



Actionable Patient Safety Solution (APSS) #11A: POSTPARTUM HEMORRHAGE (PPH)

Executive Summary Checklist

Obstetric Hemorrhage is the most common complication in pregnancy leading to severe maternal morbidity and preventable mortality. The National Partnership for Maternal Safety, an alliance of the professional organizations of maternity care professionals and advocates, selected this safety topic for priority development and national implementation. Representative experts from these organizations developed the bundle to outline critical clinical practices that should be implemented in every maternity unit. To underscore the importance of this work. In depth description of this bundle has been simultaneously published in 5 peer reviewed journals representing the involved organizations. As will all maternal safety bundles, the Obstetric Hemorrhage bundle is organized into 4 domains: Readiness, Recognition and Prevention, Response, and Reporting and System Learning. Although the bundle components may be adapted to meet the resources available in individual facilities, standardization within an institution is strongly encouraged. References contain sample resources to assist with implementation. (<http://www.safehealthcareforeverywoman.org/>)

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^{1,2,3,4,5,6,7}
- Ensure teams have immediate access to hemorrhage medications (kit or equivalent)^{1,2,3,4,5,6,7,8,9,10}
- Establish a response team - who to call when help is needed (blood bank, advanced gynecologic surgery, other support and tertiary services)^{1,2,3,4,5,6,7,8,9,11}

¹ Postpartum hemorrhage. ACOG practice bulletin No. 76. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2006;108:1039-47. Available until 4/17/16.

² American College of Obstetricians and Gynecologists. Safe motherhood initiative. Available at: <http://www.acog.org/About-ACOG/ACOG-Districts/District-II/SMI-Registration>. Retrieved September 22, 2014.

³ Lyndon A, Lagrew D, Shields L, Melsop K, Bingham B, Main E. (Eds). Improving health care response to obstetric hemorrhage. Stanford, CA: California Maternal Quality Care Collaborative; 2010.

⁴ Preparing for clinical emergencies in obstetrics and gynecology. Committee opinion No. 590. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2014;123:722-5.

⁵ Florida Perinatal Collaborative. Obstetric hemorrhage initiative (OHI) tool kit for hospital implementation. Available at: <https://www.dropbox.com/sh/1jz1mn3tllmsrmt/GsbzbCxMXn>. Retrieved September 22, 2014.

⁶ Association of Women's Health, Obstetric and Neonatal Nurses. AWHONN postpartum hemorrhage project. 2014. Available at: <http://www.pphproject.org/resources.asp> on 8/28/14. Retrieved September 22, 2014.

⁷ Bingham D, Melsop K, Main E. CMQCC Obstetric hemorrhage hospital level implementation guide. Stanford, CA: California Maternal Quality Care Collaborative; 2010.

⁸ World Health Organization. WHO recommendations for the prevention and treatment of postpartum haemorrhage. Geneva, Switzerland: World Health Organization; 2012.

⁹ Evanson A, Anderson J. Postpartum hemorrhage: Third stage pregnancy. In: Leeman L, editor. Advanced life support in obstetrics provider syllabus. Leawood, KS: American Academy of Family Physicians; 2014.

¹⁰ Association of Women's Health, Obstetric and Neonatal Nurses. Oxytocin administration for management of third stage of labor. Practice brief number 2, May 2014. Available at: http://www.pphproject.org/downloads/awhonn_oxytocin.pdf. Accessed September 22, 2014

¹¹ The Joint Commission. Preventing maternal death. Sentinel event alert issue 44. Available at: http://www.jointcommission.org/sentinel_event_alert_issue_44_preventing_maternal_death/. Retrieved September 22, 2014.



