

The Alliance for Innovation on Maternal Health:  
**OB Hemorrhage Change Package**



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This change package was developed based on content created through the Alliance for Innovation on Maternal Health project and was tailored to Ohio hospitals and providers.

“The Alliance for Innovation on Maternal Health (AIM) is the national, cross-sector commitment designed to lead in the development and implementation of patient safety bundles for the promotion of safe care for every U.S. birth. Founded in 2014 through a cooperative agreement funded by the Health Services Resources Administration (HRSA) and executed by ACOG, the AIM program provides expert technical support and capacity building to multidisciplinary state-based teams, most often perinatal quality collaboratives, leading targeted rapid-cycle quality improvement (QI) via implementation of patient safety bundles.”

“An Alliance for Innovation on Maternal Health (AIM) patient safety bundle is a structured way of improving the process of care and patient outcomes: a small, straightforward set of evidence-based practices that, when performed collectively and reliably, have been proven to improve patient outcomes. Patient safety bundles (PBSs) are developed by expert multidisciplinary working groups, supported by the Alliance for Innovation on Maternal Health (AIM) staff at the American College of Obstetricians and Gynecologists (ACOG). Working groups include representatives appointed by professional member organizations, known experts and researchers specializing in the clinical topic, and patients with lived experience. The bundle development process includes design of measure and metrics for implementation and multiple levels of review from engaged stakeholders.”

To learn more about AIM and patient safety bundles, please visit <https://saferbirth.org/>.

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# Introduction

This document reflects a review of clinical, scientific and patient safety recommendations. The information presented here should not be used as a standard of care, but it is a collection of resources that may be adapted by participating hospitals in order to develop standardized protocols for obstetric hemorrhage.

The Maternal Safety QIP utilizes quality improvement science to achieve the SMART (specific, measurable, achievable, realistic, and timely) aims which are to:

- 1) decrease the total number of hemorrhages of greater than or equal to 1000 cc blood loss in persons giving birth from X to X
- 2) increase the percentage of mothers who had a hemorrhage risk assessment with risk level assigned from X% to X
- 3) increase the percentage of OB drills performed from X% to X% all by September 2024.

The majority of the 22 pregnancy-related deaths due to hemorrhage, 77% occurred within 24 hours of delivery.<sup>2</sup> The others all occurred within the next two weeks: two the day after delivery, one within a week, and two within two weeks. The majority of pregnancy-related deaths due to hemorrhage occurred in the hospital (86%). Figure 1 describes the place of death and specifies hospital location.

Utilizing a modified version of the Institute for Healthcare Improvement (IHI) Model for Improvement, participating sites will form a project team and develop rapid feedback Plan-Do-Study-Act cycles to test interventions designed to equip providers with best clinical practices to provide care to pregnant and postpartum mothers. This change package was developed by the project team, based on the Alliance for Innovation on Maternal Health's Obstetric Hemorrhage patient safety bundle, to inform best clinical practices.

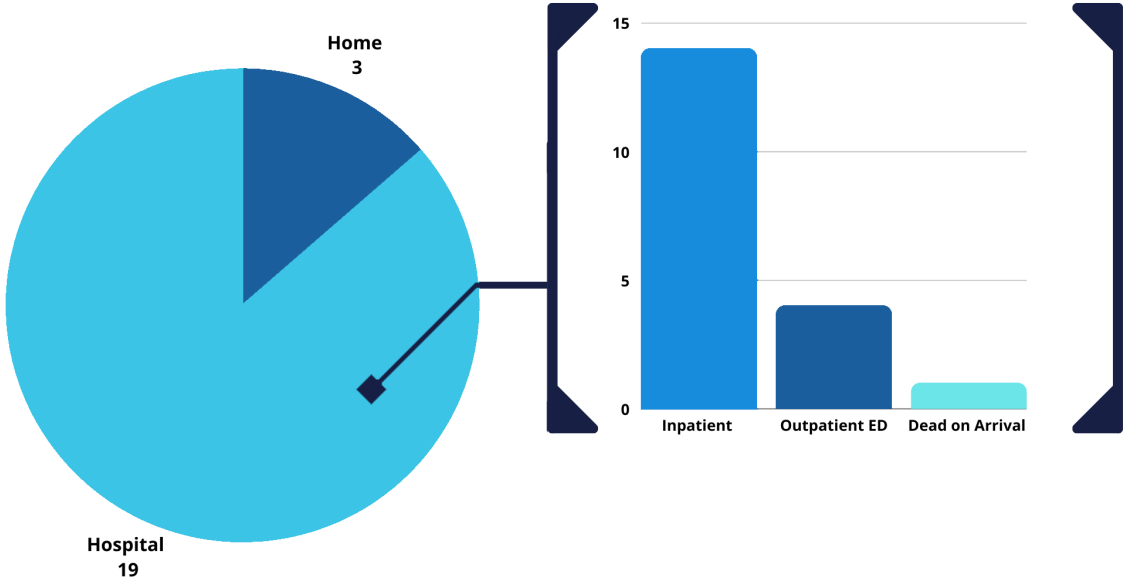
## Scope of the Problem

The Ohio Department of Health (ODH) established the Ohio Pregnancy-Associated Mortality Review (PAMR) to identify and review pregnancy-associated deaths with the goal of developing interventions to reduce maternal mortality, particularly for pregnancy-related deaths. Recently, a report with data from state maternal mortality review committees in nine states, including Ohio, found that hemorrhage, cardiovascular, and coronary conditions were tied for the leading cause of pregnancy-related deaths.<sup>1</sup> In Ohio, hemorrhage was the third leading cause. An obstetrical emergency is diagnosed when there is excessive blood loss after the delivery of the placenta. Postpartum hemorrhage (PPH) complicates approximately 4% of vaginal deliveries and has been traditionally defined as loss of more than 500 ml of blood. PPH complicates approximately 6 to 7% of cesarean deliveries and has been traditionally defined as loss of more than 1,000 ml of blood.<sup>2</sup> Other causes are an abnormally adherent placenta, lacerations, or maternal bleeding disorders. From 2008 to 2016 there were 23 pregnancy-associated deaths with hemorrhage as the underlying cause of death, twenty-two (96 %) were pregnancy-related.<sup>2</sup>

Among pregnancy-related hemorrhage deaths cause of death defined as uterine atony/ postpartum hemorrhage was the most common (n=7), followed by ruptured ectopic pregnancy (n=4), and hemorrhage -rupture/laceration/intra-abdominal bleeding (n=3).<sup>2</sup> Most deaths occurred among women aged 35 to 44, with a high school diploma (or equivalent), who were non-Hispanic white, were married, and lived in metropolitan counties. There was a disproportionate number of deaths among non-Hispanic black women, compared with the overall population.


The majority of the 22 pregnancy-related deaths due to hemorrhage, 77% occurred within 24 hours of delivery.<sup>2</sup> The others all occurred within the next two weeks: two the day after delivery, one within a week, and two within two weeks. The majority of pregnancy-related deaths due to hemorrhage occurred in the hospital (86%). Figure 1 describes the place of death and specifies hospital location.

**Figure 1. Place of Death and Specific Hospital**



**How to Use This Change Package**

Readers are advised to adapt the guidelines and resources based on their local facility's level of care and patient populations served and are also advised to not rely solely on the guidelines presented here. This change package is a working draft. As more recent evidence-based strategies become available, hospitals and providers should update their guidelines and protocols accordingly.



# For the Providers: Physicians, Nurses, Midwives, APNs, Anesthesia, Blood Bank Staff, Rapid Response Team Members

## **About Postpartum Hemorrhage**

Obstetrical hemorrhage is the most common obstetrical complication of childbirth. Defined as cumulative blood loss of greater than or equal to 1,000 mL of blood loss accompanied by signs or symptoms of hypovolemia within 24 hours after the birth process, it is an unavoidable part of obstetrical care teams experience in providing care to birthing persons.

While not every patient will experience hemorrhage, all patients are at risk for hemorrhage. While mortality in the United States attributable to hemorrhage has been decreasing, the incidence of hemorrhage has continued to increase. Further, there appear to be increased rates of severe maternal morbidity (SMM), including transfusion > 4 units of packed red blood cells and hysterectomy. Such morbidity can further expose birthing persons to complications of transfusion, resuscitation, thromboembolic events, pituitary necrosis, infertility when treated with hysterectomy, and increased psychological stress. Fortunately, though, there appear to be opportunities to affect such outcomes and meaningfully decrease them. Experiences from hospital-, health network-, and state-based quality improvement initiatives have demonstrated that standardized approaches involving readiness, recognition, and response to hemorrhage events can substantively address the emergency that is postpartum hemorrhage.

The American College of Obstetricians and Gynecologists breaks obstetric hemorrhage into primary and secondary causes. Primary causes of hemorrhage typically occur within the first 24 hours of birth, while secondary causes occur after 24 hours and up to 12 weeks postpartum. Management of these conditions can vary greatly among patients and depends on the underlying and contributing etiologies and available treatments as well as the timeliness with which recognition and intervention is implemented.

**Table 1. Primary and Secondary Causes of Hemorrhage**

<i>Risk Factors</i>	<i>Diagnosis</i>	<i>Treatment/ Management</i>
<b>Uterine Atony Occurs 70%-80% of time</b>		
<ul style="list-style-type: none"> <li>• Prolonged Labor</li> <li>• Induction of Labor</li> <li>• Prolonged use of oxytocin</li> <li>• Chorioamnionitis</li> <li>• Multiple gestation</li> <li>• Polyhydramnios Uterine leiomyomas</li> </ul>	Physical examination reveals presence of a soft, poorly contracted uterus	Drainage of bladder Bimanual pelvic examination to facilitate intrauterine clot removal and uterine massage Administration of uterotonic agents Potential placement of intrauterine devices or surgical intervention to aid in temponade
<b>Genital Tract Trauma: Lacerations</b>		
	Cervical lacerations, arterial bleeding sources, and proximal (high) vaginal lacerations repaired immediately	Treated in delivery suite Cervical lacerations, arterial bleeding sources, and proximal (high) vaginal lacerations repaired immediately Distal lacerations of the vagina, vulva, periclititoris, and perineum tissues do not always require repair unless they are contributing to ongoing bleeding issues or other clinical circumstances
<b>Genital Tract Trauma: Hematomas</b>		
<ul style="list-style-type: none"> <li>• Precipitous delivery or operative vaginal delivery</li> <li>• Labial, rectal and/or pelvic pressure or pain</li> <li>• Significant deterioration in vital signs and clinical status</li> </ul>	Bleeding tends to occur in space that tracks within the labia, vagina, broad ligament, and retroperitoneum	Can be difficult to pinpoint Conservative management is appropriate unless there is rapid expansion of the hematoma/ clinical deterioration of the patient In severe cases- incision and drainage, surgical exploration to allow for suturing or packing, or arterial embolization may need to be considered (patients may require movement to operative theaters or interventional radiology suites- collaborate with other services like anesthesia, interventional radiology, blood banks, and trauma surgery)
<b>Retained Placenta</b>		
Manual removal of the placenta and prior uterine surgery	Can be made via bedside ultrasound or manual exploration of the intrauterine cavity (see presence of an echogenic mass within the uterus)	Includes attempts at manual or instrumented (curettage or forcep) removal. Take caution if morbidly adherent placenta is potentially present that may require surgical management.
<b>Coagulopathy</b>		
Excessive, ongoing, massive hemorrhage		Aggressive resuscitation with volume replacement Initiation of massive transfusion to replace lost
Contributing etiologies such as placental abruption and amniotic fluid embolism		coagulation factors (fresh frozen plasma, cryoprecipitate) and sustain tissue oxygen delivery (packed red blood cells)→deal with underlying source for coagulopathy
<b>Uterine Inversion Rare occurrence</b>		
Bleeding involved can be rapid and substantial	Occurs when the uterine corpus descends to and at time through the uterine cervix Typically reveals a firm mass at or below the cervix with the inability to palpate the uterine fundus	Manual replacement should occur when identified with the use of uterine relaxants such as terbutaline, magnesium sulfate, general anesthesia, or nitroglycerin depending on access and availability. Do not attempt to remove placenta (if present) before replacement and restoration of the uterus to its usual anatomic position Surgical techniques occasionally required



In addition to the above conditions, there are occasionally secondary causes that will need to be considered on a case-by-case basis and will often have the features of primary causes such as uterine atony and intrauterine tissue. Infection from endometritis is important to consider given the need for antibiotic utilization and is usually demonstrated by the presence of uterine tenderness and fever. Secondary bleeding may also be the first time that a bleeding disorder is encountered by a patient. Management also should consider the specific contributing clinical circumstances. Often uterotonics may be sufficient, but if bleeding persists, curettage may be worthwhile even without visualized intrauterine tissue on exam or ultrasound as even small amounts of retained products of conception may result in ongoing hemorrhage. Supportive care should occur concurrently with volume resuscitation and transfusion as needed.

## **Risk Assessment**

The Joint Commission recommends that all patients undergo hemorrhage risk assessment using an evidence-based risk assessment tool upon admission to labor and delivery (L&D) and at the time of transfer to postpartum care. Multiple risk factor assessment tools exist. The California Maternal Quality Care Collaborative (CMQCC), the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN), and the American College of obstetricians and Gynecologists' (ACOG) Safe Motherhood Initiative all have well-established risk assessment tools incorporating many known risk factors for hemorrhage.<sup>3-5</sup> These tools stratify women into low, medium, and high-risk groups and provide pretransfusion recommendations on the basis of risk status. We have included the Risk Assessment tables from ACOG in the Tools section of this change package.

Research suggests that there may also be additional risk factors which are not included in any of the risk assessment tools, including hypertensive disorders of pregnancy, and medication use such as SSRIs, all of which are notable for their prevalence.<sup>13-18</sup> Importantly, multiple studies have demonstrated that approximately 40% of hemorrhages occur in women without risk factors.<sup>7-9,11</sup> As early recognition of hemorrhage may improve outcomes, vigilance is imperative for all women, regardless of risk.

Antepartum risk assessment represents an underutilized opportunity to improve outcomes. It is particularly important to identify women with the most significant risk factors, such as placenta accrete spectrum, placenta previa, bleeding disorders, and women who decline blood products. In addition to intrapartum and postpartum assessments, antepartum assessment early in pregnancy may allow for interventions such as optimization of maternal hematocrit and ensuring that delivery occurs in a resource-appropriate environment.

