

National Partnership for Maternal Safety: Maternal Safety Bundles

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Abstract US maternal mortality has unexpectedly increased over the past 25 years. A national imperative exists to identify and evaluate the causes of these deaths as well as characterize preventable factors. Evidence demonstrates that implementing comprehensive protocols improves outcomes. In fact, bundles, evidence-based interventions that are designed to be implemented together resulting in improved outcome, are recognized as the explanation for the dramatic decrease in California's maternal mortality rate as compared to the continued rise in national maternal mortality rate between 2008 and 2013. Consequently, the National Partnership for Maternal Safety (NPMS), housed within the Council on Patient Safety in Women's Health Care, created bundles for each of the three most common preventable conditions resulting in severe maternal morbidity or mortality: obstetric hemorrhage, severe hypertension, and venous thromboembolism.

Keywords Maternal safety · Maternal morbidity · Maternal mortality · Bundles · Evidence-based implementation · Obstetric care management plans · Standardization · Obstetric hemorrhage · Hypertensive disorders of pregnancy · Thromboembolic disease

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Introduction

The USA is one of only eight countries worldwide and the only developed nation where maternal mortality has increased since 1990 [1]. Parturients in this country are three times more likely to die from pregnancy related complications than women in Britain, Germany, or Japan [1]. These findings are shocking, especially considering that prior to 1982, maternal mortality in the USA had improved dramatically over the last century [2]. Improvement in survival was attributed to advances in medical care, more deliveries in hospitals, more babies being born by the hands of those trained in obstetrical care, and better aseptic technique [3].

Traditionally, the most common causes of maternal death have been hemorrhage, hypertensive disorders, thromboembolic events, and infections [4•, 5]. The fraction of deaths due to these conventional causes is now declining, and a significant proportion of maternal deaths are attributable to cardiovascular conditions and other co-existing medical diseases [5, 6]. Interestingly, anesthetic complications leading to mortality are becoming rarer, estimated to be 1.2 per 1 million live births, a 60% decline since 1979 [7]. These changes underscore the need for anesthesiologists not only to provide safe labor analgesia and anesthesia for cesarean delivery but also to broaden the scope of their attention to assist women through a safe pregnancy and birth. Not only has maternal mortality increased but also severe maternal morbidity has more than doubled in the twenty-first century, affecting 50,000 women every year [8].

The reason for this acceleration of morbidity and mortality is unclear, but several possible explanations exist. First, we are observing an increased incidence of parturients in the USA with advanced maternal age [9], but this trend is also seen in other parts of the world where mortality rates are not increasing [10]. Second, we are performing a disproportionately high

rate of cesarean deliveries as compared to other developed countries [11] which leads to a variety of complications including an increased incidence of placental implantation abnormalities such as placenta accreta [12]. The most compelling explanation may instead be related to the surge of chronic health conditions such as obesity, hypertension, diabetes, and chronic heart disease in the parturient [6, 8, 13, 14]. Some authors have blamed the lack of universal health care in the USA as a reason for poor baseline health in mothers prior to pregnancy contributing to poor outcomes [15]. Socioeconomically disadvantaged minority women suffer especially high rates of morbidity and mortality [16].

Evidence: California, New York, and UK

In response to the increase in maternal mortality and morbidity in this country, two states, California (District IX of the American Congress of Obstetricians and Gynecologists [ACOG]) and New York (ACOG District II), have become national leaders via their exemplary collaborative efforts to improve maternal safety.

In the state of California, where more than 10% of US births take place, numerous interventions were instituted after data published on maternal deaths between 2002 and 2004 documented 207 deaths with nearly 40% of those deaths potentially preventable [17]. Three conditions were found to have the greatest level of preventability of mortality: obstetric hemorrhage, deep vein thrombosis, and preeclampsia/eclampsia. In response to these findings, the California Maternal Quality Care Collaborative created free, easily accessible online “toolkits” and mandated their use statewide. Toolkits include a collection of articles, guidelines, implementation guides, and educational documents with the goal of preventing poor outcomes. The first toolkit released was on obstetric hemorrhage. Over the next 5 years, maternal mortality in California decreased dramatically as compared to the national maternal mortality rate, which continued to rise between 2008 and 2013 [18].

