings and to require all employees in the delivery room to speak up if they see something that appears unsafe or improper. These programs also often incorporate simulations of emergency medical events. A study by the Joint Commission, which accredits hospitals, found that problems in communications figured in 65 percent of catastrophic events during childbirth.²³
2. Adopting "bundles" aimed at ensuring adherence to accepted protocols in traditional problem areas, such as in the use of oxytocin, a synthetic hormone used to induce labor that has historically been involved in more than 50 percent of cases involving birth trauma.²⁴
3. Reducing unnecessary cesarean section deliveries.

Related to items 2 and 3 above, a concerted campaign in recent years has sought to eliminate elective deliveries by inductions or cesareans prior to 39 weeks of gestation. Numerous studies have found that the likelihood of complications for babies born from normal pregnancies at 37 weeks is significantly higher than for those born at 39 weeks.

This report enumerates improvements in outcomes stemming from implementation of safety initiatives by four organizations: Hospital Corporation of America; New York Presbyterian Hospital-Weill Cornell Medical Center; Ascension Health; and the Premier Inc. health care alliance. Inclusion of these organizations in this report should not be taken to suggest that they are the only ones instituting obstetric safety programs.

These organizations' initiatives have overlapped in many respects and have encompassed some or all of the reform themes enumerated above. The results they reported, while varying and often lacking in detail, are enviable. If extrapolated across the entire country, they would yield staggering reductions in fatalities and other tragedies.

²² See, e.g., Robert K. Stoelting, *Foundation History*, ANESTHESIA PATIENT SAFETY FOUNDATION (undated; viewed on Feb. 25, 2015), <http://bit.ly/1JOiywp> and Joseph T. Hallinan, *Once Seen as Risky, One Group of Doctors Changes Its Ways; Anesthesiologists Now Offer Model of How to Improve Safety, Lower Premiums*, THE WALL STREET JOURNAL (June 21, 2005), <http://on.wsj.com/1ApXlc8>. (Steven L. Clark, cited throughout this report, told Public Citizen "anesthesia showed us the way." Taylor Lincoln, research director of Public Citizen's Congress Watch division, interview with Steven L. Clark, M.D., professor Baylor College of Medicine/Texas Children's Hospital (Feb. 19, 2015).)

²³ *Sentinel Event Data Root Causes by Event Type 2004 -2Q 2014*, THE JOINT COMMISSION (Sept. 30, 2014), <http://bit.ly/1vTeWTl>.

²⁴ PH CHEROUNY, FA FEDERICO, C HARADEN, S LEAVITT GULLO, R RESAR, INSTITUTE FOR HEALTHCARE IMPROVEMENT, *IDEALIZED DESIGN OF PERINATAL CARE* (2005), at 9, <http://bit.ly/1qLPITy>.

Though there is little centralized policy-setting authority in the U.S. health care system, the federal government has played a role in these obstetrics-safety initiatives. In response to those favoring legislation to change medical malpractice laws, President Obama announced in a 2009 speech before a joint session of Congress that he would direct the secretary of the Department of Health and Human Services (HHS) to fund a number of projects to test ideas “to put patient safety first and let doctors focus on practicing medicine.”²⁵

Subsequently, the Agency for Healthcare Research and Quality, an agency within HHS, funded seven demonstration projects at a total cost of \$19.7 million. Included among these were three-year grants of \$3 million each to Ascension Health and Premier Inc. to continue and expand obstetric-safety initiatives that they had already begun.²⁶

These grant-funded projects have been completed, but only anecdotal results have yet been released. Several papers stemming from them have been submitted for publication.²⁷ Those who have been involved with the projects have suggested that they have yielded exemplary results.²⁸

For instance, the AHRQ’s James Battles, who oversaw administration of the grants, described the projects as being, in his view, “wildly successful.” Battles said that the project results demonstrated that bundles, communications training, simulations and teamwork practice are the “magic sauce” to managing unexpected perinatal events in a way that minimizes the likelihood of bad outcomes.²⁹

While research funded by the grants was being performed, AHRQ in 2011 issued a \$5.4 million contract to Research Triangle Institute (RTI) of Research Triangle Park, N.C. This contract, the existence of which has not previously been reported, directed RTI to apply findings from research literature and emerging data from the grant-funded projects to

²⁵ President Barack Obama, remarks on health care before a joint session of Congress (Sept. 9, 2009), <http://1.usa.gov/170DwcQ>.

²⁶ *Medical Liability Reform and Patient Safety Demonstration Grants*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (last updated October 2014), <http://1.usa.gov/1FPUq9M>. (Note: AHRQ listed Fairview Health Services in Minneapolis, Minn., as the point of contact on this grant. However, several people familiar with the grant indicated that the organization in charge of administering it was Premier Inc. See, e.g., Press release, Premier Inc., *AHRQ Grant Will Enable Premier Healthcare Alliance Perinatal Safety Initiative to Continue via Award to Fairview Health Services National Collaborative Reducing Preventable Birth Injuries Stresses Adherence to Evidence-Based Best Practices, Communications, Simulation and Teamwork Among OB Suite; Participants Also Reducing Supply Chain Costs* (August 19, 2010), <http://bit.ly/1vOJXbi>.)

²⁷ E.g., Ann Hendrich, chief quality/safety nursing officer, Ascension Health, e-mail to Taylor Lincoln, research director for the Congress Watch division of Public Citizen (Feb. 23, 2015) and Alison Hunt, communications officer, Agency for Healthcare Research and Quality e-mail to Taylor Lincoln, research director of the Congress Watch division of Public Citizen (Feb. 24, 2015).

²⁸ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with James Battles, social science analyst at AHRQ (Feb. 12, 2015).

²⁹ *Id.*

develop a perinatal safety program and implement it in 50 hospitals. The contract is slated to run through October 2016.³⁰

Measuring the level of national adoption of the safety initiatives discussed in this report is difficult both because there are few reporting requirements and adoption of many practices could not be measured in a binary way even if reporting were required.

But Public Citizen interviewed several experts, and none suggested that the types of safety practices described in this report have been comprehensively implemented.

“Adoption of updated and new best practices is variable across the country,” the American Congress of Obstetricians and Gynecologists (ACOG), the professional association of obstetricians, wrote in response to questions from Public Citizen.

ACOG attributed uneven adoption in part to lesser capacities at rural providers and it advocated improved referral networks to match patients’ needs with resources. The association also called for “creating tools that will help us get from guidelines to implementation.”³¹ [Public Citizen’s questions and ACOG’s responses are printed in full in the Appendix.]

Availability of resources may explain some variability. But the majority of safety strategies described in this report – such as conducting teamwork training – are not particularly resource intensive. Some elements merely seek to compel adherence to longstanding ACOG recommendations. For instance, since 1979, ACOG has counseled against initiating elective deliveries before 39 weeks. Yet this practice increased markedly in recent decades.³²

“Any hospital could do it – it’s not about money, it’s about changing the culture to make it safer to deliver babies,” said Amos Grunebaum, an obstetrician and the lead author of a 2011 article describing a remarkably successful initiative at New York Presbyterian Weill-Cornell Hospital.³³

The juxtaposition of discrete successes at reducing untoward outcomes coupled with incomplete adoption of safety practices evokes both optimism and disappointment.

³⁰ Alison Hunt, communications officer, Agency for Healthcare Research and Quality, e-mail to Taylor Lincoln, research director of the Congress Watch division of Public Citizen (Feb. 24, 2015).

³¹ Kate Connors, director, media relations and communications of the American Congress of Obstetricians and Gynecologists, e-mail to Taylor Lincoln, research director of Public Citizen’s Congress Watch Division (Feb. 11, 2015).

³² See, e.g., Tina Rosenberg, *Reducing Early Elective Deliveries*, THE NEW YORK TIMES (March 12, 2014), <http://nyti.ms/1w4akF7>.

³³ Gale Scott, *Obstetricians Take Big Steps to Avoid Malpractice Medical; Journal’s Report Shows How Breakthrough Obstetrics Reforms Tied to NY Presbyterian/Weill Cornell Hospital Dramatically Reduced Staff Errors and Sliced Medical Malpractice Payouts by More Than 99%*, CRAIN’S NEW YORK BUSINESS (March 4, 2011, updated March 7, 2011), <http://bit.ly/1Flvd3y>.

News that institutions have managed to greatly reduce the likelihood of tragedies in childbirth that have long vexed the health care profession is unambiguously cause for celebration. However, indications that other providers have failed to adopt methods with a demonstrated record at averting adverse outcomes would seem to yield a conclusion that some – perhaps many – otherwise avoidable tragic events are continuing to occur.

Regardless of one's interpretation of past developments, the track record of the initiatives described in this report should serve as an urgent call for all stakeholders to redouble efforts to hasten their adoption.

I. Recommended Practices Concerning Communications and Simulations Programs

In 2014, the Joint Commission, which accredits hospitals to be eligible to receive Medicare funding, implicated communications issues in 65 percent of “sentinel events” concerning perinatal care.³⁴ A sentinel event is an “unexpected occurrence involving death or serious physical or psychological injury.”³⁵

That finding followed up on a 2004 study by the Joint Commission that focused in a more in-depth manner on the causes of perinatal sentinel events. In that inquiry, respondents from 55 percent of organizations studied singled out “organization culture as a barrier to effective communication and teamwork.” The Joint Commission described organizational culture issues as “hierarchy and intimidation, failure to function as a team, and failure to follow the chain-of-communication.” Of 109 sentinel events in the 2004 Joint Commission study, 93 resulted in an infant’s death and 16 involved major permanent disability.³⁶

In its 2004 report describing those findings, the Joint Commission recommended that providers “conduct team training in perinatal areas to teach staff to work together and communicate more effectively.” Also, “for high-risk events, such as shoulder dystocia, emergency cesarean delivery, maternal hemorrhage and neonatal resuscitation,” the Joint Commission recommended that providers “conduct clinical drills to help staff prepare for when such events actually occur.”³⁷

Initiatives to improve communications in the delivery room have typically sought to create an environment in which all employees are required to speak up when they see something amiss, a departure from traditional medical customs.

Industries with high-reliability records are the antithesis of “a medical model in which the attending physician functions as the unchallenged captain of the ship, and the protection of physician autonomy is promulgated as a desirable goal,” authors Steven L. Clark *et al.* wrote in 2008. “We suggest that both ideas are antiquated and counterproductive. There is no highly reliable organization that develops guidelines for use in critical situations that are even remotely affected by concerns for preservation of pilot or operator autonomy.”³⁸

³⁴ *Sentinel Event Data Root Causes by Event Type 2004 –2Q 2014*, THE JOINT COMMISSION (Sept. 30, 2014), at 21, <http://bit.ly/1vTeWTI> and *Medicare FAQs*, THE MEDICARE NEWSGROUP (Feb. 25, 2015), <http://bit.ly/1LDAcig>.

³⁵ *Sentinel Event*, JOINT COMMISSION (viewed on Feb. 25, 2015), <http://bit.ly/1DUZLw4>.

³⁶ *Sentinel Event Alert, Preventing Infant Death and Injury During Delivery*, THE JOINT COMMISSION (July 21, 2004), <http://bit.ly/Xd8KGf>.

³⁷ *Id.*

³⁸ Steven L. Clark, Michael A. Belfort, Spencer L. Byrum, Janet A. Meyers, Jonathan B. Perlin, *Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety*, 199 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 105.e1, 105.e2. (August 2008).

A broad term for programs to improve communications is crew-resource management (CRM), which refers to an initiative spearheaded by NASA to disseminate research showing that poor communication was a leading cause of air traffic accidents.³⁹

Although no single officially recognized CRM program exists, a commonality of CRM programs is an acceptance that errors are inevitable and that it is necessary to work as a team to reduce them. Team members “must be willing to advocate for safety whenever risk is identified and to listen to risk concerns, irrespective of hierarchy,” Maya Suresh *et al.* wrote in 2013.⁴⁰

A communications program that has been adopted by some in the health care industry is Team Strategies and Tools to Enhance Performance and Patient Safety, or TeamSTEPPS. The system, which emphasizes teamwork and communications, was developed by the U.S. Department of Defense in conjunction with AHRQ.⁴¹

Training in TeamSTEPPS often involves the use of simulations that are filmed to enable participants to review their actions and communications. “What TeamSTEPPS does is allow you to drill down on the categories of communication,” Stanley Davis, a formerly practicing obstetrician who now teaches TeamSTEPPS curricula, told Public Citizen.⁴²

Efforts to change communications practices in the delivery room are hindered by deeply ensconced traditions in the culture of medicine, such as a view that the “doctor is a demigod who should not be questioned,” said Davis, who served as the lead researcher of the \$3 million grant issued in 2010 by AHRQ to 16 hospitals within the Premier Inc. network.⁴³

Changing the view that a lead doctor should not be questioned by nurses and others in the delivery room is an ambitious undertaking, Davis concedes. But some obstacles to improvements are simpler. For instance, agreeing on standardized ways of articulating common occurrences can improve communication without taking on ensconced cultural customs.