Patient Safety

M O V E M E N T

zero preventable deaths by 2020

- Establish massive and emergency release transfusion protocols (type-O negative/uncrossmatched)^{1,2,3,4,5,6}
- Unit education on protocols, unit-based drills (with post-drill debriefs)^{1,2,3,4,5,6,8,9,10}

Recognition & Prevention in Every Patient

- Assessment of hemorrhage risk (prenatal, on admission, and at other appropriate times)^{1,2,3,4,5,6,7}
- Assessment of:^{1,2,3,4,5,6,7,9}
 - 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)^{1,2,3,4,5,6,7,9}
 - Weigh the pads for quantitative measurement
- Active management of the 3rd stage of labor (department-wide protocol)^{1,2,3,4,5,6,7,8,9,10}

Response

- Unit-standard, stage-based, obstetric hemorrhage emergency management plan with checklists^{1,2,3,4,5,6,8,9}
 - Obstetric rapid response teams, Team Steps.
- Support program for patients, families, and staff for all significant hemorrhages^{1,2,3,4,5,6,8}

Reporting

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities^{1,2,3,4,5,6,7}
- Multidisciplinary review of serious hemorrhages for systems issues^{1,2,3,4,5,6,7}
- Monitor outcomes and process metrics in perinatal quality improvement (QI) committee^{1,2,3,4,5,6,7}

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.¹² A majority of deaths (64%) occur from the day of delivery through 41 days postpartum.¹³ That equates to about 830 women dying every day, 550 occurring in sub-Saharan Africa, 180 in Southern Asia, and 5 in developed countries.¹⁴

Within the United States it is estimated that approximately 600 women die each year;¹⁵ 14.0 per 100,000 live births.¹⁶ While that number seems to pale in comparison on the global scale the US ranks 46th in the world for maternal mortality.¹⁷ 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.¹⁸

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.⁵ 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.¹

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.^{19,20} Additionally, the obesity epidemic gives rise to chronic conditions such as hypertension, diabetes, and chronic heart disease increase the risk of complications during pregnancy.^{21,22,23,24}

Over a third of maternal deaths in the US are preventable, 40% could be avoided if women had access to quality care.^{6,25} Most notably, black women have a 3 to 4-fold increased risk of death due to pregnancy compared to any other race or

¹² WHO. Maternal deaths fell 44% since 1990 – UN [Press Release]. 2015. Retrieved from <http://www.who.int/mediacentre/news/releases/2015/maternal-mortality/en/>

¹³ Creanga AA, Berg CJ, Syverson C, Seed K, Bruce FC, Callaghan WM. Pregnancy-related mortality in the United States, 2006–2010. *Obstet Gynecol* 2015;125:5–12.

¹⁴ WHO. Global Health Observatory (GHO) data: Maternal mortality. 2015. Retrieved from http://www.who.int/gho/maternal_health/mortality/maternal_mortality_text/en/

¹⁵ Centers for Disease Control and Prevention (CDC). Pregnancy-Related Deaths. 2015. Accessed on December 29 2015. <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-relatedmortality.htm>

¹⁶ WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Trends in maternal mortality: 1990 to 2015. November 2015.

¹⁷ Merck for Mothers Blog. Sobering statistics about giving birth in the United States. November 30 2015. Accessed on December 28 2015. <http://www.mhtf.org/2015/11/30/sobering-statistics-about-giving-birth-in-the-united-states/>

¹⁸ RH Reality Check. Maternal Mortality Down Worldwide, Except in United States. November 13 2015. Accessed on December 28 2015. <http://rhrealitycheck.org/article/2015/11/13/maternal-mortality-worldwide-except-united-states/>

¹⁹ Jolly M, Sebire N, Harris J, et al. The risks associated with pregnancy in women aged 35 years or older. *Hum Reprod*. 2000;15(11):2433-37.

²⁰ Bewley S, Davies M, Braude P. Which Career fire? The most secure age for childbearing remains 20-35. *BMJ*. 2005 Sep;331(7517):588-589.

²¹ Centers for Disease Control and Prevention (CDC). Pregnancy Mortality Surveillance System. 2015. Accessed on December 29 2015. <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html>

²² Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States: 1998–2006. *Obstet Gynecol*. 2009;113(6):1299-1306.

²³ Albrecht SS, Kuklina EV, Bansil P et al. Diabetes trends among delivery hospitalizations in the United States, 1994–2004. *Diabetes Care*. 2010;33(4):768–773.

²⁴ Kuklina EV, Callaghan WM. Chronic heart disease and severe obstetric morbidity among hospitalizations for pregnancy in the USA: 1995–2006. *Br J Obstet Gynaecol*. 2011;118(3): 345-352.

