Executive Summary Checklist

Obstetric hemorrhage is the most common complication in pregnancy leading to severe maternal morbidity and preventable mortality.

Prevention of PPH-related maternal mortality

- Commitment from hospital governance and senior administrative leadership to support maternal safety initiatives like PPH in their healthcare system.

Readiness in Every Unit

- Create a hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches based on the recommendations referenced (ACOG, 2016; Lyndon et al., 2010; ACOG, 2014; FPQC, 2014; AWHONN, 2014; Bingham et al., 2010).
- Ensure teams have immediate access to hemorrhage medications (kit or equivalent)
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)
- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)
- Unit education on protocols, unit-based drills (with post-drill debriefs)

Recognition & Prevention in Every Patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Assessment of:
  - Retained placenta
  - Failure to progress during the second stage
  - Lacerations
  - Morbidly adherent placenta
  - Instrumental delivery
  - Large for gestational age newborn (>4000 gm)
  - Hypertensive disorders
  - Induction of labor
  - Prolonged 1st or second stage of labor
- Measurement of cumulative blood loss (formal, as quantitative as possible)
  - Weigh the pads for quantitative measurement
- Active management of the 3rd stage of labor (department-wide protocol)
Response

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
  - Obstetric rapid response teams, TeamStepps.
- Support program for patients, families, and staff for all significant hemorrhages

Reporting

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of serious hemorrhages for systems issues
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee
The Performance Gap

Global maternal deaths have fallen 44% since 1990 but still over 303,000 women die each year from complications related to pregnancy, delivery, or within the first six weeks after delivery (WHO, 2015). A majority of deaths (64%) occur from the day of delivery through 41 days postpartum (Creanga et al., 2015). That equates to about 830 women dying every day, 550 occurring in sub-Saharan Africa, 180 in Southern Asia, and 5 in developed countries (WHO, 2015).

Within the United States it is estimated that approximately 600 women die each year; 14.0 per 100,000 live births (CDC, 2015; WHO and UNICEF, 2015). While that number seems to pale in comparison on the global scale the US ranks 46th in the world for maternal mortality (Agrawal, 2015). Of all industrialized countries, the US lags behind Kazakhstan, Libya and Qatar and is one of only 13 countries whose rates have continued to decline instead of improving over the last 25 years (Kempner, 2015).

A 2015 report by the United Nations (UN) agencies and World Bank Group, Trends in Maternal Mortality: 1990 to 2015, was generated to gauge whether the UN’s Millennium Development Goals would be reached (FPQC, 2014). The 2015 target was to reduce maternal mortality by three-quarters. Only 9 of the 100 countries participating reached the 2015 goal so the new target is to reduce global average maternal death rates below 70 per 100,000 live births by the year 2030, with no country above 140 per 100,000 live births (ACOG, 2006).

The reasons for the overall increase in maternal mortality within the US are unclear. Delaying childbearing and assisted reproductive technology (ie: in-vitro fertilization) have given rise to older mothers with an increased risk of complications than younger women (Joy et al., 2000; Bewley et al., 2005). Additionally, the obesity epidemic gives rise to chronic conditions such as hypertension, diabetes, and chronic heart disease increase the risk of complications during pregnancy (CDC, 2015; Kuklina et al., 2009; Albrecht et al., 2010; Kuklina et al., 2012).

Over a third of maternal deaths in the US are preventable, 40% could be avoided if women had access to quality care (Berg et al, 2005). Most notably, black women have a 3 to 4-fold increased risk of death due to pregnancy compared to any other race or ethnicity (Creanga et al., 2014; Callaghan et al., 2008). The reasons are extremely complex and not well documented. Moreover, severe maternal morbidity is much more prevalent and preventable, affecting tens of thousands of women each year (Callaghan et al., 2012; Callaghan et al., 2008).

Postpartum Hemorrhage (PPH)

Obstetric hemorrhage remains among the leading global causes of severe maternal morbidity and mortality (Callaghan et al., 2010; Calvert et al., 2012; Ross and Mullin, 2012). In some developing countries, the maternal mortality rate is as high as 1 percent of live births with nearly one-fourth of those deaths being attributable to postpartum hemorrhage (PPH) (AbouZahr, 1998). According to the most recent mortality data reported to the CDC in 2011-2012, 11% of pregnancy-related deaths in the U.S. are caused by PP (Berg et al., 1996). Between 1994-2006, the number of PPH cases has increased more than 25 percent, potentially driven by a 50 percent increase in uterine atony.