“How do you say certain things? What words do you use to describe certain things?” Davis said.⁴⁴

³⁹ MAYA SURESH, ROANNE L. PRESTON, ROSHAN FERNANDO, C. LATOYA MASON, *ANESTHESIA FOR OBSTETRICS* (Lippincott Williams & Wilkins: 2013), at 724, <http://bit.ly/1qABnbu>.

⁴⁰ *Id.*

⁴¹ Kay Daniels, and Laurie Erickson, and Pamela B. Andreatta, and Jose F. Pliego, and Dena Goffman, *Simulation-Based Team Training in Obstetric Emergencies*, *CONTEMPORARY OB/GYN* (May 1, 2012), <http://bit.ly/1oZcFfu>.

⁴² Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Stanley Davis, chief medical officer of Medical Team Consultants LLC (Aug. 19, 2014).

⁴³ *Id.*

⁴⁴ *Id.*

Six people often are involved in an emergency cesarean delivery and the number can be as high as 16, Davis said. Because the makeup of personnel in six-person (or, especially, 16-person) teams can vary greatly, taking steps to prevent misunderstandings is essential.⁴⁵

Filming simulations also can reveal easily correctable flaws in communications.

“Simulation helps because people see themselves at work,” Davis said, citing an example in which a doctor in an operating room said he did not realize how much he mumbled until he saw himself on film.⁴⁶

Communications and simulations training also can reveal problems that a department’s leadership might not otherwise know about. “You get front line staff’s views on what’s good and not good about what’s really going on,” Davis said. “People on the front lines tell you what the problems are.”⁴⁷

Reliable data on the level of adoption of communications protocols is not easily obtainable. Davis estimated that as few as 5 percent of obstetrics departments have implemented such systems.⁴⁸ James Battles, a project manager at AHRQ who oversaw the Premier Inc. grant for which Davis served as lead investigator, said that as many as one-third of hospitals have implemented TeamSTEPPS to at least some degree, although not necessarily within obstetrics departments.⁴⁹

TeamSTEPPS training can take as little as four hours, Davis told Public Citizen. Davis attributed the relative paucity of hospitals that have adopted communications protocols to hospitals’ low profit margins, the cost of training due to paying staff for time that cannot be billed, and a desire among decision makers to invest resources on things that will generate revenue.

Decision makers “would rather buy another robotic device” than pay for communications training, Davis said in a generalized reference to a desire to purchase revenue-generating equipment.⁵⁰

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with James Battles, social science analyst at AHRQ (Feb. 12, 2015).

⁵⁰ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Stanley Davis, chief medical officer of Medical Team Consultants LLC (Aug. 19, 2014).

II. Using Bundles to Avoid Adverse Events

The Institute for Healthcare Improvement (IHI), a Cambridge, Mass., nonprofit, was founded in 1991 to increase the use of proven best practices in medical care. “Sound science exists on the basis of which the costs and outcomes of current health care practices can be greatly improved, but much of this science lies fallow and unused in daily work,” IHI founder and CEO Donald Berwick wrote in 2004. “There is a gap between what we know and what we do.”⁵¹

In 2004, IHI began issuing perinatal “bundles,” which consisted of three to five elements regarding a given process that, if done correctly, would yield optimized outcomes.⁵² Most of these elements are considered essential in the provision of proper care, but may not be regularly fulfilled in practice. Measurement of compliance of each element is a signature aspect of bundles.⁵³

Clinicians often assume that the bundle elements are being reliably performed, “but, when they collect their data, they are often surprised to learn that only 10 to 20 percent of their patients received the type of care they should have,” IHI Director Sue Gullo told Public Citizen.⁵⁴

To encourage complete compliance, if any element is not followed, the team’s score for compliance with the entire bundle is zero.⁵⁵

Among the first bundles created by IHI were two involving the use of oxytocin. Oxytocin is a hormone naturally released during labor that also can be synthetically produced and administered as a drug to induce labor.⁵⁶ Labor induction is a procedure that incorporates the use of oxytocin or other drugs to stimulate uterine contractions during pregnancy before labor begins on its own and, thus, induce labor.

If oxytocin accelerates labor too much, it can cause hyperstimulation of the uterus, resulting in tearing of the uterus and slowing of the supply of blood and oxygen to the fetus.⁵⁷ The

⁵¹ *The Breakthrough Series: IHI’s Collaborative Model for Achieving Breakthrough Improvement*, DIABETES SPECTRUM (Nov. 2, 2004), <http://bit.ly/1BaFUrW>.

⁵² HOW-TO GUIDE: PREVENT OBSTETRICAL ADVERSE EVENTS: INSTITUTE FOR HEALTHCARE IMPROVEMENT (2012), at 21, <http://bit.ly/1uppAOg>.

⁵³ Public Citizen Researcher Taylor Lincoln interview with Sue Leavitt Gullo, director, Institute for Healthcare Improvement (Feb. 24, 2015).

⁵⁴ *Id.*

⁵⁵ Public Citizen Researcher Taylor Lincoln interview with Sue Leavitt Gullo, director, Institute for Healthcare Improvement (Sept. 3, 2014).

⁵⁶ HOW-TO GUIDE: PREVENT OBSTETRICAL ADVERSE EVENTS, INSTITUTE FOR HEALTHCARE IMPROVEMENT (2012), at 7, <http://bit.ly/1uppAOg>.

⁵⁷ Laura Landro, *New Practices Reduce Childbirth Risks Amid Soaring Liability Costs, Hospitals Curb Use of Drugs and Other Procedures to Speed Labor*, THE WALL STREET JOURNAL (July 12, 2006), <http://on.wsj.com/XFbvjm>.

drug has often been used to induce nonmedically indicated deliveries prior to 39 weeks of gestation, which has been shown to increase maternal and neonatal morbidity.

Oxytocin has historically been involved in more than 50 percent of all birth trauma cases.⁵⁸ During the early part of last decade, leaders at Ascension Health and Premier Inc. sought input from IHI on how to reduce risks associated with the use of the drug. Ascension and Premier subsequently incorporated the use of bundles involving oxytocin at their institutions.⁵⁹

The following paragraphs describe some of the bundles that have been developed and the risks that prompted their creation.

Induction Bundle

Accepted best practices discourage delivery of babies before 39 weeks of gestation unless there are medical reasons to do otherwise.

The American Congress of Obstetricians and Gynecologists (ACOG) considers a gestation period of 37 weeks or more to constitute the expected “term” for giving birth, as opposed to “preterm” for gestation ages of fewer than 37 weeks.⁶⁰ But ACOG and other experts have long discouraged initiating deliveries before 39 weeks of gestation, and they categorize deliveries before then as “early.” “A nonmedically indicated early-term delivery is not appropriate,” ACOG flatly stated in 2013.⁶¹

Numerous studies have found that deliveries before 39 weeks carry additional health risks for the mother and child. The brain weighs only 80 percent as much at 37 weeks as it does at 40 weeks.⁶² The likelihood of any adverse outcome in an uncomplicated pregnancy is more than twice as likely (5.9 percent) for deliveries occurring before 39 weeks as those

⁵⁸ PH CHEROUNY, FA FEDERICO, C HARADEN, S LEAVITT GULLO, R RESAR, INSTITUTE FOR HEALTHCARE IMPROVEMENT, *IDEALIZED DESIGN OF PERINATAL CARE* (2005), at 9, <http://bit.ly/1qLPITy>.

⁵⁹ Public Citizen Researcher Taylor Lincoln interview with Sue Leavitt Gullo, director, Institute for Healthcare Improvement (Sept. 3, 2014).

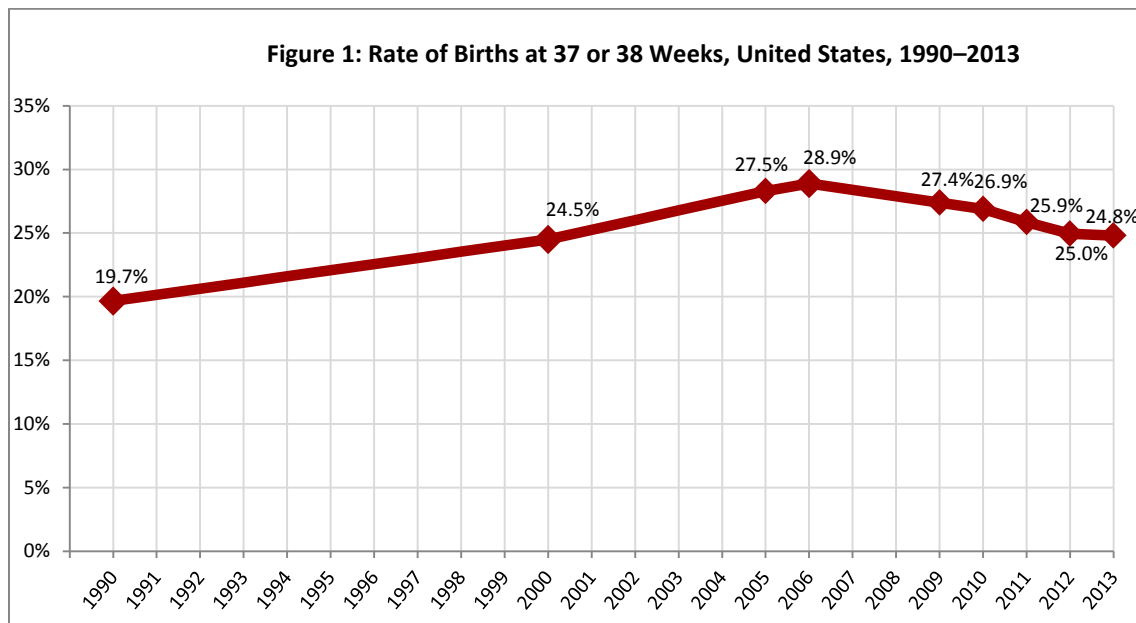
⁶⁰ See, e.g., Steven L. Clark, Donna R. Frye, Janet A. Meyers, Michael A. Belfort, Gary A. Dildy, Shalece Kofford, Jane Englebright, and Jonathan A. Perlin, *Reduction in Elective Delivery 39 Weeks of Gestation: Comparative Effectiveness of 3 Approaches to Change and the Impact on Neonatal Intensive Care Admission and Stillbirth*, 203 AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 449.e1-449.e6 (November 2010) and Bonnie Rochman, *Patience, Mom: More Hospitals Say No to Scheduled Delivery Before 39 Weeks*, TIME (Aug. 26, 2011), <http://ti.me/1Dylio1>.

⁶¹ *Nonmedically Indicated Early-Term Deliveries, Committee Opinion Number 561*, THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS (April 2013), <http://bit.ly/YEIDK7>.

⁶² ELLIOTT MAIN, BRYAN OSHIRO, BRENDA CHAGOLLA, DEBRA BINGHAM, LEONA DANG-KILDUFF AND LESLIE KOWALEWSKIF (authors), MARCH OF DIMES, CALIFORNIA MATERNAL QUALITY CARE COLLABORATIVE, MATERNAL, CHILD AND ADOLESCENT HEALTH DIVISION, AND CENTER FOR FAMILY HEALTH CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (organizations), “ELIMINATION OF NON-MEDICALLY INDICATED (ELECTIVE) DELIVERIES BEFORE 39 WEEKS GESTATIONAL AGE,” at 11 (Aug. 31, 2011), <http://bit.ly/1qtg6l5>. [Hereinafter *Main August 2011*]

occurring at 39 or 40 weeks (2.5 percent).⁶³ The likelihood of respiratory failure or the need to use ventilators are 2.8 times higher for babies born at 37 weeks than 39 weeks.⁶⁴

The infant mortality rate for deliveries at 37 weeks of gestation (4.1 per 1,000 births) is nearly double that at 39 weeks of gestation (2.2 per 1,000 births).⁶⁵ Despite these risks, deliveries between 37 and 38 weeks of gestation increased from 19.7 percent in 1990 to 28.3 percent in 2006, before declining to 24.8 percent in 2013.⁶⁶ [Figure 1]



Source: Centers for Disease Control and Prevention, <http://1.usa.gov/17NYubT>

Critics have blamed the use of elective inductions (those that do not occur in response to a medical diagnosis) as a contributing factor in the overall increase in deliveries before 39 weeks of gestation.⁶⁷ From 1990 until 2011, the rate of inductions increased from 9.6 percent to 23.7 percent of deliveries.⁶⁸ [Figure 2]

⁶³ *Id.*, at 10.