²⁵ Berg CJ, Harper MA, Atkinson SM, et al. Preventability of pregnancy-related deaths: results of a state-wide review. *Obstet Gynecol*. 2005 Dec; 106(6):1228-34.

ethnicity.^{10,26} 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.^{27,28}

Postpartum Hemorrhage (PPH)

Obstetric hemorrhage remains among the leading global causes of severe maternal morbidity and mortality.^{29,30,31,32} 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).³³ 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.³⁴ Between 1994-2006, the number of PPH cases has increased more than 25 percent, potentially driven by a 50 percent increase in uterine atony.¹⁸

PPH is a "low-volume, high-risk" event for birth facilities, which has led to the down-prioritization for developing standardized intervention protocols.³⁵ 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.^{36,37,38}

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 (28).³⁹ 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.

²⁶ Creanga AA, Bateman BT, Kuklina EV, Calaghan WM. Racial and ethnic disparities in severe maternal morbidity: a multistate analysis, 2008-2010. *AJOG*. 2014 May;210(5):435.e1-e8.

²⁷ Callaghan WM, Creanga AA, Kuklina EV. Severe Maternal Morbidity Among Delivery and Postpartum Hospitalizations in the United States. 2012 Nov;120(5):1029-36

²⁸ Callaghan WM, Mackay AP, Berg CJ. Identification of severe maternal morbidity during delivery hospitalizations, United States 2001-2003. *Am J Obstet Gynecol* 2008;199:133.e1-8.

²⁹ Callaghan WM, Kuklina EV, Berg CJ. Trends in postpartum hemorrhage: United States, 1994-2006. *Obstet Gynecol*. 2010;202:353.e351-356.

³⁰ Callaghan WM, Creanga AA, Kuklina EV. Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstet Gynecol*. Nov 2012;120(5):1029-1036.

³¹ Calvert C, Thomas SL, Ronsmans C, Wagner KS, Adler AJ, Filippi V. Identifying regional variation in the prevalence of postpartum haemorrhage: a systematic review and meta-analysis. *PLoS One*. 2012;7(7):e41114.

³² Cristina Rossi A, Mullin P. The etiology of maternal mortality in developed countries: a systematic review of literature. *Arch Gynecol Obstet*. Jun 2012;285(6):1499-1503.

³³ Abouzahr C. Antepartum and postpartum haemorrhage. Murray CJ, Lopez AD, eds. *Health Dimensions of Sex and Reproduction*. Boston, Mass: Harvard University Press; 1998. 172-4.

³⁴ Berg CJ, Atrash HK, Koonin LM, Tucker M. Pregnancy-related mortality in the United States, 1987-1990. *Obstet Gynecol*. 1996 Aug. 88(2):161-7.

³⁵ Audrey Lyndon, PhD, RNC, FAAN, & David Lagrew, MD. *CMQCC Obstetric Hemorrhage Toolkit Version 2*. March 2015.

³⁶ Berg CJ, Harper MA, Atkinson SM, et al. Preventability of pregnancy-related deaths - Results of a state-wide review. *Obstet Gynecol*. Dec 2005;106(6):1228- 1234.

³⁷ The Confidential Enquiry into Maternal and Child Health (CEMACH). *Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer - 2003- 2005. The Seventh Report on Confidential Enquiries into Maternal Deaths in the United Kingdom*. London: CEMACH;2007.

³⁸ California Department of Public Health. *The California Pregnancy-Associated Mortality Review. Report from 2002 and 2003 Maternal Death Reviews*. California Department of Public Health, Maternal Child and Adolescent Health Division. Sacramento. 2011.

³⁹ Baskett TF. *Complications of the third stage of labour. Essential Management of Obstetrical Emergencies*. 3rd ed. Bristol, England: Clinical Press; 1999. 196-201.

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 deceptively 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 Accreta, Increta, and Percreta
- Lacerations
- Instrumental Delivery
- Large Gestational Age (LGA) Newborns
- Hypertensive Disorders
- Induced Labor
- Augmentation of Labor With Oxytocin⁴⁰

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.

⁴⁰ Sheiner E, Sarid L, Levy A, Seidman DS, Hallak M. Obstetric risk factors and outcome of pregnancies complicated with early postpartum hemorrhage: a population-based study. J Matern Fetal Neonatal Med. 2005 Sep. 18(3):149-54.