Reassessment of a patient's risk status across all stages of her pregnancy may also improve opportunities for patient counseling and shared decision making. Antepartum risk assessment findings should be documented antenatally and reviewed upon admission for delivery. Periodic evaluation is essential for accurate risk classification, and reassessment should be performed at least once per hospital shift.

## Active Management

Compared to expectant management, active management of the third stage of labor has been found to be an effective intervention to lessen the amount of blood loss following delivery as well as the frequency of postpartum hemorrhage. In the United States, the agent most commonly employed is oxytocin, for which intravenous dosing appears to be more effective than intramuscular dosing.<sup>19</sup> The single best timing of dosing has not been established; it can be administered as early as immediately after delivery of the anterior shoulder or as late as just after the delivery of the placenta. Table 2 below (adapted from UptoDate) gives some examples of oxytocin regimens and commonly available medications that have been used, although it should be stressed that these are only examples and have not been demonstrated to be superior to alternatives.<sup>20</sup> Most importantly, given the different protocols that exist, in order to limit the chance of medication error, each institution should determine and document their preferred protocol.

**Table 2**

Drug	Dose	Considerations	Major Side Effects
Oxytocin	<p>V Infusion (preferred): Example regimens:</p> <ul style="list-style-type: none"> <li>Initial: 10 units over 30 minutes adjusted to achieve a firm uterine tone.</li> <li>Maintenance: 1 to 3 units/hour adjusted to maintain uterine tone and prevent excessive bleeding.</li> </ul> <p>Or</p> <ul style="list-style-type: none"> <li>Initial: 20 units in 500mL NS infused over 1 hour</li> <li>Maintenance: 2.5 units/hour (20 units in 1L NS infused over 8 hours)</li> <li>Usual duration <math>\geq</math>4 hours. Usual maximum cumulative dose: 40 units. IM (alternative where IV access is unavailable): 10 units once.</li> </ul>	Standard of care for most patients in the United States with or without other uterotonic drugs.	Generally well tolerated. Flushing, gastrointestinal (e.g., nausea, vomiting). Risk of hypotension, tachycardia, and myocardial ischemia with rapid IV administration of high doses. Risk of hyponatremia (rare) with large doses given for a prolonged period due to water retention.
Misoprostol	Buccal/sublingual: 200 to 400 mcg once. Oral (alternative route where oxytocin is unavailable): 600 mcg once.	May also be administered rectally; however, onset may be delayed relative to buccal/sublingual.	Shivering, fever, gastrointestinal (e.g., diarrhea, vomiting), headache.
Ergot alkaloids	IM: 0.2 mg once	Due to vasoconstrictive effects, contraindicated in patients with hypertension (including preeclampsia/eclampsia), history of migraine, or vascular disease (e.g., Raynaud phenomenon).	Often not well tolerated due to vasoconstrictive adverse effects. Cardiovascular (e.g., elevated blood pressure, myocardial ischemia), headache, increase in postpartum abdominal pain, gastrointestinal (e.g., nausea, vomiting).
<ul style="list-style-type: none"> <li>Methylergometrine</li> </ul>			

Controlled traction on the umbilical cord is also often used as a component of active management. Although the number of studies is limited and data are of low quality, meta-analysis by the Cochrane collaborative suggest that controlled traction on the umbilical cord is associated with a lower chance of blood loss  $\geq 500$  mL (RR 0.93, 95% CI 0.88 to 0.99) and duration of the third stage of labor.<sup>21</sup>

## **Quantification of Blood Loss (QBL)**

Accurate accounting of blood loss is essential during an obstetric hemorrhage. It allows for timely recognition of ongoing bleeding that is escalating to a potential life-threatening process to facilitate appropriate management and intervention. Quantitative methods attempt to provide estimates of blood loss and are currently encouraged more precisely.

Historically, other methods have been used with the most common involving care teams provide visual estimates of blood loss. Visual estimates can be underestimated by 33 to 55% compared to direct measurement. Even with smaller blood losses, the presence of amniotic fluid, stool, or absorbent sponges can make accurate accounting challenging.

Quantitative blood loss methods have been shown to have benefit. Such systems allow for consistent, reproducible, and comparable approaches that can be used for every patient to identify those at risk for obstetric hemorrhage as well as better track patients with excessive blood loss to allow for appropriate interventions and services. In general, facilities should provide chart tools and regularly scheduled standardized training in formal quantitative measurement of blood loss to facilitate early recognition of and response to maternal hemorrhage. Quantitative measurement of blood loss should be a collaborative effort that includes nurses, anesthesia, and obstetric providers. While they also require ongoing training to ensure appropriate utilization, they uniformity of the approach allows all care team members to receive meaningful and valid information.

As far as how these efforts at quantification can be approached, a foundational process often involves weight measurement of blood-soaked materials. Utilizing gram scales the dry weight of materials must be subtracted from weight of blood-soaked materials. The best technique for accounting for dry weight does depend on the circumstances and volume of material.

Generally, it is as simple a process as subtracting the dry weight of absorbing materials from the weight of blood-containing materials and using the conversion 1 gram weight = 1 milliliter of blood. If such a strategy is utilized, facilities should keep an updated list of standard dry weights for materials available in-patient care areas.

Applications have been developed (such as a calculator embedded within an electronic medical record or a spreadsheet that includes standard dry weights for any items used during cesarean or vaginal birth, can facilitate easier determination of QBL. Additionally, blood-soaked materials should be placed in a precautionary container but still be able to access during an acute bleed. This not only provides a continued visual cue to the overall blood volume loss but also facilitates resolution of any discrepancies in blood volume loss assessment.

Other resources available depend on the route of delivery. For vaginal birth specifically, an under-buttocks drape with graduated markers to collect blood has been shown to be useful. In terms of quantification, immediately after the birth of the baby, the amount of fluid in the under-buttock should be noted as this value is the baseline. Any subsequent fluid collected after represents blood loss. To capture blood loss that is not collected in the under-buttocks drape, assessment of blood clots and blood-soaked materials can occur with gram scale techniques to determine the cumulative volume.

Cesarean birth can better rely on the use of suction and graduated markers on collection cannisters to provide quantified estimates of blood loss. Up to the point of rupturing the amniotic sac, blood loss can be collected into the suction cannisters. Prior to rupturing the amniotic sac, if there is a quantifiable amount of blood loss it can be recorded for accuracy. Following rupturing the amniotic sac and delivery of the baby, but before the delivery of the placenta, the surgical team should suction all amniotic fluid and stop to assess the amount of collected fluid. This value is the baseline. All subsequent fluid collected thereafter represents blood loss with appropriate subtraction of measured irrigation fluid volumes. To capture blood loss outside of the cannister, the circulating nurse assesses volume of blood loss by gram scale techniques to determine the cumulative volume.

Outside of gram scale techniques and the other methods of collection, technological solutions can also aid in quantification. Services such as Triton™ system from Gauss Surgical apply an artificial intelligence (AI) program available on portable electronic devices with cameras. Their program assesses saturations in surgical sponges and cannister collectors to provide quantified measures of blood loss. The AI can distinguish between blood and non-sanguineous fluids.

Additionally, for blood-soaked materials that are unable to be assessed by the camera, it is also connected to a gram scale to allow for appropriate accounting of ongoing bleeding. While it is more costly than the previously mentioned techniques, it does provide another tool to aid in the quantification process.

Importantly, though, the process of quantification is not devoid from utilization of other clinically observable processes. Any findings that suggest unusual visual or auditory cues to excessive bleeding should be urgently investigated. Such cues include blood on the floor, walls, or ceiling, blood dripping off the bed, table, or stretcher, continuously vibrating suction tubing or continuous full suction. Posters with volumes collected on materials commonly used in Labor and Delivery can aid in teams better recognizing visually when an excessive hemorrhage may be occurring to allow for interval tallies of blood loss.

Additionally, ongoing tallies of blood loss estimates should be reported throughout the ongoing hemorrhage at frequent intervals. Such data provides important direction to the team.

Implementation and utilization of quantitative blood loss however is at times challenging. Oftentimes, the most challenging element is often the care team concerns about the process of quantification. Some may feel that quantification may disrupt or delay the workflow of patient care.

Generally, though, teams proficient with the use of the systems can perform quantification within a matter of minutes and are able to provide meaningful information especially if bleeding does become excessive. Regarding amniotic fluid, nomograms exist for gestational ages 8-43 weeks and general assumptions about the volume of fluid can be made (normal fluid – 700 mL; oligohydramnios – 300 mL; polyhydramnios – 1400 mL). Additionally, irrigation volumes can be determined by noting the amount used and then subtracting the remaining fluid not used.

Further, quantification of blood loss is not meant to be an “exact” number as there will always be a degree of imprecision with measurement. The overall goal of quantification is to apply a standardized, consistent, reproducible, and comparable approach to improve evaluation of large blood losses. Utilizing the quantification approach in all cases ensures that large blood losses will be more easily recognized and appropriately managed as every patient is at risk of hemorrhage (though not all will experience excessive blood loss). Additionally, quantification is one part of an overall strategy to facilitate effective response to hemorrhage.

Finally, providers often express a desire to only reserve quantified processes for “severe” hemorrhage. Accepting that delays in the recognition of large blood losses are a common finding in cases of severe maternal morbidity and mortality, starting quantification only after “excessive” potentially places patients at harm. Variability between care team members regarding what constitutes “excessive” hemorrhage can lead to inconsistent and irregular application of standards for measurement and assessment. A standardized process for routine quantification ensures that staff is regularly familiar with the process of measurement and collection as well, better ensuring that valid data is obtained.

In summary, quantification can be an effective tool in aiding assessment of ongoing hemorrhage, especially to excess. It is part of an overall strategy as part of comprehensive efforts including risk assessment, preparation, management, and reporting that can assist teams in providing robust, effective, and meaningful care that has been demonstrated to reduce severe maternal morbidity and mortality. Key points and action items from this section are summarized in Table 3.

**Table 3. Key points and QBL Action Items**

1. The overall goal of quantification is to apply a standardized, consistent, reproducible, and comparable approach to evaluate blood loss.
2. Facilities should provide chart tools and regularly scheduled standardized training in formal quantitative measurement of blood loss.
3. Quantitative measurement of blood loss should be a collaborative effort that includes nurses, anesthesia, and obstetric providers.
4. If utilizing gram scales the dry weight of materials must be subtracted from weight of blood-soaked materials.
5. Facilities should keep an updated list of standard dry weights for materials available in-patient care areas.
6. A calculator embedded within an electronic medical record or a spreadsheet that includes standard dry weights for any items used during cesarean or vaginal birth, can facilitate easier determination of QBL.
7. For vaginal birth specifically, an under-buttocks drape with graduated markers to collect blood has been shown to be useful in QBL.
8. Cesarean birth can better rely on the use of suction and graduated markers on collection canisters to provide quantified estimates of blood loss.

**Medications and Interventions for Prevention and Treatment of Postpartum Hemorrhage**

*Medications*

Oxytocin is the medication of choice for both prophylaxis and treatment of abnormal postpartum uterine bleeding and postpartum hemorrhage and has a favorable side effect profile relative to other uterotonics.

**Table 4. Medications Summary**

Prevention	Treatment
Oxytocin or 10-40 units/500-1000 mL IV infusion titrated to uterine tone	Rapid infusion of IV oxytocin 10-40 units/500-1000 mL at ≥ 500 mL/hour, titrated to response
<b>OR</b>	
Oxytocin 10 u IM when no IV access	
	<b><u>Choose a standard second line agent from:</u></b>
	Methergine 0.2 mg IM Hemabate 250 mcg IM or intramyometrial
	Misoprostol 1000 mcg PR
	Tranexamic acid (TXA) 1g IV

**Pitocin® (oxytocin):** Oxytocin is a synthetic version of the natural nonapeptide produced in the posterior pituitary. The drug comes in solution at a concentration of 10 units/mL. For postpartum use, including third stage of labor, oxytocin is dosed at 10-40 units per liter of IV fluid and given as an IV infusion. The plasma half-life of oxytocin is 1-6 minutes and the clinical response is rapid after IV infusion. Alternatively, the agent may be given as an IM injection (10 units). Intramuscular response to the drug occurs within 3-5 minutes, with a clinical response lasting about 2-3 hours.

- **Side Effects:** The drug should not be given as a rapid IV bolus as it is associated with hypotension and tachycardia, and other adverse hemodynamic changes. Side effects are rare in the absence of prolonged use at low doses. Nausea and vomiting have been reported. The most serious side effect from prolonged use of IV oxytocin is water intoxication with subsequent dilutional hyponatremia.

**Methergine® (methylergonovine maleate):** Methergine is a semi-synthetic ergot alkaloid that is FDA-approved for routine management of the third stage of labor and postpartum atony. It is supplied in ampules containing 0.2 mg of active drug in a volume of 1 mL or as a single tablet of 0.2 mg of active drug. The drug is given either as an intramuscular injection (1 ampule) or orally (single tablet). When given as an oral agent, the onset of action is within 5-10 minutes with a bioavailability of 60%. When given as an intramuscular injection, the onset of action is 2-5 minutes and the bioavailability is 78% (about 25% greater than when given orally). The plasma half-life is about 3.4 hours. The agent should not be given by intravascular injection. The frequency of administration is 2-4 hours for IM administration and 6-8 hours when given orally. The IM preparation of the drug must be refrigerated when stored.

- **Side Effects:** Most common side effects are nausea and vomiting. Chest pain, arterial spasm, myocardial infarction, and hallucination have been reported in cases of toxicity.
- **Contraindications:** Methergine should be used with extreme caution in the setting of hypertension or preeclampsia. Care should be exercised when there has been recent administration of other vasoconstrictive agents (i.e., ephedrine or CYP 3A3 inhibiting agents, such as macrolide antibiotics, protease inhibitors, or azole antifungals, have recently been used.