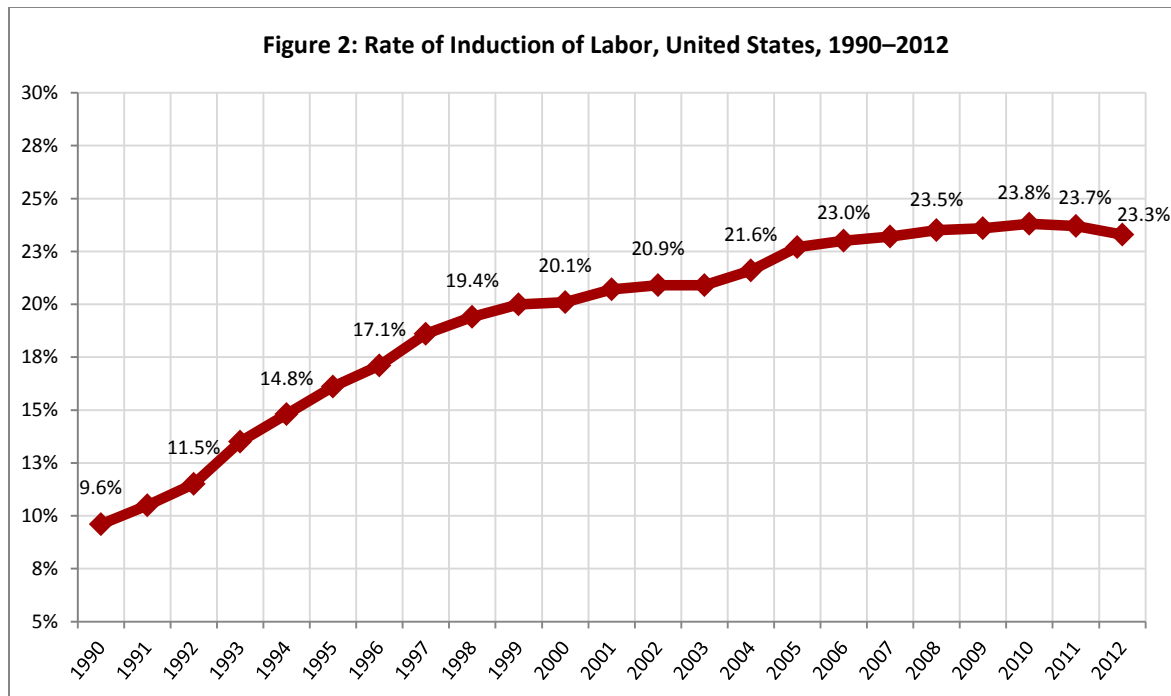
⁶⁴ *Nonmedically Indicated Early-Term Deliveries, Committee Opinion Number 561*, THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS (April 2013), <http://bit.ly/YEIDK7>.

⁶⁵ *Id.*

⁶⁶ *Births: Final Data for 2013 (Table E)*, CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL VITAL STATISTICS REPORTS (Jan. 15, 2015), <http://1.usa.gov/17NYubT>.

⁶⁷ See, e.g., *Main August 2011*, *supra* note 62, at vi.

⁶⁸ Michelle J.K. Osterman, M.H.S. and Joyce A. Martin, *Recent Declines in Induction of Labor by Gestational Age*, CENTERS FOR DISEASE CONTROL AND PREVENTION (June 2014), <http://1.usa.gov/1zSYbV0>.



Source: Centers for Disease Control and Prevention, <http://1.usa.gov/1zSYbV0>

The IHI Induction Bundle calls for four elements to be considered before using oxytocin to induce labor:

1. Assess gestational age and generally confirm an age of at least 39 weeks.
2. Ensure that the individuals assessing electronic fetal heart rate data are properly trained and that clear plans are in place to guide the team in the case of certain outcomes.
3. Conduct a pelvic assessment to confirm that the patient is a proper candidate for induction.
4. Be prepared to recognize and manage tachysystole, a condition of excessively frequent uterine contractions, which occurs significantly more frequently when oxytocin is administered.⁶⁹

The guidelines also call for following a practice standard, issued by ACOG, calling for a qualified obstetrician who can perform an immediate cesarean section to be available whenever oxytocin is administered.⁷⁰

Additional elements have been added to the oxytocin bundle, in part in response to a 2007 decision by the Institute for Safe Medication Practices (ISMP) to add oxytocin to its list of

⁶⁹ *Id.*, at 9; and Cara C. Heuser, Stacey Knight, M. Sean Esplin, Alexandra G. Eller, Calla M. Holmgren, Douglas Richards, Erick Henry, G. Marc Jackson, *Tachysystole in Term Labor: Incidence, Risk Factors, Outcomes, and Effect On Fetal Heart Tracings*, 209 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 32e1. (July 2013).

⁷⁰ HOW-TO GUIDE: PREVENT OBSTETRICAL ADVERSE EVENTS: PREVENT OBSTETRICAL ADVERSE EVENTS BY IMPLEMENTING THE COMPONENTS OF CARE RECOMMENDED IN THIS GUIDE, INSTITUTE FOR HEALTHCARE IMPROVEMENT, (2012), at 8.

high-alert medications.¹³ “High-alert” medications are those that bear a heightened risk of causing significant patient harm when used in error. This status calls for additional steps to be taken to improve access to information to the drug, limiting access to it and standardizing procedures for administering it.⁷¹

The bundle also was changed to reflect updated nomenclature to describe fetal heart patterns and classifications that was adopted as a standard of care by ACOG and the Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN) in 2008.⁷²

Augmentation Bundle

Augmentation of labor is a coordinated effort to enhance uterine contractions for a woman who is already in labor. As with induction, oxytocin is often used for augmentation. In 2004, IHI developed an augmentation bundle that included protocols very similar to those in the induction bundle.

Vacuum Bundle

About 5 percent of deliveries in the United States are operative vaginal deliveries, referring to the use of forceps or a vacuum device to assist the mother giving birth. Of these, the proportion of vacuum-assisted deliveries “has been increasing and now accounts for almost four times the rate of forceps-assisted vaginal births.”⁷³

The incidence of serious complications with the use of the vacuum extractor is about 5 percent, much higher than for non-operative deliveries. The frequency of operative deliveries varies greatly according to geography, ranging from less than 5 percent in the Northeast to up to 25 percent in the South.⁷⁴

One of the elements in IHI’s vacuum bundle is to consider alternative labor strategies. Should a decision be reached to go through with the vacuum-assisted delivery, the bundle calls for team members to develop a contingency plan, including ensuring the availability of a cesarean and resuscitation team and other necessary nursing and operating room staff should the use of the vacuum fail.⁷⁵

⁷¹ *Id.*, at 7.

⁷² *Id.*

⁷³ Unzila A. Ali and Errol R. Norwitz, *Vacuum-Assisted Vaginal Delivery*, 2 REVIEWS IN OBSTETRICS AND GYNECOLOGY 1 (2009), <http://1.usa.gov/1rYr2IL>.

⁷⁴ *Id.*

⁷⁵ HOW-TO GUIDE: PREVENT OBSTETRICAL ADVERSE EVENTS, INSTITUTE FOR HEALTHCARE IMPROVEMENT (2012), at 19, <http://bit.ly/1uppAOg>.

III. Reducing Unnecessary Cesarean Deliveries

A cesarean section is a procedure in which an incision is made through a woman's abdomen and uterus to deliver a baby or babies. It is the most common operating room procedure performed in the United States, accounting for 9 percent of procedures, *Health Affairs* reported in 2013.⁷⁶ Although this procedure is recognized as medically necessary in certain instances, experts have long counseled against its use for nonessential reasons, such as convenience for either the doctor or patient, or compensation for physicians.

The use of cesareans has risen markedly in recent decades, and a general consensus exists that the rate in the United States is too high. Moreover, numerous studies have documented widely varying frequencies of cesarean use, indicating inconsistent practices patterns.

There is no simple guidance for when to use a cesarean, but experts counsel practitioners to rely on the best science and to exercise restraint in using the procedure.

"It is important for health care providers to understand the short-term and long-term tradeoffs between cesarean and vaginal delivery, as well as the safe and appropriate opportunities to prevent overuse of cesarean delivery, particularly primary cesarean delivery," ACOG and the Society for Maternal-Fetal Medicine wrote in a 2014 consensus statement.⁷⁷ "Primary cesarean delivery" refers to the use of a cesarean for the first time on a pregnant woman.⁷⁸

"Evidence now shows that labor actually progresses slower than we thought in the past, so many women might just need a little more time to labor and deliver vaginally instead of moving to a cesarean delivery," Aaron B. Caughey, a member of ACOG's Committee on Obstetric Practice, said in a press release announcing the consensus statement. "Most women who have had a cesarean with their first baby end up having repeat cesarean deliveries for subsequent babies, and this is what we're trying to avoid. By preventing the first cesarean delivery, we should be able to reduce the nation's overall cesarean delivery rate."⁷⁹

⁷⁶ Katy Backes Kozhimannil, Michael R. Law, and Beth A. Virnig, *Cesarean Delivery Rates Vary Tenfold Among US Hospitals; Reducing Variation May Address Quality and Cost Issues*, *HEALTH AFFAIRS* (March 2013), at 527.

⁷⁷ *Obstetric Care Consensus*, THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS AND SOCIETY FOR MATERNAL-FETAL MEDICINE (March 2014), <http://bit.ly/1EN5TDA>.

⁷⁸ See, e.g., Douglas A. Levine, *Why Are Cesareans Performed?* *HEALTHLINE* (March 15, 2012), <http://bit.ly/1Ka1yB6>.

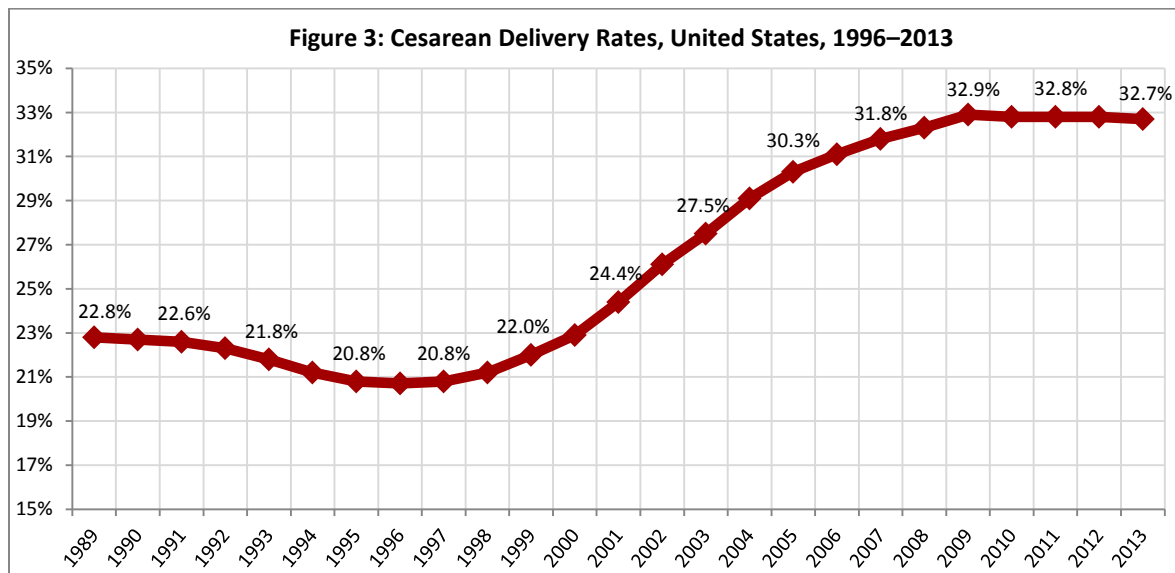
⁷⁹ THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS AND SOCIETY FOR MATERNAL-FETAL MEDICINE, Press release, *Nation's Ob-Gyns Take Aim at Preventing Cesareans New Guideline Recommends Allowing Women to Labor Longer to Help Avoid Cesarean* (Feb. 19, 2014), <http://bit.ly/1EN6qoQ>.