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.

Metrics

Topic 1:

Severe Maternal Morbidity among Hemorrhage Cases

Outcome Measure Formula:

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

Numerator: Among the denominator, all cases with any non-transfusion SMM code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM\ Rate_{baseline} - SMM\ Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)



Topic 3:

Severe Maternal Morbidity

Outcome Measure Formula:

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages

Numerator: Among the denominator, all cases with any Severe Maternal Morbidity code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM Rate_{baseline} - SMM Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)

Topic 4:

Severe Maternal Morbidity (excluding transfusion codes)

Outcome Measure Formula:

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages

Numerator: Among the denominator, all cases with any non-transfusion Severe Maternal Morbidity code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM Rate_{baseline} - SMM Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)

Workgroup

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Elliott Main, MD, California Maternal Quality Care Collaborative, Stanford Health
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Lilly Filler, MD, Retired Obstetrician
Sharon Sutherland, MD, Cleveland Clinic
Kim Werkmeister, RN, BA, CPHQ, Hospital Quality Institute (HQI)

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Jim Bialick, Ariana Longley	Initial Release	January 2016
Version 2	Steve Barker, Michael Ramsay, Kim Werkmeister, Ariana Longley	Executive Review	April 2016
Version 3	Ari Babaknia, S. Shobeiri, Jeanne Mahoney, Kim Werkmeister, Elliott Main, Steven Barker, Ariana Longley, Michael Ramsay, Joe Kiani	Workgroup and Executive Review	January 2017



Patient Safety

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zero preventable deaths by 2020

Actionable Patient Safety Solution (APSS) #11B: PRE-ECLAMPSIA

Executive Summary Checklist

Complications arising from hypertensive disorders of pregnancy are among the leading causes of severe maternal morbidity and preventable maternal mortality. This maternity patient safety topic was selected by the National Partnership for Maternal Safety for priority development and national implementation. This safety bundle outlines critical clinical practices that should be implemented in every maternity unit. They are developed by multidisciplinary work groups of the National Partnership for Maternal Safety under the guidance of the Council on Patient Safety in Women's Health Care. The hypertension safety bundle is organized into four domains: Readiness, Recognition and Prevention, Response, and Reporting and System Learning. Although the bundle components may be adapted to meet the resources available in individual facilities, standardization within an institution is strongly encouraged. References contain sample resources to assist with implementation.¹

Readiness Across Every Unit

- Adopt standards for early warning signs, diagnostic criteria, monitoring and treatment of severe preeclampsia/eclampsia (include order sets and algorithms)^{2,3,4,5,6}
- Unit education on protocols, unit-based drills (with post-drill debriefs)^{2,3,4}
- Process for timely triage and evaluation of pregnant and postpartum women with hypertension including ED and outpatient areas^{2,3,4,5,6}
- 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.^{2,3,4}
- System plan for escalation, obtaining appropriate consultation, and maternal transport, as needed^{2,3,4,5}

Recognition

- Adoption of a standard protocol for measurement and assessment of BP and urine protein for all pregnant and postpartum women^{4,6}
- 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)^{4,6}
- Implementation of facility-wide standards for educating prenatal and postpartum women on signs and symptoms of hypertension and preeclampsia^{4,6}

Response

- Facility-wide standard protocols with checklists and escalation policies for management and treatment of:^{4,6}

¹ Council on Patient Safety | Women & Mothers' Health Care. (n.d.). Retrieved from <http://www.safehealthcareforeverywoman.org>

² The American Congress of Obstetricians and Gynecologists. (n.d.). Preeclampsia and hypertension in pregnancy: Resource overview. Retrieved from: <http://www.acog.org/Womens-Health/Preeclampsia-and-Hypertension-in-Pregnancy>

³ Committee on Obstetric Practice. (2015). Committee Opinion No. 623: Emergent therapy for acute-onset, severe hypertension during pregnancy and the postpartum period. *Obstetrics and Gynecology*, 125(2), 521.

