Executive Summary Checklist

It is well established that the number of cesarean births has increased over time and many of these are unnecessary leading to short-term complications, including blood loss, infection, and venous thrombosis with the risk of maternal and fetal mortality (Bauserman 2015).

Readiness in Every Unit

- Build a health care provider and maternity unit culture that values vaginal birth and understands the risks for current and future pregnancies of cesarean birth (Chaillet 2007, Spong 2012).
- Optimize patient and family engagement in education, informed consent, and shared decision making about normal healthy labor and birth (Declercq 2017).
- Develop healthcare provider expertise in approaches to labor that maximize the likelihood of vaginal birth in areas such as assessment of labor, methods to promote labor progress, labor support, and both pharmacologic and non-pharmacologic pain management and shared decision-making. (Chaillet 2007, Bisognano 2014, Hodnett 2013)

Recognition & Prevention in Every Patient

- Implement standardized admission criteria, triage management, education, and support for women presenting in spontaneous labor (Spong 2012, Safe Prevention of primary cesarean delivery ACOG/SMFM 2014, ACOG 2017)
- Offer standardized techniques of pain management and comfort measures that promote labor progress and prevent dysfunctional labor (Hodnett 2013)
- Use standardized methods in the assessment of the fetal heart rate status including interpretation, documentation using NICHD terminology and encourage methods that promote freedom of movement (Macones 2008)
- Adopt protocols for timely identification of specific problems, such as herpes and breech presentation, for patients who can benefit from proactive intervention before labor to reduce the risk for cesarean birth (Hollier 2008, Hofmeyr 2015)

Response

- Have available an in-house maternity care health care provider or alternative coverage that guarantees timely and effective responses to labor problems (Rosenstein 2015, Iriye 2013, Nijagal 2015)
- Uphold standardized induction scheduling to ensure proper selection and preparation of women undergoing induction (ACOG 2009)
- All providers follow standardized evidence-based labor algorithms, policies and techniques which allow for prompt recognition and treatment of dystocia (Spong 2012, Zhang 2010)
- Adopt policies that outline standard responses to abnormal fetal heart rate patterns and uterine activity (Clark 2013)
- Make available special expertise and techniques to lessen the need for cesarean birth, such as breech version, instrumented birth and twin birth protocols (Hollier 2008, Barrett 2013)

Reporting

- Track and report labor and cesarean measures in sufficient detail to: 1) compare to similar institutions, 2) conduct case review and system analysis to drive care improvement, and 3) assess individual health care provider performance (Challitt 2007, CMQCC 2016)
- Track appropriate metrics and balancing measures that assess maternal and newborn outcomes resulting from changes in labor management strategies to ensure safety
**The Performance Gap**

The cesarean section, or C-section, is the United States’ most commonly performed surgery with approximately 1.3 million women giving birth by cesarean annually (HCUP, 2014). Between 1970 and 2009, the total cesarean rate rose from 5.5% to a high of 32.9% and current data show that it remains plateaued at 31.9% (Placek and Taffel, 1981; Martin et al., 2011; Martin et al., 2017). Among first-time mothers with low-risk births, also called the Nulliparous, Term, Singleton, Vertex (NTSV) population, 25.7% give birth by cesarean, a 40% increase since 1997 (Martin et al., 2017). Evidence shows that the rise in utilization of the cesarean was not accompanied by a reduction in cases of perinatal morbidity and mortality (Gregory et al., 2011), nor can it be explained solely by patient characteristics, demographics or comorbidities (Li, 2003).

Rates of cesarean utilization rose globally as well (Betran et al., 2016), primarily in developed countries. In contrast to the trend of over-utilization in many wealthier countries, women in many developing regions of the world do not have appropriate access to obstetric care (and therefore cesarean births), resulting in high rates of perinatal injury and death (Thomas et al., 2016). Increased incidence of cesarean births in countries lacking the infrastructure to safely manage the downstream consequences of a primary cesarean has resulted in an increased incidence of postpartum hemorrhage, abnormal placentation, infection and other complications associated with perinatal morbidity and mortality, illustrating the positive and negative public health implications of both the short and long-term consequences of primary cesarean births at the population level (Beltman et al., 2011).

A 2013 study identified a ten-fold variation in cesarean rates across the United States (U.S.) (Kozhimannil et al., 2013).