The Frequency of Cesareans Has Risen Markedly

For decades, health care experts have decried the rising use of cesareans.

The World Health Organization (WHO) in 1985 wrote, “There is no justification for any region to have [cesarean rates] higher than 10-15 percent.”⁸⁰ The U.S. Department of Health and Human Services set a goal during the 1990s to reduce the rate to 15 percent for all deliveries and 12 percent for first-time deliveries by 2000.⁸¹

Despite these objectives, the use of cesarean section deliveries has increased markedly since the mid-1990s, from 20.7 percent in 1996 to 32.7 percent in 2013.⁸² [Figure 3]



Source: Centers for Disease Control and Prevention, <http://1.usa.gov/17NYubT>

More recent goals on reducing cesarean section rates have been less ambitious. For example, the federal government’s “2020 goals” call for reducing the rate of cesareans for low-risk deliveries for first time mothers to 23.9 percent.⁸³

Many cesareans have historically been performed before 39 weeks of gestation, which violates accepted practices unless there are medical reasons for proceeding.⁸⁴ A 2009 study

⁸⁰ LUZ GIBBONS, JOSE M. BELIZAN, JEREMY A LAUER, ANA P BETRAN, MARIO MERIALDI AND FERNANDO ALTHABE, WORLD HEALTH ORGANIZATION, BACKGROUND PAPER 30: THE GLOBAL NUMBERS AND COSTS OF ADDITIONALLY NEEDED AND UNNECESSARY CAESAREAN SECTIONS PERFORMED PER YEAR: OVERUSE AS A BARRIER TO UNIVERSAL COVERAGE (2010), at 4, <http://bit.ly/1qgCell>, quoting from *Appropriate Technology for Birth*. LANCET (Aug. 24, 1985), at 436-437.

⁸¹ HEALTHY PEOPLE 2000 FINAL REVIEW, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (2001), at 215, <http://1.usa.gov/1spFh3A>.

⁸² *Births: Final Data for 2013, Table 21. Births, by Method of delivery and Race and Hispanic Origin of Rother: United States 1989–2013*, CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL VITAL STATISTICS REPORTS (Jan. 15, 2015), <http://1.usa.gov/17NYubT>.

⁸³ *Main December 2011*, *supra* note 12, at 12.

published in the *New England Journal of Medicine*, for instance, found that more than a third of more than 24,000 elective cesareans in mothers who had previously had cesareans took place prior to 39 weeks.⁸⁵

The use of cesareans varies markedly by geographic region and among providers within the same regions, which experts attribute to provider preferences trumping scientific evidence.

The California Maternity Quality Care Collaborative (CMQCC), which has investigated issues surrounding cesarean prevalence extensively, reported in 2011 that overall cesarean rates in California varied among providers from 18 percent to well over 50 percent of all births and that the rates for low-risk first births varied from 9 percent to 51 percent.⁸⁶

An earlier (1995) study cited by the CMQCC found that county hospitals had 47 percent fewer primary cesarean deliveries than private for-profit hospitals.⁸⁷

“The fact that cesarean delivery rates and practices vary widely among states, regions, hospitals, and providers for both primary and repeat cesareans demonstrates that hospitals and clinicians can differ in their responses to the same conditions,” authors Elliott Main *et al.* of CMQCC wrote in 2011. “This fact suggests the need for more precise clinical practice guidelines and/or greater accountability and incentives for following them.”⁸⁸

A study published in 2013 in *Health Affairs* examining a year’s births in nearly 600 U.S. hospitals that each delivered at least 100 babies found that cesarean section use ranged from 7.1 percent to 69.9 percent for all births and from 2.4 percent to 36.5 percent for low-risk mothers.

“The scale of the variation in hospital cesarean delivery rates — most notably, a fifteenfold variation among the lower-risk subgroup — indicated a wide range in obstetric care practice patterns across hospitals and signaled potential quality concerns,” the authors wrote.⁸⁹

⁸⁴ *Nonmedically Indicated Early-Term Deliveries, Committee Opinion Number 561*, THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNCOLOGISTS (April 2013), <http://bit.ly/YEIDK7>.

⁸⁵ Laura Landro, *A Push for More Pregnancies to Last 39 Weeks*, THE WALL STREET JOURNAL (March 1, 2011), <http://on.wsj.com/1qEoxpi>.

⁸⁶ Main December 2011, *supra* note 12, at 5.

⁸⁷ *Id.*, at 22, citing P Braveman, *Racial/ethnic Differences in the Likelihood of Cesarean Delivery, California*, 85 AMERICAN JOURNAL OF PUBLIC HEALTH 625-630 (May 1995).

⁸⁸ *Id.*

⁸⁹ Katy Backes Kozhimannil, Michael R. Law, and Beth A. Virnig, *Cesarean Delivery Rates Vary Tenfold Among US Hospitals; Reducing Variation May Address Quality and Cost Issues*, HEALTH AFFAIRS (March 2013), at 533.

The Use of Cesareans Poses Health Risks

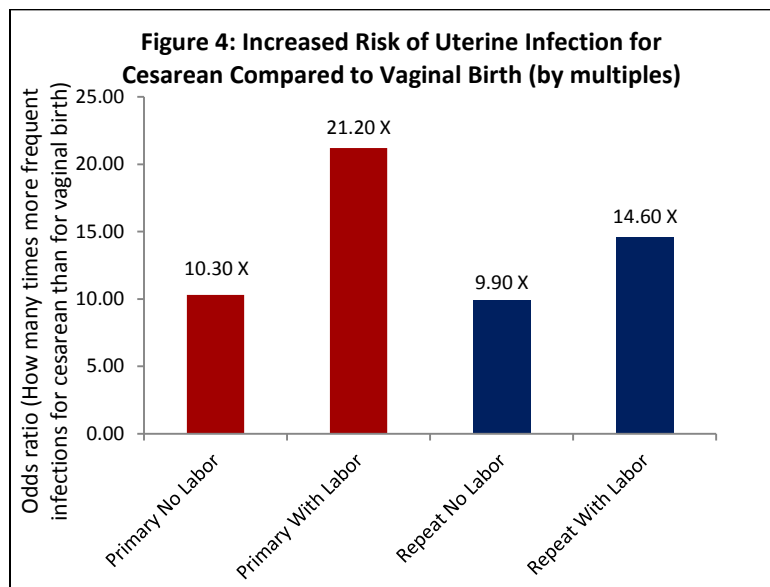
Physical Risks to Mothers

Cesarean deliveries have long been associated with greater risk to mothers. For instance, ACOG reported in 2000 that research indicated that the mortality rate for mothers giving birth by cesarean is three to seven times greater than by vaginal delivery.⁹⁰

AGOC and the Society for Maternal-Fetal Medicine said in 2013: “For certain clinical conditions – such as placenta previa or uterine rupture – cesarean delivery is firmly established as the safest route of delivery. However, for most pregnancies, which are low-risk, cesarean delivery appears to pose greater risk of maternal morbidity and mortality than vaginal delivery.”⁹¹

The CMQCC reported in 2011: “There is considerable evidence that cesarean surgery, even among otherwise healthy women, is associated with increased rates of infection, hemorrhage, and other serious medical and psychological complications and hospital readmission.”⁹²

Separately, the CMQCC cited a study involving 33,000 women giving birth between 1995 and 2000 finding that those giving birth via cesarean were 10 to 21 times more likely to contract infections than those giving birth vaginally.⁹³ [Figure 4]



Source: California Maternity Quality Care Collaborative, <http://bit.ly/1gqQLVx>

⁹⁰ *Evaluation of Cesarean Delivery*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNCOLOGISTS (2000).

⁹¹ *Id.*

⁹² *Main December 2011*, *supra* note 12, at 8.

⁹³ *Id.*, at 29.

Health Risks to Infants

Overwhelming evidence indicates that babies born by cesarean delivery experience significantly greater risk of health complications compared to babies born vaginally.

For instance, the CMQCC reported in 2011: The order of magnitude of the increase of neonatal complications with cesarean births is typically two-fold, with the absolute risk of 2 to 4 percent. In particular, babies born by scheduled cesarean deliveries have significantly higher rates of respiratory complications compared to those born vaginally. The complications include severe breathing problems (respiratory distress syndrome), retained fluid with moderate breathing problems (transient tachypnea of the newborn, or TTN), infections, and prolonged neonatal intensive care unit length of stay.”⁹⁴

Cesareans Impose Extra Costs on the Health Care System

The use of cesareans, including the significant percentage of cesareans that appear unnecessary, exacts significant costs on the U.S. health care system.

Costs for a cesarean delivery average \$18,500 compared to \$11,500 for a vaginal birth. Bringing cesareans to a 15 percent rate would save up to \$441.5 million in California alone, the Pacific Business Group on Health concluded. This estimate did not include savings that would be realized by reducing maternal readmission and extra “Neonatal Intensive Care Unit (NICU) costs related to excess neonatal respiratory morbidity due to cesarean deliveries.”⁹⁵

The use of cesareans also imposes significant costs on taxpayers. Medicaid covers more than 40 percent of all births.⁹⁶

Reasons for Increase in Use of Cesareans

Experts have proffered numerous explanations for the increase in cesareans that do not have to do with optimizing the level of care for the mother and infant. The CMQCC reported on several based on its interviews with practitioners. Many theories focused on the fact that cesarean deliveries are faster and can be scheduled.

Among the proposed explanations were physicians’ “desire for balance between work and the rest of life;” “institutional pressures and the pace of high-volume facilities;” physicians’ and mothers’ impatience with the pace of progress in labor, especially in cases in which inductions are used; fear of litigation; and misaligned economic incentives.”⁹⁷

⁹⁴ *Id.*, at 27.

⁹⁵ *Id.*, at 35-36.

⁹⁶ *Medicaid Matters: Understanding Medicaid’s Role in Our Health Care System*, HENRY J. KAISER FAMILY FOUNDATION (March 2011), <http://bit.ly/1qZCIsq>.

⁹⁷ *Main December 2011*, *supra* note 12, at 10.

“A significant portion of the obstetric global fee is delivery-based, creating incentives for obstetricians to deliver their own patients when they are on call,” the CMQCC wrote, suggesting physicians might schedule a cesarean delivery to ensure that they are compensated for that delivery.⁹⁸

Some have speculated that requests of mothers seeking less arduous deliveries are responsible for the increase in the use of cesareans. But the weight of evidence suggests that providers are the most significant driver of the trend, the CMQCC concluded.⁹⁹

A 2006 survey of new mothers found that at least one woman in four felt pressured by health care professional to have a cesarean. Meanwhile, “fewer than 1 percent of women reported choosing a nonmedically indicated cesarean for their first birth,” CMQCC reported.¹⁰⁰

At least one study found that the presence of round-the-clock in-house coverage resulted in reduced cesareans. “Hospitals that provide 24-hour, dedicated in-house physician coverage show lower cesarean delivery rates” compared with hospitals that either did not have such practices or previously had not had such practices,” ACOG reported in 2000.¹⁰¹

If the existence of a 24-hour dedicated physician reduces the urgency to perform cesareans for reasons of convenience, a bias toward conducting deliveries during standard work hours may do the opposite.

Clark *et al.* analyzed the days and times of births involving more than 20,000 women in 72 hospitals over a four-month period in 2013. They found that the primary cesarean rate was 33.6 percent on weekdays and 24.7 percent on weekends. Meanwhile, the weekday rate for cesareans spiked at lunch time and in immediate post-office hours. These time-sensitive trends did not occur on weekends.¹⁰²

The authors attributed the weekday spikes in cesarean rates to a desire to adjust to other demands in the more structured weekday. The chart of weekday versus weekend cesarean and noncesarean births “suggests that approximately one third of primary cesarean deliveries in nulliparous women might be avoided without compromising patient safety simply by altering the current system of intrapartum care to make everyday a weekend day in terms of physician convenience,” they wrote.¹⁰³

⁹⁸ *Id.*

⁹⁹ *Id.*, at 9-10.

¹⁰⁰ *Id.*

¹⁰¹ *Evaluation of Cesarean Delivery*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (2000).

¹⁰² Steven L. Clark, Jonathan B. Perlin, Sarah Fraker, Jamee Bush, Janet A. Meyers, Donna R. Frye and Thomas L. Garthwaite, *Association of Obstetric Intervention With Temporal Patterns of Childbirth*, 124 OBSTETRICS & GYNECOLOGY 873-880 (November 2014).