New York took its own initiative to decrease maternal mortality. In 2013, a group of clinicians met to optimize obstetric care together with leaders from ACOG District II, an area covering the state of New York, to create the Safe Motherhood Initiative (SMI), which includes 10,000 healthcare providers and over 100 birthing facilities [19]. The SMI offered standardized risk assessment tables, protocols, checklists, and algorithms to minimize variability in practice. They created bundles: evidence-based interventions that are designed to be implemented together resulting in improved outcomes [20], one on hemorrhage, one on hypertension, and one on venous thromboembolism (VTE). They made their information readily available online with Continuing Medical Education credits to encourage clinicians to visit their website. They offered bundle boxes which

include a binder with implementation guidance including posters, brochures, checklists, algorithms, and tables. They posted PowerPoint® and audio recordings on the website to assist in learning, and those who developed and implemented the bundles provide practical advice on implementation.

In the UK, systemic educational interventions to reduce the incidence of pulmonary embolism in pregnancy were implemented on a national stage. In 2004, The Royal College of Obstetricians and Gynaecologists published a guideline “Thromboprophylaxis during pregnancy, labour and after normal vaginal delivery” that called for increased risk assessment, surveillance, and prophylactic treatment of VTE [21]. A decline in maternal mortality due to thromboembolism was subsequently observed and the guidelines were credited with improving maternal safety [22].

Success stories of systematic educational interventions leading to decreased mortality provide encouragement. The effectiveness of instituting protocols with the intention of reducing severity of maternal hemorrhage has been evaluated. Looking at over 32,000 deliveries during the periods before and after institution of a hemorrhage protocol, Shields et al. observed a significant reduction in blood products transfused and a nonsignificant reduction in the number of puerperal hysterectomies performed [23]. These findings provide the best evidence to date that increasing education and resources and providing tool kits may have a meaningful impact on patient outcomes.

Formation of the Partnership

In response to the increase in maternal mortality and morbidity in this country, a national imperative exists to identify and evaluate the causes of these deaths as well as identify preventable factors. Four years after he led the efforts in California, Dr. Elliott Main issued a call to action to bring similar resources and infrastructure to a national stage [10]. Representatives from a variety of organizations met in Atlanta in 2012 to create a collaborative approach to optimizing maternal health care. The group set priorities for deployment of efforts focusing on obstetric safety. The manifestation of these meetings resulted in formation of the National Partnership for Maternal Safety (NPMS), housed within the Council on Patient Safety in Women’s Health Care; its mission was to “continually improve patient safety in women’s health care through multidisciplinary collaboration that drives cultural change [24].” An important element of the NPMS is the wide range of professional organizations represented (Table 1).

The NPMS goal is to reduce maternal morbidity and mortality in the USA by 50%. One means of accomplishing that is to create bundles similar to those created in California. NPMS began by creating materials on three topics, hemorrhage, hypertension in pregnancy, and VTE, and publishing their

Table 1 Voting membership council for patient safety in women's health care

- American Academy of Family Physicians (AAFP)
- American Association of Nurse Anesthetists (AANA)
- American Board of Obstetrics and Gynecology (ABO+G)
- American College of Nurse-Midwives (ACNM)
- American College of Obstetricians and Gynecologists (ACOG)
- American College of Osteopathic Obstetricians and Gynecologists (ACOGG)
- American Society of Anesthesiologists (ASA)
- American Society for Reproductive Medicine (ASRM)
- American Urogynecologic Society (AUGS)
- Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN)
- Committee on Patient Safety and Quality Improvement (ACOG)
- Junior Fellow
- National Association of Nurse Practitioners in Women's Health (NPWH)
- Patient Advocate (2 seats)
- Preeclampsia Foundation
- Society for Academic Specialists in General Obstetrics and Gynecology (SASGOG)
- Society of Gynecologic Oncology (SGO)
- Society for Maternal-Fetal Medicine (SMFM)
- Society for Obstetric Anesthesia and Perinatology (SOAP)
- Society of OB/Gyn Hospitalists (SOGH)
- Society for Reproductive Endocrinology and Infertility (SREI)

findings on their website: <https://www.safehealthcareforeverywoman.org>. All the information on the website is free and available to the public, but a login and password is needed to access the site to help the NPMS keep track of who utilizes the information.