PPH is a "low-volume, high-risk" event for birth facilities, which has led to the down-prioritization for developing standardized intervention protocols (Lyndon et al., 2015). Limited consideration for the implementation of coordinated approaches persists despite a consistent global recognition that the lack of communication, patient engagement, and clinical intervention strategies for managing acute hemorrhage in the postpartum period lead to an increase in maternal morbidity and mortality (Lewis et al., 2007; CAPH, 2011).

There are many potential causes for PPH, but chief among them is uterine atony or the inability of the uterus to contract and retract following childbirth. PPH in a previous pregnancy also can increase the risk of hemorrhage during a subsequent delivery. A contributing factor to the lack of standard coordinated approaches to PPH is the issue that there is no precise definition for the condition. Literature defines PPH as blood loss of more than 500 mL following a vaginal delivery or more than 1000 mL following a cesarean section delivery (Baskett, 1999). PPH is also classified by time frame with Primary PPH occurring in the first twenty-four hours and secondary or late-term PPH occurring in the subsequent period.

Further, blood loss during delivery can be difficult to measure, which is attributable to lack of standardization on how to manage blood collected during childbirth as well as improvements in medical products that can absorb a deceivingly high amount of fluid. The lack of clear guidelines for measuring blood loss during childbirth often leads to underestimation and a clinician may not diagnose Primary PPH.
Population-based studies have identified some significant risk factors that may result in PPH:

- Retained Placenta
- Failure to Progress During the Second Stage Of Labor
- Placenta Acreta, Increta, and Percreta
- Lacerations
- Instrumental Delivery
- Large Gestational Age (LGA) Newborns
- Hypertensive Disorders
- Induced Labor
- Augmentation of Labor With Oxytocin (Scheiner et al., 2005)

Another issue that leads to the missed diagnosis of PPH is the physiological difference between expectant mothers. On average, mothers of single pregnancies have between 30-50 percent higher blood volume than a non-pregnant woman. Within the pregnant population, other blood-related physiological traits such as anemia, underlying cardiac conditions, or preeclampsia will also impact a mother's ability to tolerate blood loss.

Lack of timely and medically appropriate response to PPH is what results in poor outcomes. Early recognition of PPH and a timely, coordinated intervention are essential to reducing associated morbidity and mortality.

Leadership Plan

- Individual practices, hospitals, and hospital systems should develop systems of care that deliver risk-appropriate care to women pre- and post-delivery.
- Managing PPH requires a comprehensive and interdisciplinary commitment from administrative and medical leaders.
- While there are prescriptive clinical interventions, highlighted in the practice plan, engaging expectant mothers and those supporting them is critical to the holistic improvement of an institution's obstetric safety including PPH.
- Women with risk factors for PPH should be identified and counseled as appropriate for their level of risk and gestational age.
- It is important that leaders ensure availability of resources such as personnel, equipment, blood products and trained personnel.
- Establishing PPH protocols, creation of PPH kits, and appropriate training and simulation drills reduces the risk of PPH.

Practice Plan

The Council on Patient Safety in Women’s Health Care developed comprehensive bundles and list of resources that applies to the prevention of harm from PPH and other maternal safety issues. The bundles are a roadmap for hospitals to use in the prevention of harm for these two pregnancy-related conditions.

It is important to remember that approach to management of PPH depends on the etiology in a patient who has had a vaginal delivery or a cesarean section. Treatment of atony depends on the route of delivery. Coagulopathies are managed medically whilst trauma related PPH is managed surgically.

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)
  - Web-based/EHR predictive algorithms that elicit specific data such as but not limited to vital signs (BP, Temp, HR, RR, and SpO2) lab values, nurses notes, and event reports.
- Close monitoring of hemodynamics such as heart rate and blood pressure
- Ultrasound technology for assessment of retained products, retained placenta or abruption.