¹⁰³ *Id.*

IV. Progress on Postponing Births Until 39 Weeks

Since 1979, ACOG has counseled against initiating delivery before 39 weeks of gestation unless there are medical reasons for doing so.¹⁰⁴ However, many practitioners discounted concerns that there were safety risks to delivering in weeks 37 or 38.¹⁰⁵

As shown above, rates of deliveries before 39 weeks rose markedly between 1990 and 2005.¹⁰⁶ The past few years have seen a concerted effort to reduce the rate of early-elective deliveries. This initiative is related but somewhat distinct from protocols on inductions and cesareans, discussed above.

In 2001, Intermountain Healthcare, which at that time operated 21 hospitals in Utah and Idaho, implemented a policy aimed at eliminating early-elective deliveries. Within six months, the network's rate of early-elective deliveries dropped from 28 percent to 10 percent. Within six years, the rate dropped to 3 percent.¹⁰⁷

Babies born at 39 weeks fared better than those born at 38 weeks, and those born at 38 weeks fared better than those born at 37 weeks, Intermountain's retrospective data showed. The rate of admissions to the neonatal intensive care unit for babies born from normal pregnancies was 8.9 percent for births at 37 weeks, 4.5 percent for those at 38 weeks and 3.3 percent for those at 39 weeks. Similarly, rates of ventilator use for deliveries without complications were 1.4 percent for deliveries at 37 weeks, 0.5 percent for 38 weeks and just 0.3 percent 39 weeks.¹⁰⁸

Clark *et al.* of Hospital Corporation of America studied the outcomes by gestation period for more than 4,600 planned, elective deliveries (cesareans and inductions) at 27 hospitals in 2007. They found a neonatal intensive care unit admission rate of 17.8 percent for births at 37 weeks, 8 percent at 38 weeks and 4.6 percent at 39 weeks or more.¹⁰⁹ Subsequently, Clark *et al.* estimated that if the national rate of early-elective deliveries were reduced to 1.7 percent (which certain HCA hospitals achieved in 2007 by banning purely elective

¹⁰⁴ *Main August 2011*, *supra* note 62, at vi, citing *Assessment of Fetal Maturity Prior to Repeat Cesarean Delivery or Elective Induction of Labor*. AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (1979).

¹⁰⁵ See, e.g., Bryan T. Oshiro, *et al.*, *Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System*, 113 OBSTETRICS AND GYNECOLOGY 804, 805 (April 2009).

¹⁰⁶ Joyce A. Martin, Brady E. Hamilton, Michelle J.K. Osterman, Sally C. Curtin, and T.J. Mathews, *Births: Final Data for 2012*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES: NATIONAL VITAL STATISTICS REPORT (Dec. 30, 2013), <http://1.usa.gov/1Bz8rnG>.

¹⁰⁷ Bryan T. Oshiro, *et al.*, *Decreasing Elective Deliveries Before 39 Weeks of Gestation in an Integrated Health Care System*, 113 OBSTETRICS AND GYNECOLOGY 804, 806 (April 2009).

¹⁰⁸ *Id.*, at 806-807.

¹⁰⁹ Steven L. Clark, Darla D. Miller, Michael A. Belfort, Gary A. Dildy, Donna K. Frye, Janet A. Meyers, *Neonatal and Maternal Outcomes Associated With Elective Term Delivery*, 200 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 156.e1 (2009).

deliveries before 39 weeks), the United States would save about \$1 billion in intensive care costs.¹¹⁰

In response to a request from the March of Dimes, which began an initiative in 2006 to reduce births before 39 weeks, HCA developed a reporting standard for early-elective deliveries.¹¹¹

The March of Dimes lobbied entities with oversight authority to adopt the standard.¹¹² The National Quality Forum, a publicly and privately funded entity that seeks to improve health care quality,¹¹³ endorsed the HCA reporting standard and several other perinatal safety standards (including a reporting standard on the rates of cesarean delivery) in 2008.¹¹⁴ In 2009, the Joint Commission announced that hospitals could voluntarily report data pertaining to early-elective delivery reporting standard, as well as four other perinatal measures.¹¹⁵

In 2010, the Leapfrog Group, a hospital-rating organization, began asking providers to voluntarily provide data on early-elective deliveries via the reporting standard. It succeeded in obtaining data from about 750 hospitals, which accounted for about 50 percent of births in the United States.¹¹⁶

In 2012, the Centers for Medicare and Medicaid Services (CMS) announced that it would require reporting of early-elective delivery rates.¹¹⁷ Beginning in 2014, the Joint Commission began requiring hospitals delivering more than 1,100 babies a year to report their rate of elective deliveries prior to 39 weeks.¹¹⁸ CMS, in turn, has announced that

¹¹⁰ Steven L. Clark, Donna R. Frye, Janet A. Meyers, Michael A. Belfort, Gary A. Dildy, Shalece Kofford, Jane Englebright and Jonathan A. Perlin, *Reduction in Elective Delivery at <39 Weeks of Gestation: Comparative Effectiveness of 3 Approaches to Change and the Impact on Neonatal Intensive Care Admission and Stillbirth*, 203 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 449.e1, 449 e5 (November 2010).

¹¹¹ Steven L. Clark, professor Baylor College of Medicine/Texas Children's Hospital, e-mail to Taylor Lincoln, research director of Public Citizen's Congress Watch Division (Feb. 20, 2015) and Cynthia Pellegrini, Office of Government Affairs, March of Dimes Foundation, e-mail to Lincoln (Feb. 27, 2015).

¹¹² Cynthia Pellegrini, Office of Government Affairs, March of Dimes Foundation, e-mail to Taylor Lincoln, research director of Public Citizen's Congress Watch Division (Feb. 27, 2015).

¹¹³ See, e.g., *Funding*, NATIONAL QUALITY FORUM (viewed on Feb. 27, 2015), <http://bit.ly/1LR9faO>.

¹¹⁴ *A Better Start for Moms and Babies*, NATIONAL QUALITY FORUM (undated; viewed on Feb. 24, 2015), <http://bit.ly/1AHBS7h> and *Preventing Harm to Newborns and Mothers: A Case Study on Early Elective Deliveries*, NATIONAL QUALITY FORUM (June 2013), <http://bit.ly/1AHFh6f>.

¹¹⁵ Press release, the Joint Commission, *The Joint Commission Introduces Perinatal Care Core Measures* (Nov. 20, 2009), <http://bit.ly/18ixtP3> and *TJC Introduces Perinatal Care Core Measure Set*, AHC MEDIA (Jan. 1, 2010), <http://bit.ly/1DmrC5A>.

¹¹⁶ *Id.* and Tina Rosenberg, *Reducing Early Elective Deliveries*, THE NEW YORK TIMES (March 12, 2014), <http://nyti.ms/1w4akF7>.

¹¹⁷ 77 FEDERAL REGISTER 53528 (Aug. 31, 2012), <http://1.usa.gov/1FV28zH>.

¹¹⁸ See, e.g., *Questions And Answers: The Perinatal Care Core Measure Set*, THE JOINT COMMISSION (2013), <http://bit.ly/1JV2oBI>.

performance on early-elective deliveries will be one of the graded benchmarks upon which it will issue bonuses or penalties in payment rates beginning in 2017.¹¹⁹

Meanwhile, about a dozen states have enacted policies of various forms to discourage early elective deliveries. These policies include complete bans on early-elective deliveries, as well as prohibitions on Medicaid payments, reductions in Medicaid payments and imposition of paperwork requirements for early-elective deliveries, officials from the March of Dimes told Public Citizen. Additionally, numerous insurance companies have instituted payment policies to discourage early deliveries.¹²⁰

These actions have coincided with a significant reduction in early-elective deliveries, although the practice has not been eradicated. The Leapfrog Group reported that the rate fell from 17 percent of all births in 2010 to 4.6 percent in 2013. Meanwhile, 1,740 hospitals enrolled in the Partnership for Patients, a CMS program, reported a 64 percent drop in incidence from 2010 to 2013. But rates among states varied from 2 percent to 22 percent, according to the latest CMS data, the National Quality Forum reported in 2014.¹²¹

Several experts interviewed for this report credited the incentives in payment policies with causing the reduction in early-elective deliveries. “It took not just 30 years of ACOG saying it, but it also took someone with their hands on the money,” Steven L. Clark, former medical director for women’s and children’s Services at HCA, told Public Citizen.¹²²

Regrettably, the revenue that hospitals receive from treating newborns in neonatal intensive care units (NICU) may have dampened hospitals’ enthusiasm for curtailing early deliveries. This is because infants delivered early account for a disproportionate percentage of NICU admissions, and those admissions generate substantial revenue.

“NICU costs are a perverse incentive,” Sue Gullo, a director of the Institute for Healthcare Reform, told Public Citizen. For regions that have several neonatal intensive care units in close proximity, Gullo proposed a reform in which hospitals with high NICU admission rates would be required to refer their newborns in need of special care to hospitals with low NICU admission rates in order to avoid rewarding poor performers with extra revenue.¹²³

California Maternal Quality Care Collaborative Medical Director Elliott Main, whose work on cesareans and early deliveries is cited extensively in this report, told *The New York Times*

¹¹⁹ Sabriya Rice, Maureen McKinney and Melanie Evans, *More Hospitals to Get Bonuses Than Penalties in 2015 Under Value-based Purchasing*, MODERN HEALTHCARE (Dec. 18, 2014), <http://bit.ly/1AqkIvZ>.

¹²⁰ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Cynthia Pellegrini and Nikki Garro of the March of Dimes Foundation (Feb. 23, 2015).

¹²¹ *Playbook for the Successful Elimination of Elective Early Deliveries*, NATIONAL QUALITY FORUM (Maternity Action Team) (August 2014), <http://bit.ly/18dLJaX>.

¹²² Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Steven L. Clark, professor Baylor College of Medicine/Texas Children’s Hospital (Feb. 19, 2015).

¹²³ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Sue Leavitt Gullo, director, Institute for Healthcare Improvement (Feb. 24, 2015).

that hospitals have complained privately about declining NICU revenue due to reducing early deliveries.¹²⁴

A study published in 2013 spoke to effects of safer care on revenue. Researchers looked at the effects on patient safety and hospital revenue of a perinatal safety initiative undertaken at Minneapolis-based Fairview Health Services. The researchers found that the initiative was associated with “an 11 percent decrease in the rate of maternal and neonatal adverse outcomes between 2008 and 2011.” But that “as a result of the adverse events avoided, the hospital system saved \$284,985 in costs but earned \$324,333 less revenue, which produced a net financial decrease of \$39,348.”¹²⁵

The initiative “produced better clinical results at a lower cost, which represents potential savings for payers, but the hospital system offering increased quality reaped no clear financial rewards,” the authors wrote. “These results highlight the important role for shared-savings collaborations (among patients, providers, government and third-party payers, and employers) to incentivize quality improvement.”¹²⁶

¹²⁴ Tina Rosenberg, *Reducing Early Elective Deliveries*, THE NEW YORK TIMES (March 12, 2014), <http://nyti.ms/1w4akF7>.

¹²⁵ Katy B. Kozhimannil, *A Perinatal Care Quality and Safety Initiative: Hospital Costs and Potential Savings*, 39 JOINT COMMISSION JOURNAL ON QUALITY AND PATIENT SAFETY 339-348 (August 2013), <http://1.usa.gov/1BWxglK>.

¹²⁶ *Id.*

V. Initiatives by Selected Providers to Reduce Adverse Events in Childbirth

The initiatives described in this report involved similar, often overlapping, practices to improve safety in childbirth.

This report discusses initiatives at Hospital Corporation of America, commonly known as HCA, which is the largest obstetrical health delivery system in the United States and annually delivers about 220,000 babies, which is upwards of 5 percent of all deliveries in the United States;¹²⁷ New York Presbyterian-Weill Cornell Medical Center (“New York Presbyterian”), which handled about 5,000 deliveries per year in the latter part of last decade;¹²⁸ Ascension Health, the nation’s third-largest health care network by revenue, which has reported handling about 75,000 deliveries annually; and a project encompassing 16 hospitals within Premier Inc., which bills itself as a healthcare performance improvement alliance of approximately 3,400 U.S. hospitals.¹²⁹

It is important to note that numerous other institutions have instituted comprehensive safety protocols. Those discussed here were included in part for the degree of access to data flowing from their programs and due to publicity their programs have received.