**Hemabate® (carboprost or 15 methyl PGF2 alpha):** Hemabate is FDA-approved for the treatment of postpartum hemorrhage secondary to uterine atony not responsive to conventional treatment (massage and oxytocin). The drug is supplied in 1 mL ampules containing 250 mcg of the drug. The dose is one ampule given as an IM injection. In refractory cases, additional dosing at 15-90 minute intervals may be beneficial. The total amount of drug given should not exceed 2 mg (8 doses). The clinical response may be enhanced with concomitant use of oxytocin. It may be less effective when used in the setting of chorioamnionitis.

- **Side Effects:** Recognized side effects include nausea, vomiting, diarrhea, fever (up to 1 degree Celsius), bronchospasm, and hypertension.
- **Contraindications:** It is recommended that the drug be given with caution to patients with active hepatic or cardiovascular disease, asthma, or hypersensitivity to the drug.

**Cytotec® (misoprostol):** This agent is a synthetic prostaglandin E1 analog. This agent is FDA approved for reducing the risk of NSAID-induced gastric ulcers. It comes in either 100 or 200 mcg tablets. This agent is not FDA-approved for uterine atony or obstetrical hemorrhage. The drug is water-soluble and is quickly absorbed after sublingual, oral, vaginal, and rectal use. The drug undergoes a series of chemical reactions after ingestion, converting the agent to a prostaglandin F analog, making the drug very similar to hemabate (15 methyl PGF2 alpha). Therefore, it is unlikely that misoprostol would be effective if hemabate has failed, or vice versa. Unlike hemabate, misoprostol does not appear to exacerbate bronchoconstriction in patients with asthma. Treatment of postpartum hemorrhage with 1000 mcg rectally is a reasonable therapeutic regimen in delivery setting where other medications are difficult to maintain and stock, or as a second line therapy when hemorrhage is unresponsive to oxytocin.

- **Side Effects:** Diarrhea, shivering, pyrexia and headaches are the most common side effects.
- **Contraindications:** Hypersensitivity to the drug.



**Tranexamic acid (TXA):** is an inhibitor of fibrinolysis and may reduce bleeding in the setting of coagulation abnormalities. The WOMAN international randomized controlled trial showed a 31% reduction in death from hemorrhage when 1g of TXA was administered intravenously within 3 hours after the diagnosis of PPH.

TXA has a reassuring safety profile for the dosage used in the WOMAN trial (1gm intravenous over 10 minutes with a second 1 gm dose administered at 30 minutes if the bleeding persists).

- **Side Effects:** Dizziness, nausea, vomiting, diarrhea are the most common side effects.
- **Contraindications:** Hypersensitivity to the drug, underlying renal disease, history of thromboembolic event (i.e. deep venous thrombosis, pulmonary embolus, cerebrovascular event), underlying seizure disorder, eclamptic seizure, known thrombophilia

There is little data to evaluate which second line therapy is preferable and as stated in the WHO recommendations: "Decisions in such situations must be guided by the experience of the provider, the availability of the drugs, and by known contraindications."

### *Interventions*

- Uterine tamponade and use of intrauterine vacuum-induced hemorrhage-control devices can be a simple and effective intervention for abnormal postpartum uterine bleeding and/or postpartum hemorrhage.
- Uterine balloon, intrauterine vacuum-induced hemorrhage-control device (JADA system) and compression suture procedures should be practiced by the clinical team to ensure understanding of the sequence of steps and availability of necessary supplies and equipment.
- It is important to inspect for unrepaired lacerations prior to balloon or JADA system placement and to monitor vital signs closely after placement, even when visible bleeding is reduced or eliminated.
- For training provider and nursing staff, we recommend reviewing instructions and practicing during a drill or simulation.

Uterine balloon tamponade is a simple and effective option that can easily be learned. It is usually placed in when individuals do not respond to uterotonics or if uterotonics are not available or contraindicated. The postpartum uterine cavity requires a balloon of sizable volume to adequately apply pressure against its walls.

Commercially available devices designed specifically for uterine balloon tamponade available include the silicone Bakri™ Postpartum Balloon, the silicone BT-Cath® tamponade balloon, and the polyurethane Ebb® double balloon (vaginal and uterine) tamponade system. All three devices have a double lumen shaft, which allows ongoing drainage from the uterine cavity to be quantified externally.

Placement of the balloon should be executed via a transvaginal or transabdominal route. Once the balloon is optimally filled, gentle traction on the stem should seat the balloon within the lower uterine segment. The catheter should be attached to a drainage bag. Tight vaginal packing may be needed to adequately retain the balloon within the uterine cavity and prevent hour-glassing through the partially dilated cervix. Judgment is required to determine the optimal balloon filling volume and will involve an assessment of how well the uterus is contracted to begin with (and therefore the residual uterine cavity volume) and the tone of the uterus as the balloon is filled.

The Jada System, a novel intrauterine vacuum-induced hemorrhage control device is a FDA-cleared device that utilizes vacuum to stimulate the natural physiological response of postpartum uterine contraction. It is placed transvaginally and requires 3 cm cervical dilation at a minimum for transcervical placement. Once in place, the cervical seal is filled with 60–120 mL sterile fluid to ensure seal for vacuum. Prior to connecting to the device, the vacuum is set to 80 mm Hg ( $\pm 10$  mm Hg). Once in place and connected, the provider can monitor uterine collapse either through transabdominal fundal palpation after a vaginal birth or after the abdomen is closed post cesarean

or through direct observation at cesarean if the abdomen is still open. The evacuated blood is observed and

**Although there is no specific evidence supporting the practice, most manufacturers and authors have suggested the empiric use of a prophylactic antibiotic while the balloon or the intrauterine vacuum-induced hemorrhage control device remains in the uterus (24 hours maximum).**

quantified as it passes through the tubing into a graduated canister. The intrauterine device remains in place for 1.5 hours at minimum (24 hours maximum), and the therapy time is up to the discretion of the provider. Another approach that should be available in every institution is the use of uterine compression sutures.

The key step is to manually squeeze the uterus from top to bottom while cinching the stitch rather than use the stitch itself try and compress the uterus while being tied down (pulling extensively on the stitch during tie down is likely to tear the myometrium). At the very least, this simple step can buy time to prepare for other interventions. The placement of an intra-uterine balloon or intrauterine vacuum-induced hemorrhage control device after a B-Lynch suture has been successfully reported in a small number of cases.

Temporary arterial occlusion is typically used as a prophylactic measure when conditions such as placenta accreta spectrum are diagnosed in the antenatal period. The occlusive balloons are placed preoperatively while the patient is stable. Embolization is typically used in patients with persistent postpartum postoperative bleeding who are hemodynamically stable enough to tolerate transport to the interventional radiology suite. These procedures should be performed only by experienced interventional radiologists, given the critical state of postpartum hemorrhage patients, and the potential for complications.

The possibility of severe complications from arterial balloon occlusion and embolization have been reported. Serious complications include uterine necrosis, thromboembolic events, and fistulae. Given the severity of these reports, one should use these techniques only when sufficient expertise is available and after full review of the risks and benefits with the patient or surrogate decision maker.

B-Lynch “suspender-style” suturing with heavy gauge absorbable suture such as 1-Chromic or 1 Monocryl is the most commonly utilized method, but there are several other techniques described that are more locally focused on smaller areas (typically for focal accretes). The B-Lynch suture is typically done at cesarean delivery when uterine atony persists despite uterotonics. It is both easy (takes under 90 seconds to apply and is easily taught) and can be quite effective when initiated early in the treatment of atony. The key step is to manually squeeze the uterus from top to bottom while cinching the stitch rather than use the stitch itself to try and compress the uterus while being tied down (pulling extensively on the stitch during tie down is likely to tear the myometrium). At the very least, this simple step can buy time to prepare for other interventions. The placement of an intra-uterine balloon or intrauterine vacuum-induced hemorrhage control device after a B-Lynch suture has been successfully reported in a small number of cases.

## **Special Cases**

Transfusion is critical to optimizing obstetric outcomes in the setting of hemorrhage; however, situations arise where blood product administration is not a therapeutic option. Patients may decline blood product transfusion if they are a Jehovah’s Witness, have a history of a severe transfusion reaction, or have concerns regarding the safety of blood products.

Discussion of the acceptability of transfusion is an integral part of antenatal care and risk-stratification, which facilitates discussion and planning in advance of obstetric emergencies. Understanding the unique needs and perspectives of each individual pregnant patient who declines transfusion is essential to the shared decision-making process.<sup>24</sup> As such, an individualized approach is critical to developing the safest possible plan in the event obstetric hemorrhage occurs, which can be facilitated by use of a checklist (Figure 1).<sup>26</sup> Conversations during antenatal care should serve to clarify patient preferences, build trust, provide support and evidence-based counseling, and develop a thoughtful delivery plan to minimize blood loss and optimize outcomes. Adopting the principles of Bloodless Medicine is suggested to minimize risk (Box 1).<sup>27</sup>

Adequate documentation of patient preferences and the plan of care is also critical to ensure the plan translates from the outpatient to the inpatient care setting.

*Recommendations*

Prenatal Care	Labor and Delivery/Postpartum
1. Comprehensive counseling on hemorrhage-related risks with use of shared decision making and a checklist to identify acceptable interventions (Figure 1).	1) On admission for delivery, reassess hemorrhage risk and availability of surgical options (cell saver, Interventional Radiology).
2. Patients refusing blood product transfusion should have an advanced directive.	2) Review checklist of acceptable interventions and ensure availability.
3. Aggressive prevention and correction of anemia. <ul style="list-style-type: none"> <li>a. Iron (PO or IV therapy), folate, and B12 supplementation or replacement as indicated</li> <li>b. Erythropoietin</li> </ul>	3) Early anesthesia consultation.
4. Consider consultations with MFM, Hematology, Anesthesiology	4) Ensure entire care team is aware of patient preferences and plan.
	5) Meticulous control of bleeding / Bloodless Medicine Management (Box 1) / Be Decisive (6).
	6) Aggressive treatment of anemia postpartum (similar to prenatal care above).

**Figure 1:**  
**Checklist for Patients Declining Blood Production Transfusion (Adopted from reference 5)**

**Considerations for Discussion/Documentation:**

- Discussed the risks and benefits of accepting blood product transfusion and NOT of accepting blood product transfusion.
- Discussed the risks and benefits of extracorporeal circulatory and salvage techniques
- Patient is aware that blood product refusal may result in organ or tissue damage or even death.
- Patient adamantly refuses the blood component therapies indicated below, even if faced with death.
- Patient realizes that with these restrictions, the care team may be forced to proceed more quickly to definitive procedures that have a chance of stopping the bleeding (cesarean delivery, hysterectomy, etc.)
- Patient understands that he or she may reverse these restrictions at any time and accept blood. If this occurs, the care team will abide by all patient privacy standards and not discuss the acceptance of blood products in front of family or clergy without patient consent.

## Box 1. Principles of Bloodless Medicine

### Antenatal Care:

- Employ multidisciplinary treatment approach to blood conservation
- Minimize laboratory testing
- Use low volume microtainers for phlebotomy
- Aggressive treatment and prevention of anemia
- Risk stratification and early transfer of care to a tertiary center

### Intrapartum/Intraoperative Care:

- Develop plan for avoiding and controlling blood loss
- Intraoperative autologous blood salvage
- Meticulous surgical technique
- Perioperative antifibrinolytics (tranexamic acid)
- Topical sealants and hemostatic agents
- Avoiding perioperative hypothermia
- Point of care coagulation testing (thromboelastographic)
- Decisive interventions, including surgery & be prepared to modify routine practice when appropriate

## Blood Consent Checklist for Patient Counseling

<b>Allogenic Human Blood Products</b>		
Whole Blood	Yes	No
Packed Red Blood Cells	Yes	No
Fresh Frozen Plasma	Yes	No
Platelets	Yes	No
<b>Human Blood Fractions and Medications Containing Human Blood Fractions</b>		
Cryoprecipitate	Yes	No
Albumin	Yes	No
Human Immunoglobulin (RhIG, IVIG)	Yes	No
Plasma-derived clotting factor concentrates (fibrinogen, factor VIII, factor IX)		
Tissue adhesives/ Fibrin glue	Yes	No
Erythropoietin	Yes	No
<b>Extracorporeal Techniques for Blood Conservation Treatment</b>		
Intraoperative blood salvage (cell saver)	Yes	No
Autologous banked blood (self-donation)	Yes	No
Cardiopulmonary bypass	Yes	No
Chest drainage autotransfusion	Yes	No
Plasmapheresis	Yes	No
Hemodialysis	Yes	No

## Placenta Accreta Spectrum

Placenta accreta spectrum (PAS) is a condition characterized by abnormal trophoblast invasion into the myometrium, which can extend beyond the serosa. The clinical spectrum of PAS includes placenta accreta (attachment of placenta to the myometrium without intervening decidua), placenta increta (trophoblast invasion into the myometrium), and placenta percreta (trophoblast invasion through the myometrium and serosa into surrounding structures). The most important risk factor for PAS is a history of cesarean delivery and current placenta previa. PAS occurs in approximately 11% of patients with one prior cesarean delivery and a placenta previa, and the risk increases substantially with increasing number of prior cesareans.<sup>24</sup> However, PAS can also occur after other uterine or gynecologic surgeries or procedures including myomectomy, hysteroscopic resections, dilation and curettage, endometrial ablation, manual removal of the placenta, and in vitro fertilization.<sup>25,26</sup> Given the risk of massive hemorrhage and severe maternal morbidity, PAS remains one of the most dangerous conditions associated with pregnancy. Patients with PAS have increased risks of hysterectomy, transfusion, disseminated intravascular coagulation, intensive care unit admission, urinary tract or other operative injury, multisystem organ failure, and death.<sup>27,28</sup> Therefore, prenatal identification is critical to improving maternal and neonatal outcomes by facilitating patient counseling, antenatal delivery planning, and referral to an appropriate care setting for delivery (maternal level III or IV center).