⁴ California Maternal Quality Care Collaborative. Improving Health Care Response to Preeclampsia: A California Quality Improvement Toolkit. Retrieved from: <https://www.cmqqc.org/resources-tool-kits/toolkits/preeclampsia-toolkit>

⁵ American College of Obstetricians and Gynecologists. (2013). Optimizing Protocols in Obstetrics. Key Elements for the Management of Hypertensive Crisis In Pregnancy (In-Patient). Retrieved from: [http://www.ilpqc.org/docs/htn/Recognition/ACOGDII\(NY\)KeyElementsManagementHypertensiveCrisisPregnancy.pdf](http://www.ilpqc.org/docs/htn/Recognition/ACOGDII(NY)KeyElementsManagementHypertensiveCrisisPregnancy.pdf)

⁶ New York State Department of Health (2013, May). Hypertensive disorders in pregnancy. Retrieved from: https://www.health.ny.gov/professionals/protocols_and_guidelines/hypertensive_disorders/2013_hdp_guideline_summary.pdf



- Severe hypertension
- Eclampsia, seizure prophylaxis, and magnesium over-dosage
- Postpartum presentation of severe hypertension/preeclampsia
- Minimum requirements for protocol:^{4,6}
 - **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 hypertension⁴

Reporting/Learning in Every Unit

- Establish a culture of huddles for high risk patients and post-event debriefs to identify successes and opportunities⁴
- Multidisciplinary review of all severe hypertension/eclampsia cases admitted to ICU for systems issues
- Monitor outcomes and process metrics^{4,7}
 - 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
- Timeliness of triage and evaluation⁴

⁷ Council on Patient Safety in Women's Health Care. (2016). Hypertension Process Metrics Could Include:. Retrieved from: <http://safehealthcareforeverywoman.org/wp-content/uploads/2016/09/Reporting-3-Process-Metrics.pdf>

The Performance Gap

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⁸ World Health Organization. (2015). Maternal deaths fell 44% since 1990 - UN. Retrieved from: <http://www.who.int/mediacentre/news/releases/2015/maternal-mortality/en/>

⁹ Creanga, A. A., Berg, C. J., Syverson, C., Seed, K., Bruce, F. C., & Callaghan, W. M. (2015). Pregnancy-related mortality in the United States, 2006–2010. *Obstetrics & Gynecology*, 125(1), 5-12

¹⁰ World Health Organization. (2015). Global Health Observatory (GHO) data: Maternal mortality. Retrieved from: http://www.who.int/gho/maternal_health/mortality/maternal_mortality_text/en/

¹¹ Centers for Disease Control and Prevention. (2015). Pregnancy-Related Deaths. Retrieved from: <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-relatedmortality.htm>

¹² World Health Organization, & UNICEF. (2015). Trends in maternal mortality: 1990-2015: Estimates from WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division

¹³ Agrawal, P. (2015, November 30). Sobering statistics about giving birth in the United States. Retrieved from: <http://www.mhtf.org/2015/11/30/sobering-statistics-about-giving-birth-in-the-united-states/>

¹⁴ Kempner, M. (2015, November 13). Maternal mortality down worldwide, except in United States. Retrieved from: <http://threalitycheck.org/article/2015/11/13/maternal-mortality-worldwide-except-united-states/>

¹⁵ Jolly, M., Sebire, N., Harris, J., Robinson, S., & Regan, L. (2000). The risks associated with pregnancy in women aged 35 years or older. *Human Reproduction*, 15(11), 2433-2437.

¹⁶ Bewley, S., Davies, M., & Braude, P. (2005). Which career first?: The most secure age for childbearing remains 20-35. *BMJ: British Medical Journal*, 331(7517), 588–589.

¹⁷ Centers for Disease Control and Prevention. (2015). Pregnancy mortality surveillance system. Retrieved from: <http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html>

¹⁸ Kuklina, E. V., Ayala, C., & Callaghan, W. M. (2009). Hypertensive disorders and severe obstetric morbidity in the United States. *Obstetrics & Gynecology*, 113(6), 1299-1306.

¹⁹ Albrecht, S. S., Kuklina, E. V., Bansil, P., Jamieson, D. J., Whiteman, M. K., Kourtis, A. P., ... & Callaghan, W. M. (2010). Diabetes trends among delivery hospitalizations in the US, 1994–2004. *Diabetes Care*, 33(4), 768-773.