The initiatives run by Ascension and Premier were bolstered in 2010 when they were provided with grants by the federal government’s Agency for Healthcare Research and Quality (AHRQ). The grants were part of a patient safety and medical liability program announced by President Obama during a speech before a joint session of Congress in September 2009.¹³⁰

¹²⁷ See, e.g., Steven L. Clark, James T. Christmas, Donna R. Frye, Janet A. Meyers and Jonathan B. Perlin, *Maternal Mortality in the United States: Predictability and the Impact of Protocols on Fatal Postcesarean Pulmonary Embolism and Hypertension-Related Intracranial Hemorrhage*, 2011 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 32.e1 (2014) and Jon Perlin, *When Is Full Term “Full Term” in a Pregnancy*, HCA TODAY (Feb. 10, 2012), <http://bit.ly/1ERuozm>.

¹²⁸ Amos Grunebaum, Frank Chervenak and Daniel Skupski, *Effect of a Comprehensive Obstetric Patient Safety Program on Compensation Payments and Sentinel Events*, 204 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 97, 103 (2011). [Hereinafter, *Grunebaum*] (Estimate based on paper’s assertion that the hospital handled 15,932 deliveries over final three years of study.)

¹²⁹ *About Us*, PREMIER INC. (viewed on Feb. 25, 2015), <http://bit.ly/1Drjl05>.

¹³⁰ President Obama, Speech before a joint session of Congress (Sept. 10, 2009), <http://1.usa.gov/1A80ntp>.

Hospital Corporation of America (HCA)

Starting in about 2000, in part due to concerns over the size of obstetric-related medical malpractice payments, HCA embarked on a program to reduce risks associated with childbirth.¹³¹ Steven L. Clark, director of women's and children's services at HCA from 2004 to 2014, co-authored a 2008 paper in the *American Journal of Obstetrics & Gynecology* outlining the initiative. The initiative was guided by philosophies that:

1. Uniform processes and procedure result in improved quality;¹³²
2. "Every member of the obstetric team should be not only empowered but also required to intervene and halt any process that is deemed to be dangerous";¹³³ and
3. Physicians should aspire to reduce malpractice risks by seeking a "reduction in adverse outcomes and the development of unambiguous practice guidelines, rather than by attempting to make unusual care more 'defensible' through the use of nonspecific guidelines."¹³⁴

The hospital network also took steps to improve peer review, the effectiveness of which is sometimes hindered because "most reviewers find themselves either the partners or economic competitors of the individual being reviewed." To reduce conflicts, HCA created national peer review committees for certain obstetric outcomes. HCA also called for "conservative use of oxytocin and other high-risk medications" as well as "procedures such as operative vaginal delivery."¹³⁵

The hospital network's leaders also "strongly encourage and support the establishment of 24-hour in-hospital obstetric coverage programs in our facilities." Although such coverage is not considered part of the accepted standard of care and may be economically infeasible in small health centers, Clark *et al.* reported that "a review of almost 200 closed malpractice claims demonstrated that 40 percent of adverse outcomes related to intrapartum fetal hypoxia, and their associated malpractice claims, may have been avoided had such coverage been available."¹³⁶ Fetal hypoxia refers to a fetus being deprived of an adequate supply of oxygen.

¹³¹ *Perinatal Safety Improved With Focus on High-Risk Factors And Education: HCA Sees Dramatic Drops In Complications, Liability After Special Effort*, AHC MEDIA (March 1, 2006), <http://bit.ly/1LOH3VH>.

¹³² Steven L. Clark, Michael A. Belfort, Spencer L. Byrum, Janet A. Meyers, Jonathan B. Perlin, *Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety*, 199 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 105.e1, 105.e2 (August 2008).

¹³³ *Id.*, at 105.e5

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

In 2011, Clark *et al.*, published a follow-up paper documenting additional initiatives at HCA. These included expanding online education for providers; studying alternative methods to reduce deliveries prior to 39 weeks of gestation; and taking steps to prevent post-cesarean venous thromboembolism by using a pneumatic compression device on the legs of all patients undergoing cesarean delivery.¹³⁷ Venous thromboembolism, which refers to blood clots within a vein, is the most common preventable cause of death in surgical patients.¹³⁸

HCA also initiated check list protocols aimed at recognition and treatment of hypertensive crisis, recognition and management of preeclampsia-related pulmonary edema and summoning assistance and providing timely fluid, blood, and component replacement in cases of postpartum hemorrhage.¹³⁹

Results

HCA's policy of using of pneumatic compression devices for all women who underwent cesarean delivery was associated with a reduction in postoperative pulmonary embolism deaths from 7 out of 458,097 (1.5 per 100,000) cesarean births to 1 out of 465,880 births (0.2 per 100,000), a reduction of 86 percent.¹⁴⁰

Maternal deaths from hypertension were reduced from 15 to 3, a rate reduction of 77 percent.¹⁴¹ Overall maternal deaths, excluding patients who entered the hospital with terminal conditions, declined by 19 percent.¹⁴²

In the years immediately after implementing its program, HCA's obstetrical medical malpractice claims were cut by more than half. "Obstetric malpractice claims currently rank behind 'accidents on hospital grounds' in terms of litigation loss," Clark *et al.* wrote in

¹³⁷ Steven L. Clark, Janet A. Meyers, Donna K. Frye, and Jonathan A. Perlin, *Patient Safety in Obstetrics—the Hospital Corporation of America Experience*, 204 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 283-287 (April 2011).

¹³⁸ See, e.g., Martin O'Donnell and Jeffrey I. Weitz, *Thromboprophylaxis in Surgical Patients*, 46 CANADIAN JOURNAL OF SURGERY 129-135 (2003).

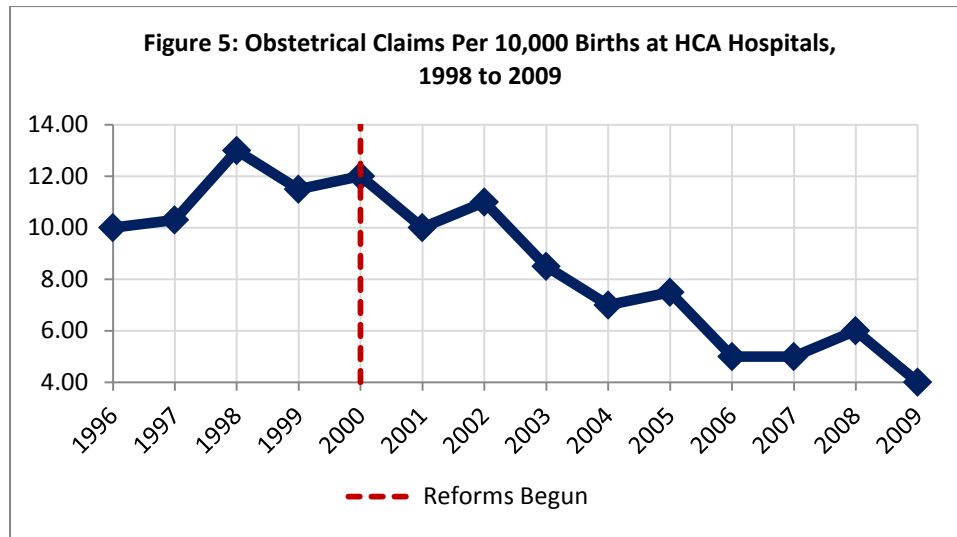
¹³⁹ Steven L. Clark, James T. Christmas, Donna R. Frye, Janet A. Meyers and Jonathan B. Perlin, *Maternal Mortality in the United States: Predictability and the Impact of Protocols on Fatal Postcesarean Pulmonary Embolism and Hypertension-Related Intracranial Hemorrhage*, 2011 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 32.e1-32.e9 (2014).

¹⁴⁰ Steven L. Clark, James T. Christmas, Donna R. Frye, Janet A. Meyers and Jonathan B. Perlin, *Maternal Mortality in the United States: Predictability and the Impact of Protocols on Fatal Postcesarean Pulmonary Embolism and Hypertension-Related Intracranial Hemorrhage*, 2011 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 32.e1 (2014).

¹⁴¹ *Id.*, at 32.e7.

¹⁴² *Id.*, at 32.e8.

2008.¹⁴³ By 2009, claims were reduced by two-thirds over what they had been prior to the beginning of the safety program.¹⁴⁴ [Figure 5]



Source: American Journal of Obstetrics & Gynecology (chart is reproduced and may not be precise)

In a 2010 interview with *Modern Healthcare*, Clark attributed much of HCA's success to an underlying philosophy of seeking to reduce bad outcomes instead of avoiding litigation. "If we have healthy mothers taking home healthy babies, we won't have litigation. And that has been the key to our success," he said.¹⁴⁵

New York Presbyterian Hospital-Weill Cornell Medical Center

From 2002 to 2009, as part of an initiative undertaken by its insurer, New York Presbyterian implemented a program to improve obstetric patient safety. The program was chronicled in a 2011 article in the *American Journal of Obstetrics & Gynecology*. New York Presbyterian obstetrician Amos Grunebaum was the article's lead author.¹⁴⁶

The first step outlined was the hospital's decision to implement a program in which all staff working on labor and delivery "including clerical staff, nurses, attending obstetricians, neonatologists, anesthesiologists, and residents" were required to participate in a four-hour team-training session.¹⁴⁷

¹⁴³ Steven L. Clark, Michael A. Belfort, Spencer L. Byrum, Janet A. Meyers, Jonathan B. Perlin, *Improved Outcomes, Fewer Cesarean Deliveries, and Reduced Litigation: Results of a New Paradigm in Patient Safety*, 199 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 105.e1, 105.e6 (August 2008).

¹⁴⁴ Steven L. Clark, Janet A. Meyers, Donna K. Frye, and Jonathan A. Perlin, *Patient Safety in Obstetrics—the Hospital Corporation of America Experience*, 204 AMERICAN JOURNAL OF OBSTETRICS & GYNECOLOGY 283-287 (April 2011).

¹⁴⁵ Linda Wilson, *An Evidence-Based Approach Is Born; Hospitals, Docs Use Protocols to Cut Costs From Avoidable OB/GYN Injuries*, MODERN HEALTHCARE (December 20/27, 2010).

¹⁴⁶ Grunebaum, *supra* note 128, at 97-105.

¹⁴⁷ *Id.*, at 97.

Staff involved in interpreting data from electronic fetal monitoring (a procedure in which instruments are used to continuously record the heartbeat of a fetus¹⁴⁸) were required to become certified in that practice by a national credentialing organization.¹⁴⁹

New York Presbyterian created an on-call schedule dedicated solely to gynecology, as opposed to having the physician on call cover both obstetrics and gynecology services. This staffing change reduced the likelihood that a physician assigned to manage deliveries would be pulled away to handle a concurrent emergency gynecological case. “The added gynecology coverage allowed the labor and delivery attending [physician] to cover the labor floor exclusively,” Grunebaum *et al.* wrote.¹⁵⁰

In addition, three new obstetric physician assistants were recruited, in part to compensate for reduced work hours by residents.¹⁵¹

A new position was created for an obstetric patient-safety nurse to work on “staff education, team training, implementation of protocol changes on labor and delivery, obstetric emergency drills, and collection of data.”¹⁵²

The hospital introduced policies limiting the doses of certain drugs and enhancing safety in the administration of them. For instance, the authors wrote, “To improve the safe use of magnesium sulfate, we implemented several changes, including the use of premixed magnesium sulfate and oxytocin solutions, color coded magnesium sulfate and oxytocin containers and intravenous lines, as well as using both with ‘smart pumps.’”¹⁵³

A single kit including the four most important drugs for postpartum hemorrhage was created.¹⁵⁴

An online communication system was created to replace a physical whiteboard. Also, a chain of communication from the nurse and junior resident level to the chairman of the department was developed to permit all staff to voice concerns.¹⁵⁵

A uniform medical records system was implemented for all patients cared for by full-time faculty. The patients accounted for about 75 percent of all deliveries at the hospital.¹⁵⁶

¹⁴⁸ See, e.g., *Frequently Asked Questions: Fetal Heart Rate Monitoring During Labor*, AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS (undated, viewed on March 2, 2015), <http://bit.ly/1F2SLu1>.

¹⁴⁹ *Id.*, at 100.

¹⁵⁰ *Id.*, at 98.

¹⁵¹ *Id.*, at 100.

¹⁵² *Id.*

¹⁵³ *Id.*, at 99.

¹⁵⁴ *Id.*, at 101.

¹⁵⁵ *Id.*, at 100.

¹⁵⁶ *Id.*, at 101.