Making the bundles available to the public is a stepwise process. First, a one-page document is published online which includes links to critical information and implementation guidance. Then, a formal detailed article is published in a variety of high impact journals. The core of the NPMS is its commitment to multidisciplinary cooperation. The publication of the bundles in a variety of sources including anesthesia, obstetrics, nursing, and midwifery journals is a testament to this commitment. Although ACOG has published practice bulletins and committee opinions for years, they have not been multidisciplinary in nature.

Bundles are a way of providing a variety of existing evidence-based recommendations such as ACOG practice bulletins into an organized and accessible format. Additionally, there is a real emphasis on allowing the individual facility to modify and tailor the bundle to meet local needs. The bundles give examples of different ways of managing and responding to maternal complications that are known to cause significant maternal morbidity and mortality. Each bundle is

formatted into four sections: Readiness, Recognition and Prevention, Response, and Reporting /System Learning.

Hemorrhage Bundle

Obstetric hemorrhage is the most common serious complication of childbirth [25••], and 93% of hemorrhage-related mortality is considered preventable [26, 27]. Studies such as those published by Shields et al. offer proof that instituting comprehensive protocols for the treatment of maternal hemorrhage can improve patient safety [23]. It has been suggested that clinicians have a tendency to underestimate blood loss at birth and that too often clinicians delay interventions [25••]. In an effort to increase awareness and recognition of hemorrhage, ACOG revised the definition of early postpartum hemorrhage to “cumulative blood loss of ≥ 1000 ml OR blood loss accompanied by signs and symptoms of hypovolemia within 24 h following the birth process.” ACOG further stated that “cumulative blood loss of 500–999 ml alone should trigger increased supervision and potential intervention as clinically indicated” [25••].

The first bundle, the Obstetric Hemorrhage Patient Safety Bundle (Fig. 1), was initially published on the website, and then a more detailed document was published in 2015 in four high impact journals simultaneously: *Anesthesia & Analgesia* [25••], *Obstetrics and Gynecology* [28], *Journal of Obstetric, Gynecologic, & Neonatal Nursing* [29], and *Journal of Midwifery and Women's Health* [17].

The bundle outlines areas for improvement including better recognition and quantitative appreciation of blood loss, increased attention to clinical signs of hemorrhage, quicker restoration of blood volume, and greater emphasis on intervening decisively [30••]. Goals of the hemorrhage bundle include limiting the proportion of hemorrhage episodes that become severe, decreasing the need for blood product transfusion, and decreasing the frequency of coagulopathy.

In order to assist birthing facilities in better preparing for maternal hemorrhage, the bundle includes a list of supplies and systems needed to prepare for hemorrhage. It recommends that each center should have hemorrhage kits and carts with appropriate medications and equipment readily available. Partnerships with the facility's local blood bank should be made in order to best prepare for rapid availability of blood products. The bundles also outline clinician assessments that should be performed for every patient such as quantitative measurement of cumulative blood loss during delivery and postpartum (e.g., weighing of bedding and pads rather than relying on visual estimates). Response plans include stage-based obstetric hemorrhage emergency management plans and detailed support programs for all patients and families. Finally, the bundle includes recommendations on how to conduct multidisciplinary reviews after severe hemorrhage

Fig. 1 Patient Safety Bundle: Obstetric Hemorrhage. This bundle summarizes the critical clinical practices to be adapted by one's local maternity unit to assist in decreasing maternal morbidity and mortality from hemorrhage. From the Council on Patient Safety in Women's Health Care (www.safehealthcareforeverywoman.org)



READINESS

Every unit

- Hemorrhage cart with supplies, checklist, and instruction cards for intrauterine balloons and compressions stitches
- 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

Every patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)
- Measurement of cumulative blood loss (formal, as quantitative as possible)
- Active management of the 3rd stage of labor (department-wide protocol)

RESPONSE

Every hemorrhage

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists
- Support program for patients, families, and staff for all significant hemorrhages

REPORTING/SYSTEMS LEARNING

Every unit

- 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

Standardization of health care processes and reduced variation has been shown to improve outcomes and quality of care. The Council on Patient Safety in Women's Health Care disseminates patient safety bundles to help facilitate the standardization process. This bundle reflects emerging clinical, scientific, and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Although the components of a particular bundle may be adapted to local resources, standardization within an institution is strongly encouraged.

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May 2015

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PATIENT
SAFETY
BUNDLE

Obstetric Hemorrhage

episodes including tips for debriefing and perinatal quality improvement committees.