### *Diagnosis*

The primary diagnostic modality for the antenatal diagnosis of PAS is obstetric ultrasonography, which has reported sensitivity and specificity of 80-90%.<sup>29,30</sup> A recent interdisciplinary task force led by SMFM provides guidance on a standardized approach to the sonographic diagnosis of PAS.<sup>31</sup> Magnetic resonance imaging also has a sensitivity and specificity of 80 to 90% for the detection of PAS.<sup>32</sup> Some experts suggest that MRI may be an important adjunctive imaging modality for the detection of PAS in specific clinical scenarios, including when the diagnosis is uncertain, in the evaluation of the posterior placenta, and for assessment of parametrial involvement or extension outside the uterus.<sup>33</sup> However, MRI is expensive and has not been demonstrated to improve diagnosis or outcomes compared to ultrasonography alone, and MRI requires expertise for interpretation that may not be widely available.<sup>34,35</sup> As such, the role of MRI in the management of PAS remains uncertain. All pregnant people with risk factors for PAS should have detailed obstetric sonography performed in the midtrimester by providers with imaging expertise in the detection and management of PAS.

### *Delivery Timing*

In patients with a suspected PAS, delivery is typically recommended in the late preterm period to balance the neonatal risks of prematurity with the risks of labor and hemorrhage. In patients with clinical and imaging findings strongly suggestive of PAS, ACOG and SMFM recommend delivery at 34w0d to 35w6d after completion of a course of antenatal corticosteroids.<sup>36</sup>

In patients with risk factors for preterm birth, antenatal bleeding, percreta, or other risk factors, consideration of delivery prior to 34w0d may be appropriate.

### *Delivery Planning and Approach*

All patients with suspected PAS based on clinical risk factors and/or ultrasound findings should be counseled about the diagnosis and potential sequelae of PAS including hemorrhage, blood transfusion, cesarean hysterectomy, maternal intensive care unit admission, and the risk for severe maternal morbidity or mortality. During prenatal care, aggressive treatment and prevention of anemia is recommended with supplementation and/or replacement of iron, B12, and folate. Patients with suspected PAS should be referred to a tertiary care facility (maternal level III or IV) with multidisciplinary expertise and experience in the management of PAS, as care in this setting has been demonstrated to improve outcomes and lower the risk of complications.<sup>37</sup> The multidisciplinary care team may include MFM, gynecologic surgery or gynecologic oncology, anesthesia, transfusion medicine, interventional radiology, urology, trauma surgery, vascular surgery, critical care medicine, neonatology and specialized nursing and support staff. Preparation for massive transfusion is imperative and delivery should be performed at a center with capacity for massive transfusion and a massive transfusion protocol. The typical surgical approach involves planned cesarean hysterectomy without attempted placental removal. At cesarean delivery, the hysterotomy is made at a uterine location that avoids placental disruption (e.g., fundal).

### **Recommendations:**

- All pregnant people with risk factors for PAS (placenta previa, history of cesarean delivery, endometrial ablation, or other uterine surgery) should undergo targeted obstetrical ultrasonography in the midtrimester to assess for PAS.
- For patients with suspected PAS, antenatal counseling should be provided regarding the risks of PAS, including the potential for massive hemorrhage, hysterectomy, surgical complications, and severe maternal morbidity.
- All patients with suspected PAS should have a preoperative delivery plan with contingency plans in the event emergent delivery is required.
- Delivery should occur at a tertiary center (maternal level III/IV center) with a multidisciplinary care team with experience and expertise in the management of PAS and the capacity for massive transfusion.
- Outcomes are improved with scheduled delivery prior to the onset of bleeding or labor. As a general approach, planned cesarean hysterectomy is recommended at 34w0d to 35w6d after administration of a course of antenatal corticosteroids.



# Inherited Bleeding Disorders in Pregnancy

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## Key Principles

1. Inherited bleeding disorders place women at risk for obstetric hemorrhage.
2. It is crucial to identify women with inherited coagulation disorders early in care and to plan in advance for supporting their safety at birth.
3. Maternal-fetal medicine, hematology and anesthesia consultation should be obtained well in advance of delivery to coordinate antepartum, intrapartum and postpartum care for women with inherited coagulation disorders.

## Background

The coagulation process is a complex biochemical chain reaction involving several pathways and proteins. Genetic abnormalities in any of these proteins can lead to serious coagulation problems. Although relatively rare in pregnant women, such abnormalities can lead to maternal hemorrhage events during antepartum, birth or postpartum and can have deleterious effects on the health of both the mother and baby. Defects may often be identified through repeated bleeding episodes or family history.<sup>1-10</sup> Identifying patients with inherited coagulation disorders and carefully planning their care is crucial for optimal outcomes. Although postpartum hemorrhage can occur in these patients, routine screening will not identify a large number of these rare cases.<sup>11-15</sup>

The most commonly identified coagulation disorders are von Willebrand disease (factor VIII platelet adhesion and coagulant deficiency), hemophilia A (factor VIII coagulant deficiency), hemophilia B (factor IX deficiency), and hemophilia C (factor XI deficiency). Basic knowledge of these disorders will help to better understand the management recommendations

below. In addition, less common disorders such as factor XIII deficiency, congenital fibrinogen deficiency, and dysfibrinogenemia can be diagnosed and successfully managed in pregnancy.<sup>16,17</sup>

**Von Willebrand disease** (vWD) is the most common hereditary coagulation abnormality described in humans with a prevalence of 1% in the general population.<sup>1,18,19</sup> It occurs less frequently as an acquired disorder (acquired von Willebrand Syndrome) manifested by the presence of auto-antibodies. Von Willebrand disease is caused by a deficiency of the plasma protein that controls platelet adhesion (VIII:vWF) and decreased activity of the protein that stabilizes blood coagulation (VIII:C). The disorder can cause mucous membrane and skin bleeding symptoms, bleeding with vaginal birth and surgical events or other hemostatic challenges. Women of childbearing age may be disproportionately symptomatic compared with other age groups.

Several types of vWD have been described.<sup>20</sup> Individuals with Type 1 make up 60-80% of

## READINESS

all vWD cases and have a quantitative defect (heterozygous for the defective gene) but may not have clearly impaired clotting function.<sup>21</sup> Decreased levels of vWF are detected in these patients, (10-45% of normal, i.e. ,10-45 IU). Most patients lead nearly normal lives without significant bleeding episodes. Patients may experience bleeding following surgery (including dental procedures), noticeable easy bruising, or menorrhagia (heavy menstrual bleeding).

Individuals with Type 2 vWD make up < 20-30% of all vWD cases and have a qualitative defect. The tendency to bleed varies between individuals. Individuals with Types 1 and 2 are usually mildly affected by vWD and pass the trait in an autosomal dominant fashion.

Type 3 vWD (1-5%) is the most severe form; it is autosomal recessive and severely affected individuals are homozygous for the defective gene. Individuals with Type 3 have severe mucosal bleeding, no detectable vWF antigen, and may have sufficiently low factor VIII. They can have occasional hemarthroses (joint bleeding), as in cases of mild hemophilia. Most vWD is diagnosed in women with a positive family history or menorrhagia. Blood testing for vWF activity provides confirmation of diagnosis and help aid management, taking into account there is a normal increase in vWF levels during pregnancy.<sup>22</sup>

**Hemophilia A** (factor VIII coagulant deficiency) is a blood clotting disorder caused by a mutation of the factor VIII gene, which leads to factor VIII deficiency. Inheritance is X-linked recessive; hence, males are affected while females are carriers or very rarely display a mild phenotype. It is the most common hemophilia, occurring in 1 in 5000 males. Women can, on rare occasion, exhibit a homozygous state if both parents carry the disorder. More frequently, carriers show atypical performance of “Lyonization” of the X chromosome, meaning they exhibit random

inactivation of the X chromosome. Women usually have 50% activity but if inactivation of the “normal” gene occurs in greater frequency, lower levels can be seen.<sup>23</sup> Of note, factor VIII activity usually increases during pregnancy.<sup>24</sup>

**Hemophilia B** (factor IX deficiency) is a blood clotting disorder caused by a mutation of the Factor IX gene, also carried on the X-chromosome. It is a less commonly seen form of hemophilia (sometimes called “Christmas Disease,” after the first afflicted patient), occurring in about 1 in 30,000 males and very rarely in females. Diagnosis can be made by measuring levels of IX activity in the blood, which does not usually change during pregnancy.

**Hemophilia C** (factor XI deficiency) is a rare condition in the general population (occurring in less than 1 in 100,000 individuals) but more common in the Ashkenazi Jewish population. It can occur in both males and females.<sup>7,25</sup> Up to 8% of these individuals are carriers (autosomal recessive) of the gene, which is located on Chromosome 4. Treatment is not usually necessary because patients have approximately 20-60% factor XI activity; however, they should be followed closely since the postpartum hemorrhage rate is 20%. Factor XI doesn’t show any significant change during pregnancy.<sup>26</sup>

**Congenital factor XIII deficiency** is a rare autosomal recessive disorder which when identified can be successfully followed and treated in pregnancy with replacement factor.<sup>17</sup> Patients with congenital fibrinogen deficiency will require monitoring of fibrinogen levels and replacement of fibrinogen with targets of > 50-100 mg/dL in the antepartum, intrapartum and postpartum periods.<sup>27</sup> Those with inherited dysfibrinogenemia require similar replacement of fibrinogen to maintain levels > 100 mg/dL and should be given anticoagulation to balance the risk between bleeding and clotting.<sup>16</sup>

Diagnosis in pregnancy of any of these coagulation disorders may be difficult due to the variability of clotting factor activity caused by hormonal changes of pregnancy.<sup>28</sup> When a patient with an inherited coagulation disorder delivers, extra-uterine bleeding and hematomas and the effect of the disorder on the fetus are significant concerns. Cesarean birth is rarely recommended.<sup>5,9,29</sup> Autoimmune acquisition of these disorders has been described and therefore may occur despite the lack of familial history.

## Recommendations

1. Review family, surgical and pregnancy history for possible clinical symptoms of excessive bleeding following surgery (including dental procedures), noticeable easy bruising, joint hemorrhage, or menorrhagia (heavy menstrual bleeding).
2. Request the following laboratory screening tests<sup>20,23</sup> for patients with suspected disorders:
  - ▶ vWD: measurement of ristocetin co-factor activity and von Willebrand antigen (VIII:Ag) activity
  - ▶ Hemophilia A: measurement of factor VIII activity (factor VIII:C assay)
  - ▶ Hemophilia B: measurement of factor IX activity (If factor VIII:C is normal)
  - ▶ Hemophilia C: measurement of factor XI activity

Additional laboratory tests to consider are complete blood count (especially platelet counts), activated partial thromboplastin time (APTT), prothrombin time, thrombin time and fibrinogen level. Note that patients with vWD typically display normal prothrombin time and variable prolongation of partial thromboplastin.

3. Affected patients or carriers, or patients with suspected history should consult with a hematologist who has specific interest and knowledge of coagulation disorders.<sup>5,9</sup>
4. Obtain perinatal and anesthesia consultation for planning and coordination of antepartum and intrapartum management of patients with bleeding disorders.<sup>5,9,30</sup> In general, regional anesthesia must be given with caution given the risks of spinal hematoma. Individualized decisions should be made in a multidisciplinary fashion. Current guidelines do not suggest the use of ROTational ThromboElastoMetry (ROTEM) or ThromboElastoGraphy (TEG) in decision-making for the use of regional anesthesia.<sup>31</sup>
5. Route of delivery for most patients with carrier status, which may cause neonatal coagulation disorders (e.g., factor VIII deficiency), should still be based on obstetric indications since studies have not shown a protective effect of cesarean for the neonate.<sup>2,3</sup>
6. Refer patients for genetic counseling regarding possible testing and evaluation of the fetus and newborn if genetic etiology is suspected.<sup>5,9,29</sup>
7. Develop intrapartum and postpartum management plans well in advance of the anticipated date of birth so specific medications and blood components are available at the time of delivery and given in consultation with a hematologist.<sup>5,9</sup> (See Section: Obstetric Hemorrhage Risk Factor Assessment on page 30.)
  - ▶ vWD: Mild forms are often treated with desmopressin acetate (DDAVP) and more severe forms require vWF and VIII factor replacement.<sup>3</sup> To identify whether patients will respond to DDAVP, perform a DDAVP challenge test.

## READINESS

- ▶ Hemophilia A/B: Concentrates of clotting factor VIII (for hemophilia A) or clotting factor IX (for hemophilia B) are slowly infused or injected into a vein. Consider DDAVP adjunctive therapy.
- ▶ Hemophilia C: Fresh frozen plasma (FFP) is the first product used to treat patients with hemophilia C. The main advantage of FFP/plasma is its availability. Disadvantages of its use include the large volumes required, the potential for transmission of infective agents and the possibility of allergic reactions.
- ▶ Factor XI activity: Factor XI concentrates provide the best source for factor XI replacement.

## EVIDENCE GRADING

LEVEL OF EVIDENCE: C

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## For the Hospitals: Tools

### Readiness

#### Key Principles

- 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)

### Form a Response Team

Having the right people on a response team is essential. Teams can vary in size and composition based on the organization and the complexity of the improvement effort. An effective team includes a Project Champion, someone in a leadership position who can get buy-in from staff members required for change to occur, and a team leader such as the safety officer who will focus on opening lines of communication across the hospital.

## **Recognition**

### **Key Principles**

- 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**

### **Key Principles**

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

## **Reporting**

### **Key Principles**

- 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

**BLOOD BANK:**

# Massive Transfusion Protocol (MTP)

In order to provide safe obstetric care, institutions **MUST**:

- Have a minimum of 4 units of O-negative PRBCs
- Have the ability to obtain 6 units PRBCs & 4 units FFP (compatible or type specific) for a bleeding patient
- Have a mechanism in place to obtain platelets & additional products in a timely fashion

**Blood transfusion or crossmatching should not be used as a negative quality marker & is warranted for certain obstetric events.**

<p><b>1 Patient currently bleeding &amp; at risk for uncontrollable bleeding</b></p> <p><b>A</b> Activate MTP — call <b>(ADD NUMBER)</b> &amp; say “activate massive transfusion protocol”</p> <p><b>B</b> Nursing/anesthesia draw stat labs              – type &amp; crossmatch              – hemoglobin &amp; platelet count, PT (INR)/PTT, fibrinogen, &amp; ABG (as needed) →</p>	<p><b>2 Immediate need for transfusion (type &amp; crossmatch not yet available)</b></p> <p><b>A</b> Give 2-4 units O-negative PRBCs</p> <p><b>B</b> <b>"OB EMERGENCY RELEASE"</b> →</p>
<p><b>3 ANTICIPATE ONGOING MASSIVE BLOOD NEEDS</b></p> <p><b>A</b> Obtain massive transfusion pack              – Consider using coolers</p> <p><b>B</b> Administer as needed in a 6:4:1 ratio              – 6 units PRBCs              – 4 units FFP              – 1 apheresis pack of platelets →</p>	<p><b>4 INITIAL LAB RESULTS</b></p> <p><b>A</b> Normal &gt; anticipate ongoing bleeding &gt; repeat massive transfusion pack &gt; bleeding controlled &gt; deactivate MTP</p> <p><b>B</b> Abnormal &gt; repeat massive transfusion pack &gt; repeat labs &gt; consider cryoprecipitate and consultation for alternative coagulation agents (Prothrombin Complex Concentrate [PCC], recombinant Factor VIIa, tranexamic acid)</p>

**IMPORTANT PROTOCOL ITEMS TO BE DETERMINED AT EACH INSTITUTION:**

- How to activate MTP:

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- Blood bank # & location; notify ASAP:

I will call: \_\_\_\_\_

- Emergency release protocol that both blood bank staff & ordering parties (MD/RN/CNM) understand:

---

- How will blood be brought to L&D?