Clinical drills were conducted “to help staff prepare for shoulder dystocia, conduct debriefings to evaluate team performance, and identify areas for improvement”¹⁵⁷ Shoulder dystocia, which occurs in about 1 percent of births, refers to a condition in which a baby’s shoulder gets stuck during delivery. In rare cases, this can cause paralysis or brain damage.¹⁵⁸

Results

New York Presbyterian reported remarkable progress during the course of its safety program.

Perhaps the most compelling evidence of the program’s success can be found in New York Presbyterian’s reduction of sentinel events. A sentinel event is “unexpected occurrence involving death or serious physical or psychological injury.”¹⁵⁹ The hospital’s obstetrics-related sentinel events fell almost every year from 2000 to 2008. In 2008 and 2009 New York Presbyterian reported zero sentinel events.¹⁶⁰ In 2000, New York Presbyterian’s rate of sentinel events was 1 per 1,000 births, which would translate to about 5 in absolute numbers for a hospital of its volume. [Figure 6]

New York Presbyterian had one infant suffer hypoxic-ischemic encephalopathy (HIE) over the final three years covered in the study. That represented a rate of 0.6 out of 10,000 deliveries, 98 percent less than the reported national rate of 25 per 10,000.¹⁶¹ HIE is a brain injury caused by oxygen deprivation and is a leading cause of death or severe impairment among infants.¹⁶² (The study did not report New York Presbyterian’s incidence of HIE earlier in the safety initiative or prior to the initiative.)

New York Presbyterian reported that it had not had a single case of maternal death during labor and delivery over the previous six years, although one maternal patient died 10 days after discharge.¹⁶³

The hospital’s payments for obstetrics-related malpractice claims dropped from \$50.9 million in 2003 to \$250,000 in 2009, a greater than 99 percent reduction.¹⁶⁴ [Figure 7]

¹⁵⁷ *Id.*

¹⁵⁸ See, e.g., *Pregnancy Complications: Shoulder Dystocia*, MARCH OF DIMES (December 2013), <http://bit.ly/18BBGxh>.

¹⁵⁹ *Sentinel Event*, JOINT COMMISSION (viewed on Feb. 25, 2015), <http://bit.ly/1DUZLw4>.

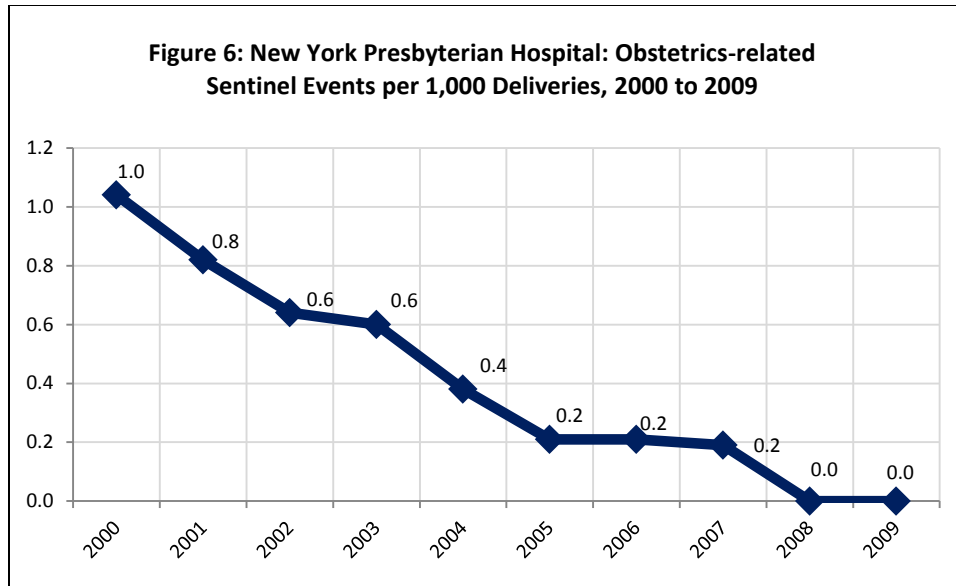
¹⁶⁰ Grunebaum, *supra* note 128, at 102.

¹⁶¹ *Id.*, at 103.

¹⁶² See, e.g., *What is Hypoxic-Ischemic Encephalopathy, or HIE, also known as Intrapartum Asphyxia*, MY CHILD AT CEREBRAL PALSY.ORG (undated, viewed on Feb. 25, 2015), <http://bit.ly/1BWYokp>.

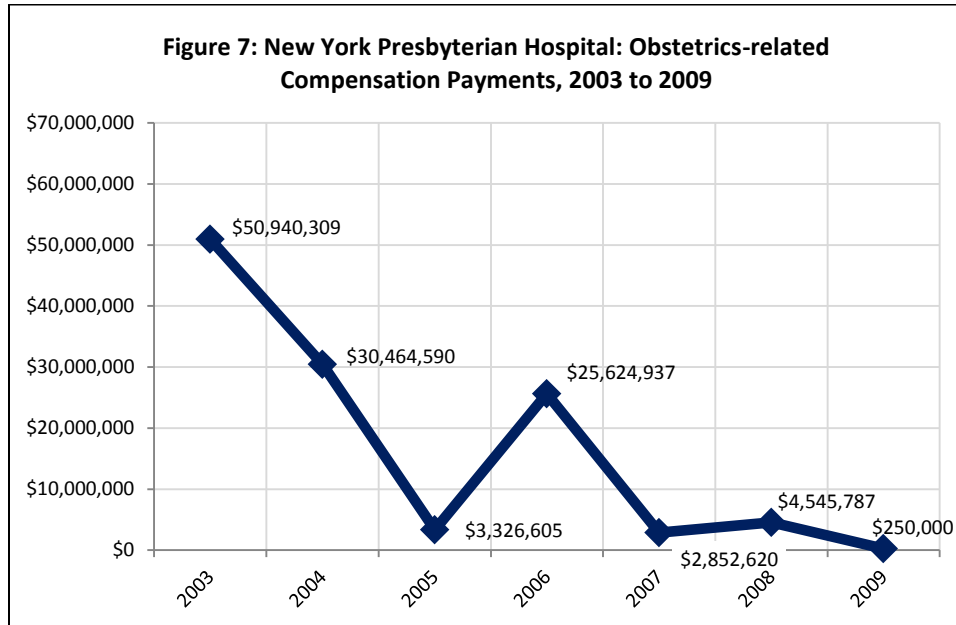
¹⁶³ Grunebaum, *supra* note 128, at 102.

¹⁶⁴ *Id.*, at 103.



Source: American Journal of Obstetrics & Gynecology

“The main goal of these changes was to improve patient safety and decrease adverse outcomes. We did not expect a rapid and significant effect on compensation payments,” Grunebaum *et al.* wrote. “Our results show that implementing a comprehensive obstetric patient safety program not only decreases severe adverse outcomes but can also have an immediate impact on compensation payments.”¹⁶⁵



Source: American Journal of Obstetrics & Gynecology

¹⁶⁵ *Id.*

The authors did not report the cost of the program, but said that costs were significantly lower than the amount saved from reduced liability. “The \$25,041,475 yearly savings in compensation payments for the last three years alone dwarf the incremental cost of the patient safety program,” they wrote. “In our opinion the documented success of our patient safety improvement program in decreasing compensation payments for the past years understates the true long-term impact of the program on patient safety, as we expect significant savings to continue into the future.”¹⁶⁶

Grunebaum told *Crains New York Business*. “Any hospital could do it – it’s not about money, it’s about changing the culture to make it safer to deliver babies.”¹⁶⁷

Public Citizen made several attempts to reach Grunebaum to obtain greater detail on the cost of New York Presbyterian’s program and to obtain insight into the unit’s results since 2009, the last year covered in the study. These efforts included making calls to the New York Presbyterian’s communications office, making calls to Grunebaum’s office and submitting questions to Grunebaum’s office by fax. Public Citizen did not receive a response.

Ascension Health

Ascension Health is the third-largest health care system in the United States.¹⁶⁸ In 2003, Ascension Health undertook a commitment to reduce the number of injuries or death to zero by July 2008. Perinatal safety was included among eight areas of focus.¹⁶⁹

Ascension initially designated three pilot sites for its perinatal safety program to address high-risk areas in labor and delivery.¹⁷⁰

During this phase, the program was implemented at the four-hospital Seton Family of Hospitals, based in Austin, Texas; at St. Mary’s Hospital for Women and Children, in

¹⁶⁶ *Id.*

¹⁶⁷ Gale Scott, *Obstetricians Take Big Steps to Avoid Malpractice*, CRAIN’S NEW YORK BUSINESS (March 7, 2011), <http://bit.ly/1kWjrYk>.

¹⁶⁸ Jim Doyle, *How a St. Louis-Based Health Care System Became One of the Nation’s Biggest*, ST. LOUIS POST-DISPATCH (Feb. 23, 2014), <http://bit.ly/1kwFLHB>.

¹⁶⁹ Frank Mazza, Judy Kitchens, Sue Kerr, Anita Markovich, Melody Best, Lora P. Sparkman, *Eliminating Birth Trauma at Ascension Health*, JOINT COMMISSION JOURNAL ON QUALITY AND PATIENT SAFETY (January 2007) and David Pryor, Ann Hendrich, Robert J. Henkel, James K. Beckmann and Anthony R. Tersigni, *The Quality ‘Journey’ at Ascension Health: How We’ve Prevented at Least 1,500 Avoidable Deaths a Year – And Aim to Do Even Better*, HEALTH AFFAIRS (April 2011), at 604.

¹⁷⁰ Ascension Health, Grant Application to Agency for Healthcare Research and Quality (application materials undated; grant awarded Aug. 19, 2010), at 78. (Grant application obtained by Public Citizen through a Freedom of Information Act request.) [Hereinafter *Ascension Grant Application*]

Evansville, Ind.; and at Our Lady of Lourdes Memorial Hospital in Binghamton, N.Y. These hospitals managed about 12,000 deliveries per year.¹⁷¹

Protocols were implemented for inducing and augmenting labor, with a goal to drastically reduce the number of elective inductions before a fetus reached 39 weeks. Procedures were implemented for the use of oxytocin, which is often used for inductions.¹⁷²

Additionally, steps were taken to ensure that operative devices were used according to ACOG guidelines and that “effective communication and collaborative practice occurred between staff and providers in recognizing fetal distress.”¹⁷³

Success during the pilot programs prompted Ascension in 2006 to broaden its program to all 43 of its hospitals, which deliver about 75,000 babies annually.¹⁷⁴ Ascension named its broadened initiative the “Handling All Neonatal Deliveries Safely” (HANDS) program.

In 2010, Ascension received a \$3 million grant from AHRQ to continue and expand the initiative. Ascension said that additional funding was necessary in part to improve standardization of practices.

“Ascension Health has identified variability in the implementation and adoption of the HANDS program elements launched in 2006 due in part to a lack of broad-based program engagement of both community and employed physicians,” Ascension wrote in its AHRQ grant application. “In addition, the current HANDS program lacks a High Reliability methodology and approach that prepares physicians, nursing leadership, and middle managers in the obstetric unit to lead their unit in a manner that will ensure a sustainable patient safety improvement program and risk reduction.”¹⁷⁵

Aside from enhancing the degree of implementation and reliability, initiatives funded by the grant included: systemwide adoption and spread of the TeamSTEPPS communication tool; broad deployment of simulation training bundles regarding shoulder dystocia and electronic fetal monitoring; and development of an error disclosure protocol for adverse events.¹⁷⁶

¹⁷¹ Frank Mazza, Judy Kitchens, Sue Kerr, Anita Markovich, Melody Best, Lora P. Sparkman, *Eliminating Birth Trauma at Ascension Health*, JOINT COMMISSION JOURNAL ON QUALITY AND PATIENT SAFETY (January 2007).

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ David Pryor, Ann Hendrich, Robert J. Henkel, James K. Beckmann, and Anthony R. Tersigni, *The Quality Journey At Ascension Health: How We’ve Prevented At Least 1,500 Avoidable Deaths a Year—And Aim To Do Even Better*, HEALTH AFFAIRS (April 2011) and *Ascension Grant Application*, *supra* note 170, at 90.

¹⁷⁵ *Ascension Grant Application*, *supra* note 170, at 87.

¹⁷⁶ Ann Hendrich, chief quality/safety nursing officer, Ascension Health, e-mail to Taylor Lincoln, research director for the Congress Watch division of Public Citizen (Feb. 23, 2015).

Results

Although safety results have not yet been published in journal articles, anecdotal data released by Ascension indicate extraordinary success in the first two phases of its perinatal safety program (the beta phase from 2004 to 2006 and the first two years of systemwide implementation). Further, some encouraging anecdotal results have been published from the phase of the program that was funded by the AHRQ grant.