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Metrics

Topic:
Severe Maternal Morbidity among Hemorrhage Cases

Outcome Measure Formula:

**Numerator:** Among the denominator, all cases with any SMM code

**Denominator:** All mothers during their birth admission, excluding ectopics and miscarriages, meeting one of the following criteria:
- Presence of an Abruption, Previa or Antepartum hemorrhage diagnosis code
- Presence of transfusion procedure code without a sickle cell crisis diagnosis code
- Presence of a Postpartum hemorrhage diagnosis code

*Rate is typically displayed as: All cases w/ any SMM code/All mothers meeting denominator criteria*

Metric Recommendations:

**Direct Impact:**
All pregnant patients

**Lives Spared Harm:**

\[
\text{Live Spared Harm} = (SMM \ Rate_{\text{baseline}} - SMM \ Rate_{\text{measurement}}) \times \text{Denominator Procedures}_{\text{measurement}}
\]

**Notes:**
Since this is a morbidity measure, the lives saved calculation is not applicable.

**Data Collection:**
HDD File (ICD9/ICD10)
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Conflicts of Interest Disclosure
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Actionable Patient Safety Solution (APSS) #11B:
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Executive Summary Checklist

Complications arising from hypertensive disorders of pregnancy are among the leading causes of severe maternal morbidity and preventable maternal mortality.

Readiness Across Every Unit

- Adopt standards for early warning signs, diagnostic criteria, monitoring and treatment of severe pre-eclampsia/eclampsia (include order sets and algorithms) (ACOG, n.d.; COP, 2015; CMQCC, n.d.; ACOG, 2013; NYDH, 2013)
- Unit education on protocols, unit-based drills (with post-drill debriefs)
- Process for timely triage and evaluation of pregnant and postpartum women with hypertension including ED and outpatient areas
- Rapid access to medications used for severe hypertension/eclampsia: Medications should be stocked and immediately available on L&D and in other areas where patients may be treated. Include brief guide for administration and dosage.
- System plan for escalation, obtaining appropriate consultation, and maternal transport, as needed

Recognition

- Adoption of a standard protocol for measurement and assessment of BP and urine protein for all pregnant and postpartum women (CPSWHC, 2016)
- Implementation of standard response to maternal early warning signs including listening to and investigating patient symptoms and assessment of labs (e.g. CBC with platelets, AST and ALT)
- Implementation of facility-wide standards for educating prenatal and postpartum women on signs and symptoms of hypertension and pre-eclampsia

Response

- Facility-wide standard protocols with checklists and escalation policies for management and treatment of:
  - Severe hypertension, eclampsia, seizure prophylaxis, and magnesium over-dosage
  - Postpartum presentation of severe hypertension/pre-eclampsia
- Minimum requirements for protocol:
  - Notification of physician or primary care provider if systolic BP ≥ 160 or diastolic BP ≥ 110 for two measurements within 15 minutes
  - After the second elevated reading, treatment should be initiated ASAP (within 60 minutes of verification)
  - Includes onset and duration of magnesium sulfate therapy
  - Includes escalation measures for those unresponsive to standard treatment
  - Describes manner and verification of follow-up within 7 to 14 days postpartum
  - Describe postpartum patient education for women with preeclampsia
- Support plan for patients, families, and staff for ICU admissions and serious complications of severe hypertension

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Reporting/Learning in Every Unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities
- Multidisciplinary review of all severe hypertension/eclampsia cases admitted to ICU for systems issues
- Monitor outcomes and process metrics (CPSWHC, 2016)
  - Adherence to protocols for acute management, appropriateness of response to early warning criteria
  - Documentation of education of pregnant and postpartum women about symptoms of preeclampsia for women at risk
  - Occurrence of post severe maternal morbidity (SMM) event debrief and outcomes
  - Timeliness of medication administration, triage and evaluation
The Performance Gap

Global maternal deaths have fallen 44% since 1990 but still over 303,000 women die each year from complications related to pregnancy, delivery, or within the first six weeks after delivery (WHO, 2015). A majority of deaths (64%) occur from the day of delivery through 41 days postpartum (Creanga et al., 2015). That equates to about 830 women dying every day, 550 occurring in sub-Saharan Africa, 180 in Southern Asia, and 5 in developed countries (WHO, 2015).