²⁰ Kuklina, E., & Callaghan, W. (2012). Chronic heart disease and severe obstetric morbidity among hospitalizations for pregnancy in the USA: 1995–2006. *Obstetric Anesthesia Digest*, 32(1), 17-18.

Over a third of maternal deaths in the US are preventable, 40% could be avoided if women had access to quality care.^{6,21} Most notably, black women have a 3 to 4-fold increased risk of death due to pregnancy compared to any other race or ethnicity.^{10,22} 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.^{23,24}

Hypertension and Preeclampsia

Hypertensive disorders occur in 12-22% of all pregnancies and are one of the leading conditions that impact women during pregnancy.²⁷ Hypertension may be pre-existent, may be induced by the pregnancy or both may co-occur.²⁵ 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).²⁶ 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.²⁷ During pregnancy, hypertensive disorders not only affect the mother but also may contribute to significant neonatal morbidity and mortality.²⁸

Chronic hypertension during pregnancy is defined as blood pressure (BP) (mmHg) of $\geq 140/90$ mmHg, prior to the 20th week of pregnancy and leads to complications in 5% of all pregnancies.^{29,30,31} Preeclampsia is defined as a BP of $\geq 160/110$ mmHg and associated with proteinuria ≥ 5 g 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.⁶ Preeclampsia is considered severe when the condition affects multiple organs, such as: thrombocytopenia (platelet count $\leq 100,000/\mu\text{L}$), pulmonary edema, or oliguria (≤ 500 ml per day). Mild preeclampsia is characterized by an elevated BP $\leq 160/120$ with proteinuria ≥ 300 mg but less than 5g per day.³² Studies show that between 50-70% of deaths due to severe preeclampsia are preventable.^{26,33,34,35} The leading patient factors among

²¹ Berg, C. J., Harper, M. A., Atkinson, S. M., Bell, E. A., Brown, H. L., Hage, M. L., ... & Callaghan, W. M. (2005). Preventability of pregnancy-related deaths: Results of a state-wide review. *Obstetrics & Gynecology*, 106(6), 1228-1234.

²² Creanga, A. A., Bateman, B. T., Kuklina, E. V., & Callaghan, W. M. (2014). Racial and ethnic disparities in severe maternal morbidity: A multistate analysis, 2008-2010. *American Journal of Obstetrics and Gynecology*, 210(5), 435-e1.

²³ Callaghan, W. M., Creanga, A. A., & Kuklina, E. V. (2012). Severe maternal morbidity among delivery and postpartum hospitalizations in the United States. *Obstetrics & Gynecology*, 120(5), 1029-1036.

²⁴ Callaghan, W. M., MacKay, A. P., & Berg, C. J. (2008). Identification of severe maternal morbidity during delivery hospitalizations, United States, 1991-2003. *American Journal of Obstetrics and Gynecology*, 199(2), 133-e1.

²⁵ Singh, S., Ahmed, E. B., Egundu, S. C., & Ikechukwu, N. E. (2014). Hypertensive disorders in pregnancy among pregnant women in a Nigerian Teaching Hospital. *Nigerian Medical Journal*, 55(5), 384.

²⁶ Walker, J. J. (2000). Pre-eclampsia. *The Lancet*, 356(9237), 1260-1265.

²⁷ Leddy, M. A., Power, M. L., & Schulkin, J. (2008). The impact of maternal obesity on maternal and fetal health. *Reviews in Obstetrics & Gynecology*, 1(4), 170-178.

²⁸ Backes, C. H., Markham, K., Moorehead, P., Cordero, L., Nankervis, C. A., & Giannone, P. J. (2011). Maternal preeclampsia and neonatal outcomes. *Journal of Pregnancy*, 2011.

²⁹ Seely, E. W., & Maxwell, C. (2007). Chronic hypertension in pregnancy. *Circulation*, 115(7), e188-e190.