---

- How will additional blood products/platelets be obtained?

---

- Mechanism for obtaining serial labs, such as with each transfusion pack, to ensure transfusion targets achieved:

---



# Recommended Instruments Checklist

HEMORRHAGE CART	
<b>VAGINAL</b>	<input type="checkbox"/> Vaginal retractors; long weighted speculum <input type="checkbox"/> Long instruments (needle holder, scissors, Kelly clamps, sponge forceps) <input type="checkbox"/> Intrauterine balloon <input type="checkbox"/> Banjo curette <input type="checkbox"/> Bright task light <input type="checkbox"/> Procedural instructions (balloon)
<b>CESAREAN/LAPAROTOMY</b>	<input type="checkbox"/> Hysterectomy tray <input type="checkbox"/> #1 chromic or plain catgut suture & reloadable straight needle for B-Lynch sutures <input type="checkbox"/> Intrauterine balloon <input type="checkbox"/> Procedural instructions (balloon, B-Lynch, arterial ligations)

MEDICATION KIT (FOR RAPID ACCESS TO MEDICATIONS)	
MEDICATION	AMOUNT
ENSURE APPROPRIATE MEDICATIONS GIVEN PATIENT HISTORY	
<input type="checkbox"/> Oxytocin (Pitocin) 10-40 units per 500-1000mL solution	2 pre-mixed bags
<input type="checkbox"/> Oxytocin (Pitocin) 10 units	2 vials
<input type="checkbox"/> 15-methyl PGF <sub>2</sub> α (Hemabate, Carboprost) 250 micrograms per mL <b>Avoid with asthma; use with caution with hypertension</b>	1 ampule *
<input type="checkbox"/> Misoprostol (Cytotec) 200 microgram tablets	5 tabs
<input type="checkbox"/> Methylergonovine (Methergine) 0.2 milligrams per mL <b>Avoid with hypertension</b>	1 ampule *

\* Needs refrigeration

## OBSTETRIC HEMORRHAGE

## Risk Assessment Tables

PRENATAL	
RISK FACTORS	<input type="checkbox"/> Suspected previa/accreta/increta/percreta
	<input type="checkbox"/> Pre-pregnancy BMI > 50
	<input type="checkbox"/> Clinically significant bleeding disorder
	<input type="checkbox"/> Other significant medical/surgical risk (consider patients who decline transfusion) <sup>1</sup>
INTERVENTION	<input type="checkbox"/> Transfer to appropriate level of care for delivery <sup>2</sup>

ANTEPARTUM		TIMING OF DELIVERY (WEEKS)
RISK FACTORS	<input type="checkbox"/> Placenta accreta	34 0/7 – 35 6/7
	<input type="checkbox"/> Placenta previa	36 0/7 – 37 6/7
	<input type="checkbox"/> Prior classical cesarean	36 0/7 – 37 6/7
	<input type="checkbox"/> Prior myomectomy	37 0/7 – 38 6/7
	<input type="checkbox"/> Prior myomectomy, if extensive	36-37
PLACENTA ACCRETA MANAGEMENT <sup>3</sup>	For 1 or more prior cesareans, placental location should be documented prior to delivery. Patients at <b>high risk</b> for placenta accreta, should:	
	<input type="checkbox"/> Obtain proper imaging to evaluate risk prior to delivery <input type="checkbox"/> Be transferred to appropriate level of care for delivery if accreta is suspected	

<sup>1</sup> See supplemental guidance document on patients who decline blood products

<sup>2</sup> Review availability of medical/surgical, blood bank, ICU, and interventional radiology support

<sup>3</sup> See supplemental guidance document on morbidly adherent placenta

## OBSTETRIC HEMORRHAGE

## Risk Assessment Tables

LABOR & DELIVERY ADMISSION		
	MEDIUM RISK	HIGH RISK
<b>RISK FACTORS</b>	<input type="checkbox"/> Prior cesarean, uterine surgery, or multiple laparotomies	<input type="checkbox"/> Placenta previa/low lying
	<input type="checkbox"/> Multiple gestation	<input type="checkbox"/> Suspected accreta/percreta
	<input type="checkbox"/> > 4 prior births	<input type="checkbox"/> Platelet count < 70,000
	<input type="checkbox"/> Prior PPH	<input type="checkbox"/> Active bleeding
	<input type="checkbox"/> Large myomas	<input type="checkbox"/> Known coagulopathy
	<input type="checkbox"/> EFW > 4000 g	<input type="checkbox"/> 2 or more medium risk factors
	<input type="checkbox"/> Obesity (BMI > 40)	/
	<input type="checkbox"/> Hematocrit < 30% & other risk	/
<b>INTERVENTION</b>	<input type="checkbox"/> Type & SCREEN, review protocol	<input type="checkbox"/> Type & CROSS, review protocol

INTRAPARTUM		
	MEDIUM RISK	HIGH RISK
<b>RISK FACTORS</b>	<input type="checkbox"/> Chorioamnionitis	<input type="checkbox"/> New active bleeding
	<input type="checkbox"/> Prolonged oxytocin > 24 hours	<input type="checkbox"/> 2 or more medium (admission and/or intrapartum) risk factors
	<input type="checkbox"/> Prolonged 2nd stage	/
	<input type="checkbox"/> Magnesium sulfate	/
<b>INTERVENTION</b>	<input type="checkbox"/> Type & SCREEN, review protocol	<input type="checkbox"/> Type & CROSS, review protocol

\* Establish a culture of huddles for high-risk patients and post-event debriefing \*

# Obstetric Hemorrhage Checklist

EXAMPLE

Complete all steps in prior stages plus current stage regardless of stage in which the patient presents.

Postpartum hemorrhage is defined as cumulative blood loss of greater than or equal to 1,000mL or blood loss accompanied by signs or symptoms of hypovolemia within 24 hours. However, blood loss >500mL in a vaginal delivery is abnormal, and should be investigated and managed as outlined in Stage 1.

## RECOGNITION:

Call for assistance (Obstetric Hemorrhage Team)

Designate:  Team leader \_\_\_\_\_  Checklist reader/recorder  Primary RN

Announce:  Cumulative blood loss  Vital signs \_\_\_\_\_  Determine stage

**STAGE 1: Blood loss >1000mL after delivery with normal vital signs and lab values. Vaginal delivery 500-999mL should be treated as in Stage 1.**

## INITIAL STEPS:

- Ensure 16G or 18G IV Access
- Increase IV fluid (crystalloid without oxytocin)
- Insert indwelling urinary catheter
- Fundal massage

## MEDICATIONS:

- Ensure appropriate medications given patient history
- Increase oxytocin, additional uterotonics

## BLOOD BANK:

- Confirm active type and screen and consider crossmatch of 2 units PRBCs

## ACTION:

- Determine etiology and treat
- Prepare OR, if clinically indicated (optimize visualization/examination)

### Oxytocin (Pitocin):

10-40 units per 500-1000mL solution

### Methylergonovine (Methergine):

0.2 milligrams IM (may repeat);

**Avoid with hypertension**

### 15-methyl PGF<sub>2</sub>α (Hemabate, Carboprost):

250 micrograms IM (may repeat in q15 minutes, maximum 8 doses); **Avoid with asthma; use**

**with caution with hypertension**

### Misoprostol (Cytotec):

800-1000 micrograms PR

600 micrograms PO or 800 micrograms SL

**Tone** (i.e., atony)

**Trauma** (i.e., laceration)

**Tissue** (i.e., retained products)

**Thrombin** (i.e., coagulation dysfunction)

**STAGE 2: Continued Bleeding (EBL up to 1500mL OR ≥ 2 uterotonics) with normal vital signs and lab values** (\*two or more uterotonics in addition to routine oxytocin administration; or ≥ 2 administrations of the same uterotonic)

## INITIAL STEPS:

- Mobilize additional help
- Place 2nd IV (16-18G)
- Draw STAT labs (CBC, Coags, Fibrinogen)
- Prepare OR

## MEDICATIONS:

- Continue Stage 1 medications; consider TXA

## BLOOD BANK:

- Obtain 2 units PRBCs (DO NOT wait for labs. Transfuse per clinical signs/symptoms)
- Thaw 2 units FFP

## ACTION:

- For uterine atony --> consider uterine balloon or packing, possible surgical interventions
- Consider moving patient to OR
- Escalate therapy with goal of hemostasis

### Tranexamic Acid (TXA)

1 gram IV over 10 min (add 1 gram vial to 100mL NS & give over 10 min; may be repeated once after 30 min)

### Possible interventions:

- Bakri balloon
- Compression suture/B-Lynch suture
- Uterine artery ligation
- Hysterectomy

**Huddle and move to Stage 3 if continued blood loss and/or abnormal VS**

Safe Motherhood Initiative

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### STAGE 3: Continued Bleeding (EBL > 1500mL OR > 2 RBCs given OR at risk for occult bleeding/coagulopathy OR any patient with abnormal vital signs/labs/oliguria)

#### INITIAL STEPS:

- Mobilize additional help
- Move to OR
- Announce clinical status (vital signs, cumulative blood loss, etiology)
- Outline and communicate plan

#### MEDICATIONS:

- Continue Stage 1 medications; consider TXA

#### BLOOD BANK:

- Initiate Massive Transfusion Protocol (If clinical coagulopathy: add cryoprecipitate, consult for additional agents)

#### ACTION:

- Achieve hemostasis, intervention based on etiology
- Escalate interventions

#### Oxytocin (Pitocin):

10-40 units per 500-1000mL solution

#### Methylergonovine (Methergine):

0.2 milligrams IM (may repeat);

**Avoid with hypertension**

#### 15-methyl PGF<sub>2</sub>α (Hemabate, Carboprost):

250 micrograms IM

(may repeat in q15 minutes, maximum 8 doses)

**Avoid with asthma;**

**use with caution with hypertension**

#### Misoprostol (Cytotec):

800-1000 micrograms PR

600 micrograms PO or 800 micrograms SL

#### Tranexamic Acid (TXA)

1 gram IV over 10 min (add 1 gram vial to 100mL NS & give over 10 min; may be repeated once after 30 min)

#### Possible interventions:

- Bakri balloon
- Compression suture/B-Lynch suture
- Uterine artery ligation
- Hysterectomy

### STAGE 4: Cardiovascular Collapse (massive hemorrhage, profound hypovolemic shock, or amniotic fluid embolism)

#### INITIAL STEP:

- Mobilize additional resources

#### MEDICATIONS:

- ACLS

#### BLOOD BANK:

- Simultaneous aggressive massive transfusion

#### ACTION:

- Immediate surgical intervention to ensure hemostasis (hysterectomy)

#### Post-Hemorrhage Management

- Determine disposition of patient
- Debrief with the whole obstetric care team
- Debrief with patient and family
- Document

Revised September 2020

# Obstetric Team Debriefing Form

**Remember:** Debriefing is meant to be a learning experience and a way to address both human factors and systems issues to improve the response for next time. There is to be no blaming/finger-pointing.

Type of event: \_\_\_\_\_ Date of event: \_\_\_\_\_

Location of event: \_\_\_\_\_

**Members of team present:** (check all that apply)

- |   |  |                                     |   |
|---|--|-------------------------------------|---|
| <input type="checkbox"/> Primary RN           | <input type="checkbox"/> Primary MD            | <input type="checkbox"/> Charge RN  | <input type="checkbox"/> Resident(s)            |
| <input type="checkbox"/> Anesthesia personnel | <input type="checkbox"/> Neonatology personnel | <input type="checkbox"/> MFM leader | <input type="checkbox"/> Patient Safety Officer |
| <input type="checkbox"/> Nurse Manager        | <input type="checkbox"/> OB/Surgical tech      | <input type="checkbox"/> Unit Clerk | <input type="checkbox"/> Other RNs              |

Thinking about how the obstetric emergency was managed,

## Identify what went well: (Check if yes)

- Communication
- Role clarity (leader/supporting roles identified and assigned)
- Teamwork
- Situational awareness
- Decision-making
- Other: \_\_\_\_\_

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## Identify opportunities for improvement: “human factors” (Check if yes)

- Communication
- Role clarity (leader/supporting roles identified and assigned)
- Teamwork
- Situational awareness
- Decision-making
- Other: \_\_\_\_\_

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## Identify opportunities for improvement: “systems issue” (Check if yes)

- Equipment
- Medication
- Blood product availability
- Inadequate support (in unit or other areas of the hospital)
- Delays in transporting the patient (within hospital or to another facility)
- Other: \_\_\_\_\_

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Revised March 2019



# Obstetric Team Debriefing Form

For identified issues, fill in table below

ISSUE	ACTIONS TO BE TAKEN	PERSON RESPONSIBLE
	①	
	②	
	③	
	④	

Safe Motherhood Initiative

Revised March 2019



## Respectful Care

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The Hemorrhage Maternal Safety Bundle Respectful Care Domain is intended to ensure that hospital units employ standard and appropriate practices to treat and address hemorrhage emergencies with mindfulness, sensitivity, and respect for all patients. This is accomplished through screening for and identifying structural and social drivers of health that could impact clinical recommendations or treatment plans, and provide linkage to resources that align with the birthing person's health literacy, cultural needs, and language proficiency. There are three key elements that each organization should utilize to fulfill the requirements of the Respectful Care domain.