Within the United States it is estimated that approximately 600 women die each year; 14.0 per 100,000 live births (CDC, 2015; WHO and Unicef, 2015). While that number seems to pale in comparison on the global scale the US ranks 46th in the world for maternal mortality (Agrawal, 2015). Of all industrialized countries, the US lags behind Kazakhstan, Libya and Qatar and is one of only 13 countries whose rates have continued to decline instead of improving over the last 25 years (Kempner, 2015).

A 2015 report by the United Nations (UN) agencies and World Bank Group, Trends in Maternal Mortality: 1990 to 2015, was generated to gauge whether the UN’s Millennium Development Goals would be reached. The 2015 target was to reduce maternal mortality by three-quarters. Only 9 of the 100 countries participating reached the 2015 goal so the new target is to reduce global average maternal death rates below 70 per 100,000 live births by the year 2030, with no country above 140 per 100,000 live births.

The reasons for the overall increase in maternal mortality within the US are unclear. Delaying childbearing and assisted reproductive technology (ie: in-vitro fertilization) have given rise to older mothers with an increased risk of complications than younger women (Jolly et al., 2000; Bewley et al., 2005). Additionally, the obesity epidemic gives rise to chronic conditions such as hypertension, diabetes, and chronic heart disease increase the risk of complications during pregnancy (CDC, 3015; Kuklina et al., 2009; Albrecht et al., 2010; Kuklina and Callaghan, 2012).

Over a third of maternal deaths in the US are preventable, 40% could be avoided if women had access to quality care (Berg et al., 2005). Most notably, black women have a 3 to 4-fold increased risk of death due to pregnancy compared to any other race or ethnicity (Creanga et al., 2014). The reasons are extremely complex and not well documented. Moreover, severe maternal morbidity is much more prevalent and preventable, affecting tens of thousands of women each year (Callaghan et al., 2012; Callaghan et al., 2008).

Hypertension and Preeclampsia

Hypertensive disorders occur in 12-22% of all pregnancies and are one of the leading conditions that impact women during pregnancy. Hypertension may be pre-existent, may be induced by the pregnancy or both may co-occur (Singh et al., 2014). Approximately 15-17% of all maternal mortality is caused by hypertensive disorders which include: chronic (preexisting) hypertension, gestational hypertension, preeclampsia, severe preeclampsia, eclampsia and HELLP (Hemolysis, Elevated Liver Enzymes, Low Platelet Count) (Walker, 2000). The causes of pregnancy-induced hypertension and the risk factors are still being widely studied. However, hypertension among pregnant women in the US has increased significantly over the last two decades due to increased rates of obesity and diabetes (Leddy et al., 2008). During pregnancy, hypertensive disorders not only affect the mother but also may contribute to significant neonatal morbidity and mortality (Backes et al., 2011).

Chronic hypertension during pregnancy is defined as blood pressure (BP) (mmHg) of ≥140/90 mmHg, prior to the 20th week of pregnancy and leads to complications in 5% of all pregnancies (Seely and Maxwell, 2007; Druzin et al., 2013; Yanit et al., 2012). Preeclampsia is defined as a BP of ≥160/110 mmHg and associated with proteinuria ≥5g per day. Gestational hypertension is defined as new hypertension associated with a systolic BP of ≥140 mmHg or diastolic BP ≥90 mmHg, or both presenting at or after 20-weeks gestation without proteinuria or other features of preeclampsia. Preeclampsia is considered severe when the condition affects multiple organs, such as: thrombocytopenia (platelet count ≤100,000/uL), pulmonary edema, or oliguria (≤500ml per day). Mild preeclampsia is characterized by an elevated BP ≤160/120 with proteinuria ≥300mg but less than 5g per day (Sibai, 2003).

Studies show that between 50-70% of deaths due to severe preeclampsia are preventable (Merkatz and Thompson, 1990; WHO, 2011; Aukes et al., 2007). The leading patient factors among maternal deaths due to preeclampsia were: delays in seeking care (42%), presumed lack of knowledge regarding the severity of a symptom or condition (39%) and underlying medical condition (39%) (Main et al., 2015).
Prevention

No clear strategies have emerged to prevent the onset of preeclampsia though some, like lose dose aspirin taken daily starting at the end of the first trimester have been shown to reduce preeclampsia among high risk women. Once diagnosed with preeclampsia it is important to recognize worsening signs and symptoms and prevent eclamptic seizures and stroke.