³⁰ Druzin, M. L., Shields, L. E., Peterson, N. L., & Cape, V. (2013). Preeclampsia toolkit: Improving health care response to preeclampsia (California Maternal Quality Care Collaborative Toolkit to Transform Maternity Care): Developed Under Contract# 11-10006 With the California Department of Public Health; Maternal, Child and Adolescent Health Division. Child and Adolescent Health Division, 91-32

³¹ Yanit, K. E., Snowden, J. M., Cheng, Y. W., & Caughey, A. B. (2012). The impact of chronic hypertension and pregestational diabetes on pregnancy outcomes. *American Journal of Obstetrics and Gynecology*, 207(4), 333-e1.

³² Sibai, B. M. (2003). Diagnosis and management of gestational hypertension and preeclampsia. *Obstetrics & Gynecology*, 102(1), 181-192.

³³ Merkatz, I. R., & Thompson, J. B. (1990). New perspectives on prenatal care. Chapman & Hall.

³⁴ World Health Organization. (2011). WHO recommendations for prevention and treatment of pre-eclampsia and eclampsia: Evidence base.

³⁵ Aukes, A. M., Wessel, I., Dubois, A. M., Aarnoudse, J. G., & Zeeman, G. G. (2007). Self-reported cognitive functioning in formerly eclamptic women. *American Journal of Obstetrics and Gynecology*, 197(4), 365-e1.

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%).³⁶

Prevention

No clear strategies have emerged to prevent the onset of preeclampsia though some, like low 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.³⁷ 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.^{38,39,40,41} 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.⁴² 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.⁴³

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

³⁶ Main, E. K., McCain, C. L., Morton, C. H., Holtby, S., & Lawton, E. S. (2015). Pregnancy-related mortality in California: Causes, characteristics, and improvement opportunities. *Obstetrics & Gynecology*, 125(4), 938-947.

³⁷ Bushnell, C., & Chireau, M. (2011). Preeclampsia and stroke: Risks during and after pregnancy. *Stroke Research and Treatment*, 2011.

³⁸ Sibai, B. M. (2004). Magnesium sulfate prophylaxis in preeclampsia: Lessons learned from recent trials. *American Journal of Obstetrics and Gynecology*, 190(6), 1520-1526.

³⁹ Magpie Trial Collaborative Group. (2002). Do women with pre-eclampsia, and their babies, benefit from magnesium sulphate? The Magpie Trial: A randomised placebo-controlled trial. *The Lancet*, 359(9321), 1877-1890.

⁴⁰ Duley, L., Gülmezoglu, A. M., & Henderson- Smart, D. J. (2003). Magnesium sulphate and other anticonvulsants for women with pre- eclampsia. *The Cochrane Library*.

⁴¹ Martin Jr, J. N., Thigpen, B. D., Moore, R. C., Rose, C. H., Cushman, J., & May, W. (2005). Stroke and severe preeclampsia and eclampsia: A paradigm shift focusing on systolic blood pressure. *Obstetrics & Gynecology*, 105(2), 246-254.

⁴² Kayem, G., Kurinczuk, J. J., Spark, P., Brocklehurst, P., & Knight, M. (2011). Maternal and obstetric factors associated with delayed postpartum eclampsia: A national study population. *Acta Obstetrica et Gynecologica Scandinavica*, 90(9), 1017-1023.

⁴³ Chescheir, N. C. (2015). Enough already!.



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.³⁵

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:

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

Numerator: Among the denominator, cases with any SMM code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM Rate_{baseline} - SMM Rate_{measurement}) \times Denominator_{baseline}$$

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:

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

Numerator: Among the denominator, all cases with any non-transfusion SMM code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM\ Rate_{baseline} - SMM\ Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)



Topic 3:

Severe Maternal Morbidity

Outcome Measure Formula:

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages

Numerator: Among the denominator, all cases with any Severe Maternal Morbidity code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM Rate_{baseline} - SMM Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)

Topic 4:

Severe Maternal Morbidity (excluding transfusion codes)

Outcome Measure Formula:

Denominator: All mothers during their birth admission, excluding ectopics and miscarriages

Numerator: Among the denominator, all cases with any non-transfusion Severe Maternal Morbidity code

Metric Recommendations:

Direct Impact:

All pregnant patients

Lives Spared Harm:

$$Lives = (SMM Rate_{baseline} - SMM Rate_{measurement}) \times Denominator_{baseline}$$

Notes:

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

Data Collection:

HDD File (ICD9/ICD10)



Workgroup

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Revision History

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