1. Utilize a shared decision making approach during the care process.
2. Provide culturally sensitive education for patients and providers.
3. Identify, assess, and address existing barriers to care.



## Utilize a shared decision making approach during the care process

Utilizing a shared decision making approach with patients is a vital component in ensuring they are able to identify and consent to the best course of action during their care process. This includes providing patients with all the information they will need to make an informed decision regarding their care. This process should be documented in the electronic medical record. More information regarding shared decision making may be found in the following sources:

Shared Decision Making Resources	
<b>Informed Consent and Shared Decision Making in Obstetrics and Gynecology<sup>1</sup></b>	<a href="https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology">https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/02/informed-consent-and-shared-decision-making-in-obstetrics-and-gynecology</a>
<b>Importance of Social Determinants of Health and Cultural Awareness in the Delivery of Reproductive Health Care<sup>2</sup></b>	<a href="https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/01/importance-of-social-determinants-of-health-and-cultural-awareness-in-the-delivery-of-reproductive-health-care">https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/01/importance-of-social-determinants-of-health-and-cultural-awareness-in-the-delivery-of-reproductive-health-care</a>
<b>Effective Patient-Physician Communication<sup>3</sup></b>	<a href="https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/effective-patient-physician-communication">https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/effective-patient-physician-communication</a>

## Provide culturally sensitive education for patients and providers

Given the existing disparities in maternal health outcomes, it is important to provide education regarding these disparities to both health care providers and patients. In addition, it is vital that health care providers develop a level of comfort and competency in discussing these issues with their patients when care is provided. Health care team members may seek to further their knowledge and training on topics such as implicit bias, anti-racism, and shared decision making through the following resources:

Provider Training	Cost	
<b>Ohio Department of Health Implicit Bias Training<sup>4</sup></b>	Free	<a href="https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/pregnancy-associated-mortality-review/Webinars">https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/pregnancy-associated-mortality-review/Webinars</a>
<b>March of Dimes Training<sup>5</sup></b>	Varies	<a href="https://www.marchofdimes.org/professionals/professional-education.aspx">https://www.marchofdimes.org/professionals/professional-education.aspx</a>
<b>ABOG - Unconscious Bias<sup>6</sup></b>	Free	

## Identify, assess, and address existing barriers to care

There are significant disparities in severe maternal morbidity (SMM) and maternal mortality in Ohio. From 2008-2016, the pregnancy related-mortality ratio (PRMR) was 29.5 for non-Hispanic Black women and 11.5 for non-Hispanic white women. Black women also experienced SMM at a higher rate, 210 per 10,000 deliveries, when compared to white women, 124 per 10,000 deliveries.

In order to address these disparate outcomes for different patient populations, it is important for hospitals to engage in activities aimed at eliminating racial disparities in obstetric outcomes. Several avenues that may be explored are addressed in this toolkit, including utilizing a shared decision making approach with patients, as well as providing education to patient and clinical providers.

Additional resources regarding disparities in maternal health outcomes, barriers to care, and health outcomes may be found below:

Resource	
<b>Reducing Disparities in Severe Maternal Morbidity and Mortality</b>	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/pdf/nihms927630.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/pdf/nihms927630.pdf</a>
<b>Reduction in racial disparities in severe maternal morbidity from hemorrhage in a large-scale quality improvement collaborative</b>	<a href="https://www.sciencedirect.com/science/article/pii/S000293782030034X?via%3Dihub">https://www.sciencedirect.com/science/article/pii/S000293782030034X?via%3Dihub</a>
<b>Importance of Social Determinants of Health and Cultural Awareness in the Delivery of Reproductive Health Care</b>	Committee Opinion
<b>Racial and Ethnic Disparities in Reproductive Health Services and Outcomes, 2020</b>	<a href="https://journals.lww.com/greenjournal/Fulltext/2021/02000/Racial_and_Ethnic_Disparities_in_Reproductive.5.aspx">https://journals.lww.com/greenjournal/Fulltext/2021/02000/Racial_and_Ethnic_Disparities_in_Reproductive.5.aspx</a>
<b>Achieving Health Equity: A Guide for Health Care Organizations</b>	IHI White Paper

Additionally, community resources for social and health care services may be found at the Ohio Colleges of Medicine Government Resource Center [website](#).

# Appendices

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Appendix A – Introduction to the Model for Improvement

Appendix B – References

Appendix C – Tool References

Appendix D - Simulation Examples

# Appendix A

## Introduction to the Model for Improvement and PDSAs

The Model for Improvement is a powerful tool for accelerating improvement. The model is not meant to replace change models that organizations may already be using, but rather to accelerate improvement. The model has three fundamental questions. The third question relates to the Plan-Do-Study-Act (PDSA) cycle, which tests changes in real work settings. The PDSA cycle guides the test of a change to determine if the change is an improvement.

### Step #1: Form a Project Team

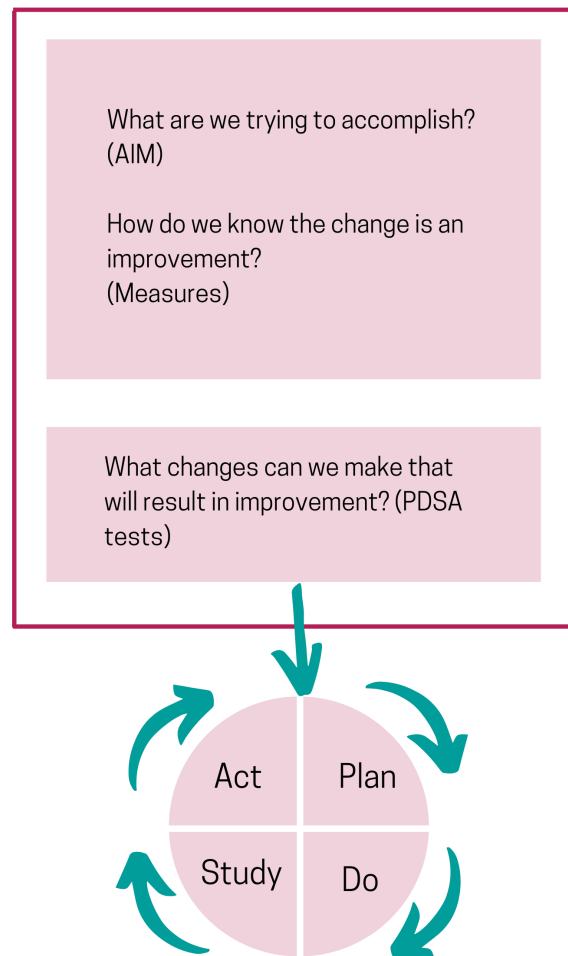
Having the right people on a quality improvement team is essential. Teams can vary in size and composition based on the organization and the complexity of the improvement effort. An effective team includes a Project Champion, someone in a leadership position who can get buy-in from staff members required for change to occur. The Project Champion may represent the following:

- Organizational Leadership
- Program Expertise
- Day-to-Day Leadership

### Step #2: Set Aims

“What are we trying to accomplish?”  
The SMART aims for the Hemorrhage QIP are to:

1. Decrease the total number of hemorrhages of greater than or equal to 1000 cc blood loss in persons giving birth from X to X;
2. Increase the percentage of mothers who had a hemorrhage risk assessment with risk level assigned from X% to X; and
3. Increase the percentage of OB drills performed from X% to X% all by September 2024.



Once you know your organization's data, these aims can be adapted for your setting.

**Step #3: Establish Measures**

“How will we know that a change is an improvement?”

Measures for the Ohio Maternal Safety QIP are:

Process Measures	
Unit drills	Provider education
Nursing education	Risk assessment
Quantified blood loss	
Structure Measures	
Patient, family & staff support	Debriefs
Multidisciplinary case reviews	Hemorrhage chart
Unit policy and procedure	Severe maternal morbidity (excluding cases with only a transfusion code) among hemorrhage cases
Outcome Measures	
Severe maternal morbidity	Severe maternal morbidity (excluding cases with only a transfusion code) among all delivering women
Severe maternal morbidity among hemorrhage cases	Severe maternal morbidity (excluding cases with only a transfusion code) among hemorrhage cases
Number of massive transfusions; number of mothers receiving 4 or more units of packed red blood cells per 1,000 mothers	

**Step #4: Select Changes**

“What changes can we make that will result in improvement?”

Changes are necessary to make improvements. Rather than completely reconfiguring your current process, develop and test changes on a small scale. Your team can also use previously gathered observations to determine the changes.

### **Step #5: Test Changes**

Start testing the selected changes! By testing these strategies on a small scale, you will learn what will work in your setting. Your team can start testing changes in order to figure out what strategies are appropriate for your practice setting. Follow the Plan-Do-Study- Act (PDSA) cycle:

**Plan:** Develop a plan to test the change (Who? What? When? Where? What data need to be collected?)

**Do:** Test the change on a small scale.

**Study:** Use data to analyze the results of the change and determine if it made a difference.

**Act:** Based on your analysis, refine the change. Determine what modification should be made and plan for the next test.

### **Step #6: Implement Changes**

After several PDSA cycles, your changes can be tested on a broader scale. Implementation is a permanent change to the current process. It may affect documentation, written policies, hiring, training, compensation, and organizational infrastructure. Implementation also requires following the PDSA cycle for continuous testing and monitoring.

### **Step #7: Spread Changes**

After successful tests, your changes can be spread and implemented to other parts of your organization.

## Appendix B

### References-Scope of the Problem and For the Providers

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# Appendix C

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# Appendix D

## Shared Courtesy of the Clinical Skills Education and Assessment Center at the Ohio State University College of Medicine

*The Ohio State University CSEAC Scenario Development Form*

**Scenario Name: PAMR Postpartum Hemorrhage**

**Author(s): Cynthia Shellhaas M.D, Mindy Walter R.N., Scott Winfield**

**Course director: Cynthia Shellhaas M.D**

**Content expert: Cynthia Shellhaas M.D, Mindy Walter R.N**

**Date of Development: 08-2014**

**Targeted Audience: OB nursing and physicians**

**Simulation Platform:**

**(HPS, SimMan3G, MetiMan, SimMom, SimNewbie, task trainers, or Other):**

### **\*Synopsis of Scenario:**

This scenario takes place in the post-partum unit and the patient delivered vaginally 1 ½ hours ago a pre-term 4lbs 6 oz baby boy. She is 36 y/o G5P5 who was non-compliant with prenatal care. The patient has a history of two previous C-section deliveries followed by three vaginal births, patient states after first vaginal delivery she had to have blood transfusion. Her psychosocial history includes daily heroin use and smoking 1 ½ packs per day. Patient admits to heroin use approx. 6hrs prior to delivery. The delivery was uncomplicated with minimal blood loss and has saturated only a 1/3 of a pad during recovery period. The uterus is one finger under umbilicus and perineum is intact. The patient is complaining of poor pain control and requesting more pain medication. Her vitals have been stable during the post-partum period and the baby is currently in the routine nursery for observation. The patient's current interventions include a 18G saline well. Pain medication was given in L&D prior to transfer (oxycodone 2 tabs). Patient voided prior to delivery, 100cc clear urine.

During this scenario, the learner will identify appropriate methods to safely and effectively manage the patient's pain. Additionally, the patient will become lethargic, less responsive to verbal commands, and her vitals will be slightly lower than initial vitals but still stable. During their next assessment, the patient's uterus becomes boggy and begins to have increased vaginal bleeding (500mL). The patient is still less responsive and vital signs will continue to decompensate until proper interventions are completed to manage the bleeding and resuscitate the patient.

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# Appendix D

## **\*Learning Objectives:**

- The care team will quickly identify, communicate, and respond to a postpartum hemorrhage situation
- The simulation will increase knowledge and understanding of medications (Uterotonics) and supplies to manage the postpartum hemorrhage (Bakri Balloon, postpartum hemorrhage cart/ kit, blood products)
- The simulation will increase the care team's ability to evaluate blood loss
- The simulation will determine availability of care team protocols to manage hemorrhage (massive transfusion protocol, rapid response team, postpartum hemorrhage protocol)

## **\*Scenario Intro (\*\*read to learner\*\*)**

### **You are getting a change of shift handoff:**

This scenario takes place in the post-partum unit and the patient delivered vaginally 1 ½ hours ago a pre-term 4lbs 6 oz baby boy. She is 36 y/o G5P5 who was non-compliant with prenatal care. The patient has a history of two previous C-section deliveries followed by three vaginal births, patient states after first vaginal delivery she had to have blood transfusion. Her psychosocial history includes daily heroin use and smoking 1 ½ packs per day. Patient admits to heroin use approx. 6hrs prior to delivery. The delivery was uncomplicated with minimal blood loss and has saturated only a 1/3 of a pad during recovery period. The uterus is one finger under umbilicus and perineum is intact. The patient is complaining of poor pain control and requesting more pain medication. Her vitals have been stable during the post-partum period and the baby is currently in the routine nursery for observation. The patient's current interventions include a 18G saline well. Pain medication was given in L&D prior to transfer (oxycodone 2 tabs). Patient voided prior to delivery, 100cc clear urine. But has refused to get up due to her pain.