While the overall trend of rising cesarean rates is attributed to a complex, multifactorial set of issues including payment incentives or disincentives (Main et al., 2012), liability fears (Main et al., 2006), cultural acceptance and resource management (Plough et al., 2017), evidence shows that unwarranted variation in rates between hospitals and providers is largely due to subjectivity in clinical decision-making. Over 60% of hospital variation in NTSV patients can be attributed to first birth labor induction rates and first birth early labor admission rates (Main et al, 2006).

Designed to identify variations between hospitals, the NTSV Cesarean Birth measure was endorsed by the National Quality Forum in 2008 and is used for hospital data reporting by The Joint Commission and the Leapfrog Group. It measures a specific subset of patients (NTSV) whose outcomes are shown to be largely influenced by physician factors, rather than patient characteristics or obstetric diagnoses, and specifically identifies variations between birthing facilities (Joint Commission, 2017).

**Risks and Sequelae of the Primary Cesarean Birth**

The risk of severe maternal morbidities is higher as a result of a cesarean birth than from a vaginal birth. Obstetric hemorrhage, complications from anesthesia, venous thromboembolism (VTE), shock, maternal cardiac arrest, uterine rupture and major infection occur at a rate of 2.7% with a cesarean birth, three times that of a vaginal birth (0.9%) (Liu et al., 2007).

Cesarean births carry a four-fold risk of maternal death compared to vaginal births and amniotic fluid embolism is 2-3 times more likely with a cesarean birth. Vaginal births have shorter average length-of-stay and shorter recovery times than cesarean births, while cesareans are associated with more neonatal intensive care unit stays and delays in the establishment of breastfeeding when compared to vaginal births. Vaginal births carry an elevated risk of third and fourth degree perineal lacerations (Caughey et al., 2014).

Any primary cesarean birth, with or without sound medical justification, disrupts a woman’s reproductive years. CDC data show that nearly 88% of the approximate 604,000 women with a history of prior cesarean who gave birth in the U.S. in 2016 did so by cesarean section (Driscol, 2017). The rate of vaginal birth after cesarean (VBAC) increased from 3% following the 1981 National Institutes of Health Consensus Conference on Cesarean Childbirth to a high of 28.3% in 1996, decreasing to a low of 8.3% in 2007 (Gregory et al., 2010), a drop which is commonly attributed to fear of liability or a hospital’s inability to meet the previously published safety recommendations for VBAC, such as having a physician “immediately available”. These limited options for patients result in an unknown proportion of patients in the U.S. who may prefer the option of VBAC, yet must consent to repeat cesarean birth or attempt an out-of-hospital trial of labor if they are unable or unwilling to travel to the nearest hospital that will offer a trial of labor after cesarean (TOLAC). In an effort to increase access to VBAC, ACOG published updated recommendations in November 2017 which removed the “immediately available” language and state that any Level I (Basic Care) facility per ACOG’s Levels of Maternal Care standards can offer TOLAC (Grobman et al., 2017).
Each repeat cesarean, however, increases a patient’s risk of placental abnormalities such as placenta accreta and the associated complications. Placenta accreta is a condition in which some or all of the placenta attaches abnormally to the wall of the uterus. The complications associated with placenta accreta include: nearly 90% of patients requiring a blood transfusion; bladder and bowel damage; amniotic fluid embolism; venous thromboembolism; infection and an estimated maternal mortality rate of 7%. The increase in incidence of placenta accreta parallels the rise in the cesarean rate, and the estimated ratio of deliveries affected by placenta accreta in the last decade is 1:333 (Belfort et al., 2010).

In 2014, SMFM and ACOG published a consensus statement on the evidence behind safely reducing primary cesarean rates (Caughey et al., 2014). Other women’s health and obstetric safety organizations, such as the CMQCC and the Council of Patient Safety on Women’s Health, have since published comprehensive toolkits to implement the recommendation (CMQCC, 2016; CPSWH, 2016). Global attention has been focused on both the over-use and under-use of cesarean births with an increasing emphasis on optimizing the rate of cesarean births via regionalization of risk-appropriate care, access to trained birth attendants, quality improvement projects, payment reform and public-facing awareness and educational campaigns (WHO, 2017; CDC, 2017; WHO, n.d.; Haelle, 2017).