The safety effort that began at the sites in 2004 showed dramatic results, according to Ascension's reports. For instance, Ascension reported that the Seton Family of Hospitals saw an 85 percent reduction in birth trauma between 2003 and 2006 and had no birth trauma incidents in all of 2007.¹⁷⁷

At about the time the grants commenced, the national rate for birth trauma was about 7.3 per 1,000 births. "By June 2006, all facilities [in the beta program] achieved birth trauma rates that were at or near zero," Ascension's Frank Mazza *et al.* reported in 2007.¹⁷⁸

Elective inductions before 39 weeks within the Seton hospitals fell from 126 in the first three quarters of 2005 to 2 in the final quarter of 2005 and first two quarters of 2006.¹⁷⁹

Ascension said that this success prompted it in 2006 to implement the tenets of the perinatal safety program across all 43 of its hospitals.¹⁸⁰

In 2006, Ascension's systemwide birth trauma rate was 0.9 per 1,000 live births, about 65 percent lower than the national average. By 2008, its rate was 0.6 per 1,000 live births, a 33 percent reduction from its internal rate two years earlier, and 77 percent less than the national rate.¹⁸¹

In 2006, Ascension's neonatal mortality rate, which refers to newborns dying before reaching 28 days of age, was 1.71 per 1,000 live births, 62 percent less than the national rate of 4.52 per 1,000. By 2008, Ascension reports that its rate had fallen to 0.86 per 1,000 live births, a nearly 50 percent reduction from two years earlier.¹⁸²

¹⁷⁷ *Ascension Grant Application*, *supra* note 170, at 87.

¹⁷⁸ Frank Mazza, Judy Kitchens, Sue Kerr, Anita Markovich, Melody Best, Lora P. Sparkman, *Eliminating Birth Trauma at Ascension Health*, JOINT COMMISSION JOURNAL ON QUALITY AND PATIENT SAFETY (January 2007).

¹⁷⁹ *Id.*, at 20.

¹⁸⁰ *Ascension Grant Application*, *supra* note 170, at 79.

¹⁸¹ Margaret Elliott, manager, account strategy, communications, Ascension Health, e-mail to Taylor Lincoln, research director for the Congress Watch division of Public Citizen (Feb. 25, 2015).

¹⁸² *Id.*

By 2010, Ascension reported that its neonatal mortality rate was 89 percent lower than the estimated national rate.¹⁸³

The AHRQ demonstration project concluded in 2013. Insight into results from it is anecdotal.

At the five demonstration sites covered by the grant, actual and potential liability cases involving shoulder dystocia were reduced 64 percent over the grant period, Ascension said. Such cases declined 46 percent over the time period across the entire Ascension system. The total rate of actual and potential liability cases declined by 52 percent at the demonstration sites over the study period and 35 percent across the Ascension system.¹⁸⁴

“We presently have four manuscripts in editorial review that will fully explain our results, claims and estimated malpractice savings for the public,” Ann Hendrich, the principal investigator on the grant, wrote to Public Citizen in an e-mail.¹⁸⁵

Premier Inc.

Premier Inc., a health care performance improvement alliance of approximately 3,400 U.S. hospitals, initiated a project in 2008 and 2009 that sought to establish perinatal best practices in 16 hospitals across the country. The elements of this initiative were similar to those undertaken by Ascension, with a focus on adhering to best practices for elective induction, augmentation and vacuum-assisted delivery. The program also called for conducting simulations for critical events and training in communications.¹⁸⁶

In 2010, Premier was awarded a \$3 million grant, to be managed at Minneapolis-based Fairview Health Centers, to extend the initiative through June 2013.¹⁸⁷

Results

Results from Premier’s initiative have not been formally published. However, Premier reported in its announcement of the AHRQ grant that the initial phase of the program had

¹⁸³ David Pryor, Ann Hendrich, Robert J. Henkel, James K. Beckmann, and Anthony R. Tersigni, *The Quality ‘Journey’ At Ascension Health: How We’ve Prevented At Least 1,500 Avoidable Deaths a Year—And Aim To Do Even Better*, HEALTH AFFAIRS (April 2011), at 607.

¹⁸⁴ Press release, *Excellence in Obstetrics Demonstration Project Featured in Health Affairs*, ASCENSION HEALTH (Jan. 7, 2014), <http://bit.ly/1lPrIlo>

¹⁸⁵ Ann Hendrich, chief quality/safety nursing officer, Ascension Health, e-mail to Taylor Lincoln, research director for the Congress Watch division of Public Citizen (Feb. 23, 2015).

¹⁸⁶ Fairview Health Services Grant Application to Agency for Healthcare Research and Quality (application materials undated; grant awarded Aug. 19, 2010), at 89-90.

¹⁸⁷ Bernie Monegain, *AHRQ Grant Aims to Reduce Birth Injuries*, HEALTHCARE IT NEWS (Aug. 20, 2010), <http://bit.ly/1oDwZTi>.

seen birth trauma reduced by 11.6 percent and birth hypoxia and asphyxia, which are associated with causing brain damage, reduced by 31.4 percent.¹⁸⁸

Carolyn Clancy, then the director of AHRQ, reported in 2012 that the project had resulted in a 74 percent reduction in preventable birth trauma to full-term newborns; a 38 percent reduction in preventable neonatal intensive care unit admissions of full-term babies; and a 12 percent reduction in the rate of birth-related maternal complications at term.¹⁸⁹

¹⁸⁸ Press release, Premier Inc., *AHRQ Grant Will Enable Premier Healthcare Alliance Perinatal Safety Initiative to Continue via Award to Fairview Health Services* (Aug. 19, 2010), <http://bit.ly/1nImT3s>.

¹⁸⁹ Carolyn Clancy, *From the Director: Research Activities, September 2012*, No. 385, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (September 2012).

Conclusion

This report provides cause for optimism, disappointment, and lessons on methods to hasten adoption of practices to make health care safer.

The reason for optimism is clear. A corpus of similar initiatives undertaken by several health providers has apparently generated dramatic reductions in undesirable – at times tragic – outcomes in one of the most vital and fraught of all health care services.

Some aspects of these initiatives, such as instituting 24-hour, on-site obstetrician coverage, may not be feasible at all institutions. But most of the elements in these initiatives amount to little more than common sense. Many simply seek to compel adherence to accepted practices. The length of time it has taken the obstetrics profession to adopt them – and the profession’s inconsistency in implementing them to this day – cannot help but evoke a profound sense of disappointment.

Ideally, caregivers and health care executives would be shaken into action by evidence that certain changes could vastly improve their patients’ safety. What more sacred duty could they have? But it appears that ensconced customs, poorly aligned incentives and preoccupation with everyday affairs have deprived safety of a place at the top of many decision makers’ priority lists.

“There is a lot of inertia,” said Baylor College of Medicine Professor Steven L. Clark, who has figured in many recent safety initiatives. Echoing others interviewed for this report, Clark attributed the varying practices in the United States to the absence of centralized policy-setting authority that exists in European health care health care systems.¹⁹⁰

Clark credits his profession with making “great strides” in recent years. Clark attributes the recent progress to the adoption of standards by National Quality Forum and to changes in payment policies, such as those penalizing early-elective deliveries. “It took not just 30 years of ACOG saying it, but it also took someone with their hands on the money,” Clark told Public Citizen.¹⁹¹

The success of those steps in reducing early-elective deliveries points to one of the chief lessons of this report. The combination of increased reporting requirements and alignment of payment incentives with best practices may be the most likely way to compel providers to adopt safe practices comprehensively.

Such requirements and policies – whether directed by Medicare (federal), Medicaid (state), nongovernmental agencies or insurance companies – may occur in the form of rewards or penalties. But they need to happen.

¹⁹⁰ Taylor Lincoln, research director of Public Citizen’s Congress Watch division, interview with Steven L. Clark, M.D., professor Baylor College of Medicine/Texas Children’s Hospital (Feb. 19, 2015).

¹⁹¹ *Id.*

Appendix: Response of the American Congress of Obstetricians and Gynecologists to Questions Submitted by Public Citizen

Public Citizen sent the American Congress of Obstetricians and Gynecologists a series of questions. The questions and ACOG's answers are listed here.

Question 1: Does ACOG agree that methods to prevent early deliveries and improve communications, as well as the use of safety bundles engender greater safety?

Response: Yes. That is why ACOG supplements our recommendations, such as our recent Obstetric Care Consensus series, by joining important partnerships focused on implementing change in a meaningful way that improves maternal care, for example the Council on Patient Safety in Women's Health Care, the Choosing Wisely initiative, and the public/private partnership Strong Start Program. We also work with partners such as the March of Dimes, American Academy of Pediatrics, American Association of Family Physicians, and more.

We recognize that the U.S. maternal mortality rate has worsened in the last 14 years, and we need systemic change that will help address that and turn the tide back in the direction of women's health. This means preventing early-elective deliveries, redefining term pregnancy to encourage longer gestation, letting women labor longer before initiating a cesarean section, and more.

This can be done, but it requires a deliberate, individualized approach to implementation that helps each care facility, birth team and individual health professional provide the best care possible to patients. It also takes time. Nine years ago, ACOG called for the end to routine use of episiotomy, but we only just recently saw the first data that demonstrate a decline in use of the procedure. Still, that is progress.

We do believe that an important part of this is ensuring that all members of the care delivery team be aware of the mother's preferences as well as the best practices given her particular medical situation and needs. This includes nurses, midwives, anesthesiologists, etc. A thorough understanding by all members of the delivery team will lead to improved care.

Question 2: Does ACOG agree that adoption of these practices is relatively low across the country?

Response: Adoption of updated and new best practices is variable across the country. It's important to note that there is wide variety among hospitals and their care capabilities. For example, many small, rural community hospitals quite simply don't have the resources or means that some private, urban hospitals may enjoy. That's why we need to focus on issues such as regionalization of care as well as creating tools that will help us get from guidelines to implementation.

Regionalization of care, as addressed in our recent Obstetric Care Consensus on Levels of Maternal Care,¹⁹² will allow facilities to meet the needs of each individual woman, whether she is at low risk for complications or a woman with multiple complicating factors. In it, we recommend an approach for facilities to evaluate and identify their own levels of care capabilities and to set up referral networks to facilities with the capacity to provide higher levels of care. Thus, a woman at high risk of obstetric complications would be referred to and/or could seek out a healthcare facility that is best prepared to meet her unique needs.

Question 3: If so, is my thesis correct that avoidable negative outcomes are likely occurring due to the failure to use these practices?

Response: Negative obstetrics outcomes, unfortunately, cannot be simply traced to individual decisions. Obstetric complications are impacted by the health and medical needs of the woman, by the fetus, and by countless external factors. Of course, our recommendations were compiled with the intent of improving maternal care and outcomes, but it would be a mistake for us to oversimplify the issue.

Labor and delivery can be a very simple, natural thing, but it can also be a very complex, volatile, and rapidly deteriorating situation.

Question 4: Does ACOG believe that policies should be enacted at the state or federal levels, or by accrediting organizations (such as the Joint Commission) to hasten adoption of any or all of these practices?

Response: Legislation is not the answer, nor do we believe that legislators should have a role in choosing or mandating what kind of care a woman receives.¹⁹³ Quite simply, there is no blanket approach to what is a highly regionalized, highly individualized problem.

It's important to remember that during childbirth, we are often dealing with many variables. We know that adverse outcomes can happen in any areas of medicine, especially during the course of labor. Many obstetric complications are not predictable, nor are they all preventable. Doctors need to be able to respond in a way that is most likely to deliver a healthy baby to a healthy mother. They should not have to follow instructions from legislators, who are not the experts in obstetric care.

After all, even when you have a sophisticated labor and delivery unit, even with guidelines and best practices in place and regular team drills, that does not guarantee that everything will turn out all right every time. But what we can do is be as well prepared as we can possibly be.

¹⁹² *Obstetric Care Consensus*, THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS AND SOCIETY FOR MATERNAL-FETAL MEDICINE (March 2014), <http://bit.ly/1ENu98p>.

¹⁹³ Steven E. Weinberger, Hal C. Lawrence III, Douglas E. Henley, Errol R. Alden, and David B. Hoyt, *Legislative Interference With the Patient-Physician Relationship* 367 NEW ENGLAND JOURNAL OF MEDICINE 1557-1559 (October 18, 2012), <http://bit.ly/1vke3TG>.