# Appendix D

## \*Facilitator briefing/ Curricular information:

### Educational Learning Model:

**Prerequisites:** PAMR Pre-Assessment

**Didactics Needs:** NA

**Learning Method:** Didactic and experiential

Debriefing Method:

**Outcome / Evaluation / Measurement / Research:** Pre- and Post-assessments

### **\*Preparation:**

#### **Supporting Files**

- PPH power point
- PPH debrief tool

#### **Roles**

- Primary Nurse
- OB Physician
- Secondary Nurses

#### **Setting**

- Post-Partum unit

#### **Monitors Available to Participant**

- ECG
- SPO2
- NIBP
- Temp

#### **Other Equipment Required**

- Code Cart
- PPH Cart for location if available
- SimMom urine bladder

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# Appendix D

## Time Duration

- Set up: 10
- Simulation: 15-20
- Debriefing:15
- Tear down: 10

## Supplies

- Methergine
- Hemabate
- Misoprostil (cytotech)
- Oxytocin 20 units per 1000mL
- Oxytocin 10mL vial.
- Bakari balloon
- Blood
- IV solution
- IV sets
- Tegaderm
- 250 mL IV solution
- 10000 mL IV solution
- 100 mL IV solution
- 500 mL Mag
- Chux
- Foley kit
- Gloves
- Syringes
- Curved hemostats
- Right angle hemostat
- Lighted Speculum

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# Appendix D

## AV/I.T. Required

- Recording: B-line mobile recording and play back
- Laptop
- EMR

### Learner Information

#### (Information given to learner during scenario)

#### Scenario Introduction (*give to learner*) :

This scenario takes place in the post-partum unit and the patient delivered vaginally 1 ½ hours ago a pre-term 4lbs 6 oz baby boy. She is 36 y/o G5P5 who was non-compliant with prenatal care. The patient has a history of two previous C-section deliveries followed by three vaginal births, patient states after first vaginal delivery she had to have blood transfusion. Her psychosocial history includes daily heroin use and smoking 1 ½ packs per day. Patient admits to heroin use approx. 6hrs prior to delivery. The delivery was uncomplicated with minimal blood loss and has saturated only a 1/3 of a pad during recovery period. The uterus is one finger under umbilicus and perineum is intact. The patient is complaining of poor pain control and requesting more pain medication. Her vitals have been stable during the post-partum period and the baby is currently in the routine nursery for observation. The patient's current interventions include a 18G saline well. Pain medication was given in L&D prior to transfer (oxycodone 2 tabs). Patient voided prior to delivery, 100cc clear urine.



# Appendix D

## General Information (SBAR):

**LOC:** Drowsy but responsive, continue to c/o pain

**Name:** Debbie Post

**Age:** 36

**Weight:** 156

**Height:** 5'6"

**Vital Signs:** (WNL) Have been Normal in the recovery period Patient History:

**History of Present Illness:** Non-compliant with prenatal care. Delivered this baby at 35 weeks gestation. Has had two previous c/sections followed by now 3 vaginal deliveries. The patient admits to daily heroin use.

Allergies: NKA

**Medications:** Oxycodone x 2- 30 minutes ago

Past Medical / Surgical History: Had two previous c/sections followed by 3 vaginal deliveries

**Intake/outputs:** The patient voided prior to delivery 100 cc/ last ate a hamburger and fries **prior** to admission to the hospital.

## **Symptoms:**

**Events leading up to Illness:** Vaginal delivery 1 1/2 hours ago

**Onset of symptoms:**

**Provocation / provokes:**

**Severity of pain:** Pain is a 10/10 despite pain medicine 30 minutes prior

## **Review of Systems:**

**CNS:** Alert but falls asleep frequently

**Cardiovascular:** Pulse strong and regular

**Pulmonary:** Wheezes and crackles in all lobes/ smokes 1 pack of cigarettes/daily Abdominal: Soft, uterus 1 under the umbilicus

**Renal:** Voided 100 cc prior to delivery. No problems of previous UTI or renal problems Psychiatric: No history of issues

# Appendix D

## Physical Exam:

**Head:** Normal

**Chest:** Normal

**Abdominal:** Postpartum/ uterus firm at 1 under the umbilicus

**Legs:** Normal

**Arms:** Normal, bruising in multiple areas/ needle "tracks"

**Back:** Normal

**Current Interventions:** The patient has a saline well in place and peripads on. Vital signs have been WNL. The fundus is firm at 1 under the umbilicus with moderate rubra on the peri pad.

Laboratory, Radiology, and Other Relevant Studies: Labs:

**Hgb:** 9.2

**Hct:** 28%

**Platelets:** 180,000

**WBC:** 14,000

# Appendix D

## Simulation Sequence

### 1. Initial Baseline:

#### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
90	110/65	98%	12	na	na	na	na	98.5 F

**Sounds/Auscultations:** breath and heart sounds normal and clear (CTA)

**Patient Responses:** complaining of uterine cramping, refuses bathroom privileges due to pain, restless EKG: sinus

**Appearance/PE:** pink, warm, dry

**Further details:** Uterus is now 2 fingers above umbilicus

**Operator details:** Patient wants more pain medication and have a smoke.

#### **Learner Objectives and Interventions:**

Consider straight urine cath if the patient continues to refuse or is unable to void

Assess cause of uterine cramping

Manage pain control

Recognize patients risk for PPH

Communicate with M.D. patient complaint

**Transition Cue: Additional pain medication given**

**Go to state: PPH**

# Appendix D

## 2. Pain Meds Given:

### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
85	105/60	96%	10	na				98.5 F

**Sounds/Auscultations:** breath and heart sounds normal and clear (CTA)

**Patient Responses:** patient has become dizzy and changed mental (confused)

**status EKG:** sinus

**Appearance/PE:** pale

**Further details:** Uterus is somewhat boggy now and rubra on pad has increased

**slightly Operator details:** Patient less conscious

**Learner Objectives and Interventions:** Recognize change in patient's mental status

Evaluate Fundus – provide massage

Assess current blood loss

Evaluate patient's decreased BP

Communicate patient's condition to healthcare team

**Transition Cue: After 2 minutes**

**Go to state: PPH**

# Appendix D

## 3. PPH:

### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
120	85/50	94%	10					97.8 F

**Sounds/Auscultations:** breath and heart sounds normal and clear (CTA)

**Patient Responses:** Moaning, unable to answer questions, dizzy.

**EKG:** sinus

**Appearance/PE:** pale, ash

**Further details:** Excessive vaginal bleeding should begin (500mL loss)

**Operator details:** Begin uterine/vaginal bleeding

### **Learner Objectives and Interventions:**

Recognize excessive vaginal bleeding

Evaluate uterine status

Assess patient's declining hemodynamics

Manage interventions and treatment (2nd IV line, Pulse Ox, weigh pads, continue fundal massage, administer uterotonics, insert Bakri, prepare for emergency blood administration) Communicate obstetric emergency

**Transition Cue: After 3 minutes (instructors cue)**

**Go to state: Further deterioration**

# Appendix D

## 4. Further Deterioration:

### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
132	72/30	90%	10					97.8 F

**Sounds/Auscultations:** breath and heart sounds normal and clear (CTA)

**Patient Responses:** unresponsive

**EKG:** sinus

**Appearance/PE:** pale,

**Further details:** continued bleeding even with pharmaceutical and **Manual interventions Operator details:** Patient is unresponsive

### **Learner Objectives and Interventions:**

Evaluate the effectiveness manual maneuvers

Evaluate effectiveness of pharmaceutical interventions

Consider trauma/emergent or available blood products

Prepare and use Bakari balloon system

**Transition Cue: Bakari Balloon inflated**

**Go to state: Recovery**

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# Appendix D

## 4. Further Deterioration:

### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
120	85/50	94%	10					97.8 F

**Sounds/Auscultations:** breath and heart sounds normal and clear (CTA)

**Patient Responses:** unresponsive

**EKG:** sinus

**Appearance/PE:** pale,

**Further details:** continued bleeding even with pharmaceutical and **Manual interventions Operator details:** Patient is unresponsive

**Learner Objectives and Interventions:**

Evaluate the effectiveness manual maneuvers

Evaluate effectiveness of pharmaceutical interventions

Consider trauma/emergent or available blood products

Prepare and use Bakari balloon system

**Transition Cue: Bakari Balloon inflated**

**Go to state: Recovery**

# Appendix D

## 5. Recovery:

### Vital signs:

HR	BP	SPO2	RR	ETCO2	CVP	PAP	CO	Temp
100	96/60	96%	12					97.8 F

**Sounds/Auscultations:** breath and heart sounds normal and clear **(CTA) Patient**

**Responses:** confused but responsive

**EKG:** sinus

**Appearance/PE:** pink

**Further details:**

**Operator details:**

**Learner Objectives and Interventions:**

Provide continued plan of care for patient

Transfer to proper acuity of care



# Appendix D

## Technician/Patient Notes

### General Information (SBAR):

**LOC:** Drowsy but responsive, continue to c/o pain .

**Name:** Debbie Post

**Age:** 36

**Weight:** 156

**Height:** 5'6"

**Vital Signs:** Have been Normal in the recovery period

**Patient History:**

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**Allergies:** NKA

**Medications:** Oxycodone x 2- 30 minutes ago

**Past Medical / Surgical History:** Had two previous c/sections followed by 3 vaginal deliveries

**Intake/outputs:** The patient voided prior to delivery 100 cc/ last ate a hamburger and fries prior to admission to the hospital

**Symptoms:**

**Events leading up to Illness:** Vaginal delivery 1 1/2 hours ago

**Onset of symptoms:**

**Provocation / provokes:**

**Severity of pain:** Pain is a 10/10 despite pain medicine 30 minutes prior

**Review of Symptoms:**

**CNS:** Alert but falls asleep frequently

**Cardiovascular:** Pulse strong and regular

**Pulmonary:** Wheezes and crackles in all lobes/ smokes 1 pack of

**Cigarettes/daily Abdominal:** Soft, uterus 1 under the umbilicus

**Renal:** Voided 100 cc prior to delivery. No problems of previous UTI or renal

**Problems Psychiatric:** No history of issues

# Appendix D

## Technician/Patient Notes

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# Appendix D

## Physical Exam:

**Head:** Normal

**Chest:** Normal

**Abdominal:** Postpartum/ uterus firm at under the umbilicus

**Legs:** Normal

**Arms:** Normal, bruising in multiple areas/ needle "tracks"

**Back:** Normal

**Current Interventions:** The patient has a saline well in place and peripads on. Vital signs have been wnl. The fundus is firm at 1 under the umbilicus with moderate rubra on the peri pad.

Laboratory, Radiology, and Other Relevant Studies: Labs:

**Hgb:** 9.2

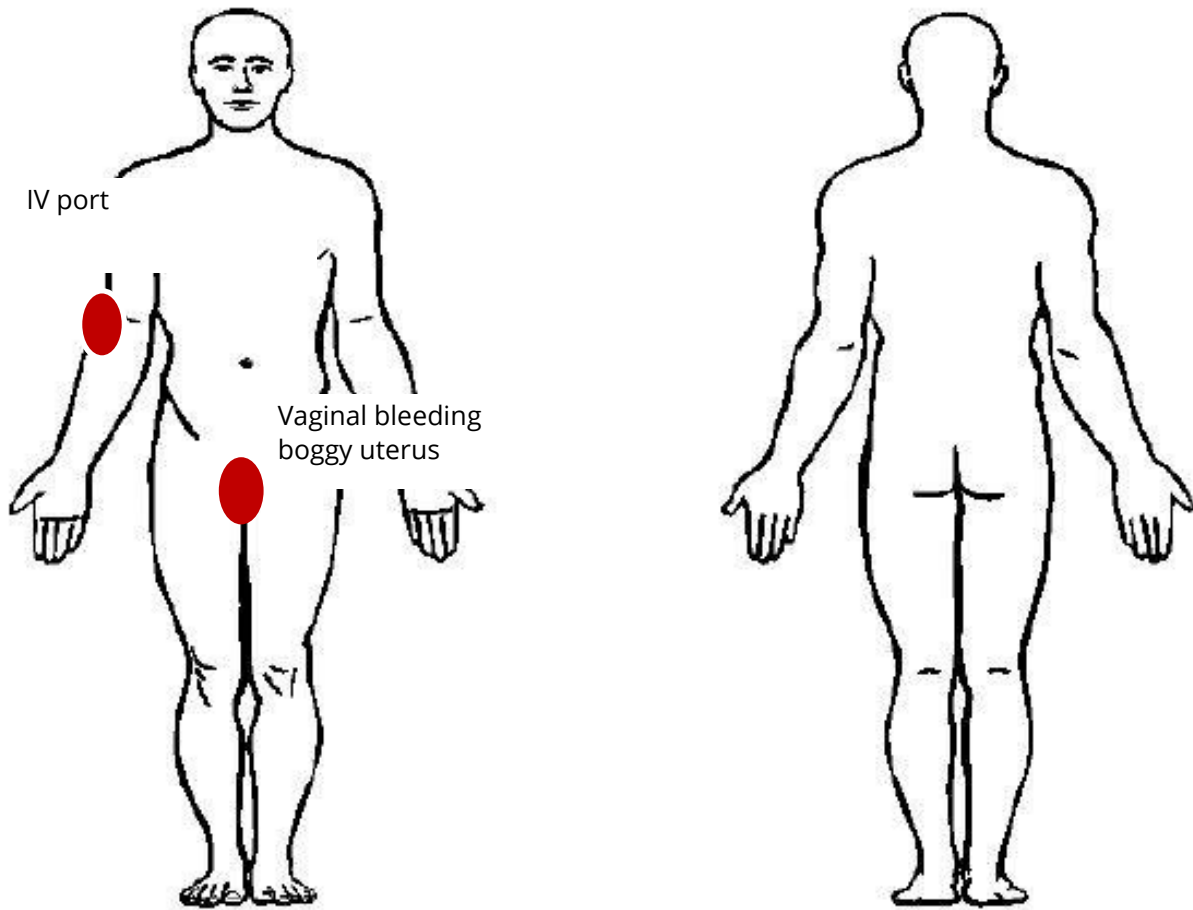
**Platelets:** 180,000

**WBC:** 14,000

**Hct:** 28%

# Appendix D

## Moulage Sheet:



HEAD:	LEGS/FEET:
CHEAST:	ARMS/HANDS:
ABDOMNIAL :	PELVIC:
BACK:	OTHER:

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# Appendix D

Shared courtesy of Kelly Gibson, MD and the MetroHealth Simulation Center

## ED Multidisciplinary Curriculum Post-Partum Hemorrhage / Neonatal Resuscitation 2020

### Goals:

Appropriately manage a woman with post-partum hemorrhage after an in-transit delivery.

Appropriately manage a newborn requiring basic resuscitation.

### Objectives:

1. Recognize a newborn in need of resuscitation.
2. Demonstrate appropriate resuscitation of a physiologically depressed newborn.
3. Demonstrate recognition and management of post-partum hemorrhage.
4. Demonstrate effective use of rapid-infuser, MTP and medications applicable to PPH.
5. Demonstrate effective teamwork skills including team structure and leadership, situational awareness, mutual support and communication techniques.