With a goal of scaling back cesarean birth over-utilization while maintaining safety for mothers and babies, a pilot program which rapidly lowered NTSV cesarean rates in several California hospitals also established two separate baselines for infants and mothers. Coordinated by the CMQCC, three hospitals seeking to lower their NTSV rates collected data on balancing measures, including the National Quality Forum’s Unexpected Newborn Complications measure and 3rd/4th degree perineal lacerations occurring in vaginal births (Lagrew et al., 2017). The hospitals averaged an 18.6% reduction in their NTSV rates in 2015, while newborn complications fell significantly by 24.5% and 3rd/4th degree perineal lacerations dropped by 4.7%.

Other recent success stories include quality improvement projects at:
- Beth Israel Deaconess Medical Center in Boston, MA (Vadnais et al., 2017)
- Carolinas Health System, headquartered in North Carolina (Bell et al., 2017)
- Brazil’s Hospital Israelita Albert Einstein (HIAE) (IHI, 2017)

The World Health Organization stated in 2015 that “[e]very effort should be made to provide caesarean sections to women in need, rather than striving to achieve a specific rate.” Regional optimization of cesarean section utilization saves lives and prevents maternal and perinatal morbidity (WHO, 2015).

Leadership Plan
- Individual practices, clinics, hospitals, birth centers and health systems should develop a culture of valuing vaginal birth by preparing their providers, redesigning their care and working with women to achieve lower cesarean section rates.
- Leadership should give staff appropriate support and educational time to focus on clinical changes and labor techniques which have been shown to reduce unnecessary cesarean birth and hold managers responsible for implementing such changes.
- Quality improvement practices should incorporate following cesarean section rates, especially those such as the nulliparous term singleton vertex cesarean rate, and make for hospital and system-wide review while transparently sharing with providers and patients.
- Special protocols and precautions should be developed and executed targeted to address the high-risk problems associated with a prior cesarean section and especially those patients with a suspected morbidly adherent placenta.
- Facilities should be redesigned to support physiologic labor methods and provider teams restructured to ensure prompt intervention for abnormal labors.
- Administrative and financial leadership should prepare for reimbursement strategies which favor vaginal delivery and shared risk.

Identify: Senior executive leadership which is committed to a culture of valuing vaginal birth and avoiding unnecessary cesarean section.
- The team is led by a physician and administrative champions who are well respected and knowledgeable.
- Obstetrician/Maternal Fetal Medicine specialist
- Nursing leaders
- Obstetrical anesthesiologist

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● Physicians in training (residents/fellows)
● Nurse Midwives/Nurse practitioners
● Doula
● Childbirth educators
● Labor/OR nurses
● Quality improvement staff
● Data analytics/information technology/EMR design and maintenance team
● Pharmacy

**Practice Plan**

**Complete:** an in-depth analysis of the facility’s current rate of cesarean sections with detailed analysis of the following:

- Indications for procedures
- Specific rates of total, primary, repeat, nulliparous term singleton vertex for the institution and individual providers
- Analysis of risk factors such as parity, age of mothers, concurrent medical diagnoses
- Audit of cesarean sections with tool evaluating possible interventions including stage of labor, induction protocols, cervical ripening, use of instrumented delivery (example of audit tools in referenced toolkits)
- Rates of inductions and techniques utilized
- Evaluation of anesthesia techniques and availability
- Scheduling protocols
- Consenting procedures for elective cesareans for declined trial of labor without medical indications
- Compliance with standard labor support techniques
- Compliance with standard intervention for failure to progress
- Compliance with standard

**Identify:** Gaps in procedures, protocols and care which can be utilized to promote vaginal birth

**Adhere:** Guidelines outlined by the ACOG/SMFM consensus statement on preventing the first cesarean section and other recommendations in toolkits such as the CMQCC Toolkit on Promoting Vaginal Birth

**Implement:** Interventions for reducing the need for cesarean section.

- Ensure that a culture valuing vaginal delivery and avoiding unnecessary cesarean section is present in the institution.
- Promote a shared decision-making process where prenatal providers discuss and promote patient-centered labor support and management.
- Develop staff expertise in labor support and management which maximizes the likelihood of successful safe vaginal delivery.
- Standardized admission criteria to prevent latent phase labor patients being admitted and requiring aggressive management to get into active labor.
- Offer a multitude of choices pharmacologic and physiologic methods for pain management to ensure patient comfort.
- Standardized intervention plans based upon defined fetal heart rate characteristics which lead to prompt appropriate intervention and minimize the risk of over intervention.
- Adherence to evidenced-based algorithms for intervention for failure to progress which increase successful labors and have minimal side effects to the mother and fetus.
- Make available standard protocols, expertise and techniques for decreasing the cesarean rate in breech presentations, history of genital herpes and twin gestations.
- Transparent reporting of cesarean section rates, risk factors and other information by facility and providers.