In all, the bundle lists 13 elements that should be implemented at each facility in the USA that performs births with the intention of decreasing hemorrhage as a cause of maternal morbidity and mortality. Such interventions have been identified as a means to decrease obstetric hemorrhage, the most common serious complication of childbirth.

Hypertension Bundle

Failure to adequately control the blood pressure or recognize clinical manifestations of preeclampsia such as hemolysis, thrombocytopenia, elevated liver enzymes, and pulmonary edema are common sources of error leading to grave complications [30••]. In the preeclamptic patient, the systolic blood

pressure is thought to be an important precursor to stroke. [25••] Consequently, a systolic blood pressure ≥ 160 mmHg in a pregnant patient is defined as a hypertensive emergency and requires immediate intervention by a clinician [31]. Administration of antihypertensive agents in a timely fashion is essential and potentially lifesaving. It has been suggested that more than half of maternal deaths from hypertension were potentially avoidable [30••]. ACOG has created standardized evidence-based guidelines including dosing regimens for intravenous labetalol and hydralazine and oral nifedipine when intravenous access is problematic for the initial management of acute severe hypertension in pregnancy [32], and this guidance has been incorporated into the NPMS hypertension in pregnancy bundle. Other concerns such as standardization of measuring blood pressure including the position of the patient (i.e., sitting or standing), the use of magnesium sulfate for

seizure prophylaxis, the identification of which labs are necessary, and how often should they be obtained are among a few key issues addressed in the bundle [33•].

The second bundle, severe hypertension in pregnancy (Fig. 2), has not been published as of this review, but it is available on the website: <http://www.safehealthcareforeverywoman.org/>. It is organized similarly to the hemorrhage bundle. The Readiness section includes diagnostic criteria and guidance on antihypertensive medications. The Recognition and Prevention section includes protocols for measurement and evaluations of blood pressure. Response includes management plans for patients with severe hypertension and eclampsia. Lastly, Reporting/System Learning includes recommendations on multidisciplinary reviews including debriefing.

Venous Thromboembolism Bundle

VTE is one of the leading causes of maternal mortality and severe morbidity. Maternal thromboembolism has increased more than 70% from 1998 to 2009 [8], but it is largely considered preventable [4••]. Thromboembolism prophylaxis is effective in decreasing maternal mortality [34]. Encouraging data from the UK demonstrated a reduction in maternal death after implementation of more widespread VTE prophylaxis [22].

Determining those patients at highest risk for VTE is necessary as those patients benefit most from pharmacologic prophylaxis. RCOG identified a variety of risk factors for developing a VTE including history of VTE or thrombophilia, obesity, maternal age >35 years, smoking, preeclampsia,



READINESS

Every Unit

- Standards for early warning signs, diagnostic criteria, monitoring and treatment of severe preeclampsia/eclampsia (include order sets and algorithms)
- 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 & PREVENTION

Every Patient

- Standard protocol for measurement and assessment of BP and urine protein for all pregnant and postpartum women
- 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)
- Facility-wide standards for educating prenatal and postpartum women on signs and symptoms of hypertension and preeclampsia

PATIENT
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BUNDLE

Hypertension

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Fig. 2 Patient Safety Bundle: Hypertension. This bundle outlines specific critical practices that one can implement at their local institution to best care for pregnant patients with severe hypertension. From the Council on Patient Safety in Women's Health Care (www.safehealthcareforeverywoman.org)



RESPONSE

Every case of severe hypertension/preeclampsia

- 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/preeclampsia
- Minimum requirements for protocol:
 - Notification of physician or primary care provider if systolic BP \geq 160 or diastolic BP \geq 110 for two measurements within 15 minutes
 - After the second elevated reading, treatment should be initiated ASAP (preferably 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

REPORTING/SYSTEMS LEARNING

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

Note: "Facility-wide" indicates all areas where pregnant or postpartum women receive care. (E.g. L&D, postpartum critical care, emergency department, and others depending on the facility).

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Hypertension

Fig. 2 (continued)

postpartum hemorrhage, and prolonged labor [35]. RCOG also made specific recommendations for prophylaxis using low-molecular weight heparin or unfractionated heparin including dosing schedules.