In the past, the focus was placed on the prevention of eclamptic seizures, which is associated with an increase in both neonatal and maternal morbidity and mortality. Delay in treating hypertension is the primary cause of concern. The majority of women who die of severe preeclampsia die from stroke (Bushnell and Chireau, 2011). Stroke can only be prevented with the rapid infusion or delivery of antihypertensive medications. This is the key to saving lives from complications of severe preeclampsia is administering an antihypertensive medication within 60 minutes. are forefront to prevent complications due to preeclampsia. Eclamptic seizures can be prevented and treated through the administration of magnesium sulfate (Sibai, 2004; MTCG, 2002; Duley et al., 2003; Martin et al., 2005. Unlike the relatively straightforward prevention of eclamptic seizures, there is a gap in knowledge and application of therapeutic interventions for stroke prevention through controlled BP. Typically, treatment of systolic BP of ≥160, and/or diastolic BP ≤105 has been recommended (Kayem et al., 2011). In practice, clinicians institute therapies at a lower level of systolic and/or diastolic blood pressures.

The most important intervention in the treatment for preeclampsia/eclampsia is delivery of the fetus and placenta. The phrase “delivery is the cure” is widely accepted however in many cases preeclampsia/eclampsia may continue for a variable amount of time after delivery. For this reason, mothers post-delivery should continue to be evaluated if they were preeclamptic. Serious clinical outcomes can continue postpartum for days and even weeks (Chescheir, 2015).

Early recognition and timely treatment of preeclampsia is a critical factor in reducing maternal morbidity and mortality.

Leadership Plan

- Individual practices, hospitals, and hospital systems should develop systems of care that deliver risk-appropriate care to women pre- and post-delivery.
- A multidisciplinary team should be built to give quality care to a woman with severe preeclampsia. The team should be comprised of an obstetric provider credentialed to perform cesarean sections, nursing, anesthesia, NICU, laboratory, blood bank, social work and other sub-specialties as needed (Aukes et al., 2007).

Practice Plan

The Council on Patient Safety in Women’s Health Care developed comprehensive bundles and list of resources that applies to the prevention of harm from severe preeclampsia. The bundles are a roadmap for hospitals to use in the prevention of harm.

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)
  - Web-based/EHR predictive algorithms that elicit specific data such as but not limited to vital signs (BP, Temp, HR, RR, and SpO2) lab values, nurses notes, and event reports.
- Blood Pressure Measurement Devices
Metrics

Topic 1:
Severe Maternal Morbidity among Preeclampsia Cases

Outcome Measure Formula:
Numerator: Among the denominator, cases with any SMM code
Denominator: All mothers during their birth admission, excluding ectopics and miscarriages, with one of the following diagnosis codes:
- Severe Preeclampsia
- Eclampsia
- Preeclampsia superimposed on pre-existing hypertension

Metric Recommendations:
Direct Impact:
All pregnant patients

Lives Spared Harm:

\[ \text{Lives Spared Harm} = (\text{SMM Rate}_{\text{baseline}} - \text{SMM Rate}_{\text{measurement}}) \times \text{Denominator}_{\text{baseline}} \]

Notes:
Since this is a morbidity measure, the lives saved calculation is not applicable.

Data Collection:
HDD File (ICD9/ICD10)

Topic 2:
Severe Maternal Morbidity (excluding transfusion codes) among Preeclampsia Cases

Outcome Measure Formula:
Numerator: Among the denominator, all cases with any non-transfusion SMM code
Denominator: All mothers during their birth admission, excluding ectopics and miscarriages, with one of the following diagnosis codes:
- Severe Preeclampsia
- Eclampsia
- Preeclampsia superimposed on pre-existing hypertension

Metric Recommendations:
Direct Impact:
All pregnant patients

Lives Spared Harm:

\[ \text{Lives Spared Harm} = (\text{SMM Rate}_{\text{baseline}} - \text{SMM Rate}_{\text{measurement}}) \times \text{Denominator}_{\text{baseline}} \]

Notes:
Since this is a morbidity measure, the lives saved calculation is not applicable.
Data Collection:
HDD File (ICD9/ICD10)

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Actionable Patient Safety Solution (APSS) #11C: REDUCING UNNECESSARY C-SECTIONS

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 (Driscoll, 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 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
- 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

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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