**Educate:** Patients and families of the long term risks and benefits of cesarean section and the benefits of vaginal birth. Review and train all providers the various techniques and protocols which reduce the need for protracted and unsuccessful labors.

**Technology Plan**
Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

Electronic Health Record (EHR)

- **Proper Data Elements**: The electronic medical record should be reviewed to make sure there are the proper data elements which are formatted and defined into standard terminologies for incorporating the alerting, measure reporting and documentation needs. For example, where national or international standards for definitions and value sets are available, such as fetal heart rate interpretations defined by NIHCD consensus. This will allow for comparisons between institutions and help in defining normal practice and thresholds.

- **Labor Tools**: Standard reporting tools, such as a labor curve, intervention curve and trending visualizations for fetal heart rate interpretations, which enable the providers to more accurately assess the overall labor status should be incorporated into systems.

- **Device Integration**: Robust device integration of fetal monitoring data, intravenous pumps, vital sign devices can reduce mundane documentation for caregivers and allow them to devote more of their time in more value-added processes such as labor support. In addition, newer monitoring devices incorporate continuous decision support/artificial intelligence and analysis which should integrate into the electronic record to ensure a single source of truth and improve provider interpretations.

- **Decision Support**: Standard practice alerts, used in a judicious manner to prevent alert fatigue, can incorporate best practice guidelines for labor interventions and responses to fetal heart rate patterns in standardized fashion. Other methods of decision support can be incorporated into documentation tools and order sets to make better documentation/reporting and standardized protocols being more frequently followed. Best practice content sources can be built into standard workflows allowing for clinicians to review more easily.

- **Embedded reporting data elements**: Collection of clinical data should become part of standardized documentation and most electronic records have the capacity to collect on-going data entered by nurses, physicians, and others. Specific data elements for labor support can assist in reviewing and training to these new techniques and evaluate on-going compliance. These should be carefully reviewed and maintained so that robust data analytics can be routine.

**Fetal Monitors**: Newer fetal monitors are having strip analysis artificial intelligence algorithms incorporated into the systems. These will aid clinicians in their interpretation skills and allow for easier and more complete documentation. Wireless monitoring also can lead to greater ambulation and positioning options for patients in active labor.

**Cervical Ripening Techniques**: Device manufacturers and pharmaceutical companies should expand the list of options for safe and effective ripening of the cervix. Induction of labor with an unripe cervix will be the target of many programs to reduce and/or eliminate. Nonetheless, the practice will be required in many labors and better methods are needed. In addition, the goal for safe outpatient methods should be proposed to reduce cost.

**Web/Mobile Based Learning Tools**: All major guidelines call for better education of providers and patients. Unfortunately, traditional didactic teaching will not be possible on that scale and newer online adult learning techniques will be required for cost-effective learning. For patients, convenient methods on hand-held devices can be developed for both learning and communication. Paired with group prenatal care the patients can also work and learn together to understand risks, benefits and techniques of modern labor.

**Workgroup**

**Chair:**
David Lagrew (Providence St. Joseph Health)

**Members:**
Gillian Abir (Stanford University)
Jill Arnold (National Accreta Foundation)
Ari Babaknia (Chapman University)

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Conflicts of Interest Disclosure

The Patient Safety Movement Foundation partners with as many stakeholders as possible to focus on how to address patient safety challenges. The recommendations in the APSS are developed by workgroups that may include patient safety experts, healthcare technology professionals, hospital leaders, patient advocates, and medical technology industry volunteers. Some of the APSS recommend technologies offered by companies involved in the Patient Safety Movement Foundation that the workgroups have concluded, based on available evidence, are beneficial in addressing the patient safety issues addressed in the APSS. Workgroup members are required to disclose any potential conflicts of interest.

References