In response to these findings, the Joint Commission issued a sentinel event alert requiring that sequential compression devices be placed prior to proceeding with cesarean procedure and remain in place until the patient is fully ambulatory [36]. They also recommend that high-risk antepartum and postpartum patients are chemically anticoagulated.

The NPMS VTE bundle (Fig. 3) has recently been published in three high impact journals simultaneously: *Anesthesia & Analgesia* [37], *Obstetrics and Gynecology* [38], and *Journal of Obstetric, Gynecologic, & Neonatal Nursing* [39]. The bundle stresses the importance of assessing

patients for VTE risk throughout pregnancy. Opportune times for clinicians to evaluate for VTE prophylaxis include the following: prenatal visits, hospitalizations during pregnancy, delivery hospitalization, and during discharge from delivery hospitalization [40]. The bundle refers to two different risk assessment tools, the Caprini and Padua scoring systems, as a way to identify which patients are at highest risk for developing VTE. Recommendations such as early ambulation and the use of compression devices for all women undergoing cesarean delivery not already receiving pharmacologic thromboprophylaxis are outlined [37]. Details on identifying and managing high-risk patients, the use of low-molecular weight heparin and unfractionated heparin, dosing recommendations, and mechanical prophylaxis are all visited in the bundle.

Fig. 3 Patient Safety Bundle: Maternal Venous Thromboembolism Prevention. This bundle presents the action plan to be incorporated by local maternity units to prevent maternal venous thromboembolism. From the Council on Patient Safety in Women's Health Care (www.safehealthcareforeverywoman.org)



READINESS

Every Unit

- Use a standardized thromboembolism risk assessment tool for VTE during:
 - Outpatient prenatal care
 - Antepartum hospitalization
 - Hospitalization after cesarean or vaginal deliveries
 - Postpartum period (up to 6 weeks after delivery)

RECOGNITION & PREVENTION

Every Patient

- Apply standardized tool to all patients to assess VTE risk at time points designated under "Readiness"
- Apply standardized tool to identify appropriate patients for thromboprophylaxis
- Provide patient education
- Provide all healthcare providers education regarding risk assessment tools and recommended thromboprophylaxis

RESPONSE

Every Unit

- Use standardized recommendations for mechanical thromboprophylaxis
- Use standardized recommendations for dosing of prophylactic and therapeutic pharmacologic anticoagulation
- Use standardized recommendations for appropriate timing of pharmacologic prophylaxis with neuraxial anesthesia

REPORTING/SYSTEMS LEARNING

Every Unit

- Review all thromboembolism events for systems issues and compliance with protocols
- Monitor process metrics and outcomes in a standardized fashion
- Assess for complications of pharmacologic thromboprophylaxis

Standardization of health care processes and reduced variation has been shown to improve outcomes and quality of care. The Council on Patient Safety in Women's Health Care disseminates patient safety bundles to help facilitate the standardization process. This bundle reflects emerging clinical, scientific, and patient safety advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Although the components of a particular bundle may be adapted to local resources, standardization within an institution is strongly encouraged.

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PATIENT SAFETY BUNDLE

Maternal Venous Thromboembolism Prevention

Finally, with an expected increase in the proportion of parturients receiving anticoagulation therapy surrounding delivery, the safe administration of neuraxial anesthesia must be considered. The bundle provides a table summarizing the recommendations for timing of neuraxial anesthesia in relation to pharmacologic thromboprophylaxis.

Other Bundles

Beyond the three core bundles, NPMS will release future bundles that address important topics such as safe reduction of primary cesarean births, patient, family, and staff support after a severe maternal event, prevention of surgical site infection, postpartum care, care of the opioid-addicted mother, and maternal mental health bundles. Each bundle will be published in multiple peer reviewed journals associated with the

organizations of those who participated in the work groups. In the meantime, more information on each bundle can be found on the website: <http://www.safehealthcareforeverywoman.org/>.

Conclusion

Recognizing that a large percentage of maternal mortality and morbidity is preventable is the key to improving outcomes in the USA. Managing patients with life-threatening emergencies requires clinicians with expertise in resuscitation and critical care. Anesthesiologists are therefore a vital part of the peripartum team and must take an active role in limiting maternal morbidity and mortality. Now, more than ever,

anesthesiologists need to act as peripartum physicians and participate with other caregivers to optimize maternal safety.

Compliance with Ethical Standards

Conflict of Interest Jennifer M. Banayan and Barbara M. Scavone declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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