### Case Summary:

32 y/o female with a precipitous delivery of a newborn in the car en-route to the hospital. She arrives with newborn in her lap. The newborn is dusky and in need of resuscitation. The mother is experiencing significant hemorrhage due to uterine atony. Participants must resuscitate newborn and recognize maternal PPH with hemorrhagic shock. Along with delivery of the placenta and uterine massage, participants must institute oxytocin, TXA and methylergonovine, along with massive transfusion protocol (level-1 infuser) and involvement of OB.

### Patient Information

32 y/o G7P5 female gave birth at home. Team to Rm 16.

History if asked:

Minimal prenatal care. EDC next week.

Water broke (clear fluid) en-route to hospital.

Mother delivered in car just before arrival.

No PMH, meds, allergies.

No tobacco / etoh. Occ THC.

Baby whimpered a little after birth just as pulling into ED driveway.

# Appendix D

Shared courtesy of Kelly Gibson, MD and the MetroHealth Simulation Center

## **Play of Case:**

The mother arrives in resuscitation bay with newborn in her lap.

Team should divide assign roles to address both patients.

Newborn

Appears pale, limp, dusky. Cut cord. Move to warmer. Turn on warmer.

Place monitors. Assess – HR 70, resp effort poor, tone poor, color dusky, whimper.

Dry, suction, stimulate. Replace linens. +/- wrap. Hook up and provide PPV via flow-inflating bag / appropriate mask driven by RA or blended FiO2 0.3. Once patient is dried, warmed, and appropriate PPV provided, HR, tone, color and resp effort (cry) improves. Pt stabilized for NICU. If inappropriate delays in care – not warmed or dried, slow / PPV delay > 1mi, then patient deteriorates – HR falls to 50, CPR needed until appropriate PPV. If delay >2 min from being placed on warmer to appropriate PPV, then HR stays <60 until after intubation / PPV and code pink team “arrival”.

## **Mother:**

Initially appears well, but shortly after newborn is resuscitated, team notes that mother gradually appears more pale, diaphoretic, and groggy, hypotensive, tachycardic. There is a large amount of bleeding noted. The team should obtain additional IV access, begin resuscitation and notify OB (tied up in 2 emergency c-sections). Blood should be sent including T&C for 6 units. The placenta should be delivered immediately and aggressive uterine massage begun. Active bleeding continues and the patient remains in shock. Oxytocin 40 units in 1 liter of NS infused rapidly, then methylergonovine 0.2 mg IV should be administered. TXA should be administered. O-neg PRBC should be infused via rapid infuser (actually set it up) and the MTP should be activated.

If all done efficiently with clear communication and teamwork, then patient will stabilize and be transferred to post-partum unit with OB.

# Appendix D

Shared courtesy of Kelly Gibson, MD and the MetroHealth Simulation Center

## **Critical Actions:**

1. Assemble team
2. Delegate duties / tasks, notify OB / code pink
3. Recognize physiologically depressed newborn
4. Dry, suction stimulate newborn
5. Provide PPV with flow-inflating bag, proper mask, RA or 0.3 FiO<sub>2</sub>
6. Recognize maternal hemorrhagic shock and PPH
7. Deliver placenta
8. Apply uterine massage using appropriate technique
9. Administer Oxytocin
10. Administer Methylergonovine
11. Administer TXA
12. Administer PRBC (O neg) via rapid infuser / warmer
13. Activate MTP

# Appendix D

Shared courtesy of Kelly Gibson, MD and the MetroHealth Simulation Center

## Equipment:

SimMom  
Super Tory  
AV recoding / debriefing package  
iSimulate x2  
MTP cooler mock-up with PRBC, FFP, Plts, paperwork

## Environment and Moulage:

In-situ ED  
Infant - Vernix / fluid  
Mother - PPH with ongoing bleeding, Clots and blood on sheets / chux, diaphoresis

## Programming / Scripting

### Infant

1. Baseline  
HR 70 RR 0 SPO2 58%  
Rhythm: NSR  
Color: cyanotic  
Tone: floppy  
Cry: none
2. Stabilized  
HR 160 RR assisted  
SPO2 90% Rhythm: ST  
Tone: improved  
Cry: yes

### Transitions

1 to 2 if proper position /  
dry / suction / stimulate /  
warming and PPV  
On-the-fly incremental if  
partial actions.

### Mother

1. Baseline  
HR 130 BP 82/58 RR 26 SPO2 97%  
Rhythm ST  
Eyes: open
2. Worsening  
HR 140 BP 50/20 RR 30 SPO2 95%  
Rhythm ST  
Eyes closed
3. PEA  
HR 40 BP -- RR -- SPO2 --% Rhythm  
wide complex PEA Eyes closed  
Lung sounds: none
4. Stabilized  
HR 118 BP 110/60 RR 22 SPO2 99%  
Rhythm ST  
Eyes open

### Transitions

On-the-fly adjustments to bleeding  
(placental delivery, massage, uteroton-  
ics), HR/BP (blood products)



## Appendix D

### PPH (postpartum hemorrhage) NYU Langone Health **SCENARIO AND SYNOPSIS (for sim team)**

Credits: Kaiser Permanente California Connie Lopez

#### Time breakdown for the scenario:

- 25 min pre-brief:
  - didactic review 10 min (or less): see didactic hand out for participants
  - review of meds: medication station
    - stages of hemorrhage, stepwise management of each
    - team work concepts to focus on: closed loop communication, situational awareness, mutual support
  - blood loss estimation station 5 min
  - Bakri ballon station 5min
  - uterus suturing station 5 min
- 15 min scenario
- 30 min group debrief

#### Room setup:

- delivery tray and c-section tray
- oxygen mask
- straight cath/foley
- epidural PCA pump and tubing if available.
- IVs
- NS bags
- laboratory tubes
- ECG leads
- pulse ox for
- patient's's chart
- fake blood to give blood transfusion
- PPH kit

#### Supplies needed:

- Hemipelvis and baby (labor and delivery) and VS monitor with central control to display BP, HR and pulse ox  2 simulated patients (actresses)
- PPH cart
- meds:

- misoprostol
- Methergine
- hemabate

## Appendix D

Pitocin

TXA

Bakri balloon

lab tubes for T+S, cbc, chem, coags

## Appendix D

### Instructions for participants:

Nurse participant is called to the room to assess a post partum patient who delivered 45 min ago and is now recovering in the labor room. Patient's regular nurse (confederate part of sim team) is going on break and asks the nurse to take over care. She has been getting regular prenatal care at Bellevue. Patient was delivered by midwives, and the midwife provider is now busy in another delivery. The only information triage nurse was able to get was that patient's name is April Jones, a 29 yo G4P4004 who was induced for oligohydramnios at 39 week and delivered a 4 kg baby. VS are stable and pt is recovering routinely. EBL was 350cc and 1 degree laceration was repaired. Pt is finishing her 20 U pit infusion started post partum. This information is given to the labor nurse who is taking over the patient. Information avail to the nurse is same as to the pt (as below) if further questions are asked. As soon as she gets this information, patient calls the call button, and the nurse participant is told to enter.

Patient is accompanied by a close friend, May Smith who is at her bedside.

### Instructions for the actress/patient April

You are a hybrid: you sit cross-legged and you control the mannequin hemi-pelvis.

**You can control the amount of bleeding that is happening by letting blood out of the foley bag in the hemipelvis.** You should empty the whole bag (2 liters) over the course of 10 min.

#### **Residents and nurses might ask you questions eliciting the following history:**

Your prior three children were born without complications.

This baby was born 45 min ago, and induced lasted overnight. You got 2 doses of misoprostol vaginally and then you were on Pitocin during the a small day. You had laceration (1st degree) chorioamnionitis in labor and were that was repaired. EBL was 350cc. treated with antibiotics. You have not 2nd state voided since lasted only 30 delivery min (meaning and the foley fully was removed right before the dilated until delivery). You had delivery. Baby was 9 lbs. Midwives were taking care of you and delivered you.

This pregnancy was uncomplicated, with exception of oligohydramnios (low fluid) which was discovered on your last clinic visit at 39 weeks. You were told that low fluid could be a sign of poor circulation and you were induced.

You are 5' 6" and 140 lbs

No prior surgeries, taking prenatal vitamins and iron. No allergies.

FOB is not involved. You are a single mom. May is your close friend. Family lives out of town.

You are allergic to penicillin (rash) and iodine (rash); this is on the bracelet.

You still have epidural in place which has been turned off since delivery but not removed yet

You pressed the call button because you noticed that the bed is wet. You cannot see what is going on but you are anxious.

**Risk factors to identify:** multip, induction, chorio, macrosomia.

## Appendix D

### Instructions for the friend May (distracting confederate):

You are acting as April's advocate. You a little disruptive because you are worried about her are trying to get more information. If you get ignored, you demand more attention.

### Instructions for the moderator (attending running the sim):

The goals for this sim is to:

1. test clinical management skills of PPH
2. test communication skills between team members/team steps
3. address communication with the family during the emergency.

You may either show vitals on a SimMom laptop if available or call out vitals as needed.

### Anticipated course:

Once nurse enters the room, she will see that patient is laying in bed with 500cc of blood on the chux. She should alert MDs to come to the room. Once MD gets to the room and examines the patient, she will see blood and alert the rest of the team. The rest of the scenario progresses as below.  
Initial simulator settings: T - 98 R - 20 P - 84 BP -110/70 SaO2- 99%

## Appendix D

Date: \_\_\_\_\_  
 Team: \_\_\_\_\_  
 R2 \_\_\_\_\_  
 R3 \_\_\_\_\_  
 R4 \_\_\_\_\_  
 RN1 \_\_\_\_\_  
 RN2 \_\_\_\_\_  
 Moderating ob attending: \_\_\_\_\_  
 Sim team member assisting: \_\_\_\_\_

**Progression:** (moderating attending record per each team)

Time	Instructor Action	Desired Action from Staff	If staff does not....	Then....
	Patient c/o feeling a gush of fluid from the vagina "I think I'm bleeding I feel wet down there. Can you please check my bleeding?" <b>500 ml</b> fake blood on the pad	Looks at perineum and takes vital signs, asks about uterine tone	Does evaluate bleeding or do VS	Blood will be draining to the floor, HR might go up
	Vitals: <u>BP 106/62 HR 88 RR 24 T 98.9 O2 sat 95%</u> Chux and pad are fully saturated with bright red blood. Fundus boggy, steady trickling of lochia with large clots. Patient's friend says "Her hands are so cold and clammy, and she is so pale."	<input type="checkbox"/> Fundal massage <input type="checkbox"/> calls for appropriate help to activate additional nursing assistance and anesthesia <input type="checkbox"/> MD to come to the bedside immediately. <input type="checkbox"/> Vital signs Q 5 min and assesses for s/s of shock.	If no fundal massage or notification of MD or vitals Q 5 minutes...	Pt continues to bleed heavily, fundus boggy and patient exhibits s/s of shock  Patient's friend becomes anxious "what is happening with my April?"
	<b>(3 to 5 minutes later)</b> Patient: "I feel so weak and light-headed" What is going on?	<input type="checkbox"/> Educate patient and family of rationale for interventions. <input type="checkbox"/> More fundal massage, continue to monitor fundus <input type="checkbox"/> Will increase Pitocin rate <input type="checkbox"/> consider Methergine, hemabate or Cytotec <input type="checkbox"/> Estimates blood loss by appearance and weight of pads/chux. It should be close to <b>1000 ml total</b> by now. <input type="checkbox"/> asks for Foley requests to record strict I+O	If no education...  No more massage  No blood loss estimate	Patient becomes anxious Patient's friend becomes more anxious "someone please help April" Pt continues to bleed heavily, fundus boggy and patient exhibits s/s of shock

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	<p>(3 to 5 minutes later)  Vitals: <u>BP 99/60 HR 110 R 30 O2 sat 90%</u>  Fundus continues to be boggy, bleeding is heavy with large clots  <b>Now EBL is 1500cc.</b></p> <hr/>	<p>☐ Continues fundal massage &amp; vitals Q 5minutes  ☐ applies oxygen with non rebreather mask at 8 to10 L/M.  ☐ Anesthesia will generally start resuscitation process ☐- Get PPH Kit  ☐ Assesses situation, gives uterotonic medication  ☐ places pt in the stirrups and does vaginal exam to r.o lacerations  ☐ asked for bedside sono to r.o retained POC  ☐ announces PPH stage 2 now (1500 ml)  ☐ Charge nurse/team lead will identify: communications person, transporter (someone who can pick up blood) and recorder (RN)  ☐ communication person calls blood bank, identify self, department and tell them initiation of massive transfusion protocol  ☐ Nurse anticipates need for second large bore IV (0.9%NS), for blood transfusion, labs  ☐ 2 pink or purple top tubes for CBC and T&amp;C</p> <ul style="list-style-type: none"> <li>• 1 blue top tube for clotting studies*</li> <li>• 1 red top tube for chemistries*</li> <li>• 1 red top tube taped to</li> </ul>	<p>If no fundal massage, Q 5 minute vitals, IV, labs or medications...</p> <p>If team not identified</p>	<p>Pt continues to bleed heavily, fundus boggy and patient exhibits s/s of shock  Patient feel faints and has ringing in her ears  Pt continues to bleed heavily, fundus boggy and patient exhibits s/s of shock</p> <p>Chaos</p>
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		<p>the wall/placed into breast pocket  <input type="checkbox"/>gives medications i.e. Hemabate or Methergine IM, Cytotec PR  <input type="checkbox"/>knows correct doses and schedule  <input type="checkbox"/>Transporter takes specimens to lab, and goes to blood bank to get 4 units PRBC, and will get more after T&amp;C complete, and Platelets and FFP when thawed. Blood placed in cooling receptacle for storage until used.  <input type="checkbox"/> moves pt to the OR for d+c, Bakri placement , possible hysterectomy  <input type="checkbox"/>tells the pt what is going on</p>		
	<p>Patient moved to OR (imaginary)          Patient complains "I have ringing in my ears and I am feeling like I am going to faint"   <b>EBL: 2000cs class 3 hemorrhage</b>   <u>VS: Hypotension, marked tachycardia (120-160), clammy skin, cold extremities</u></p>	<p><input type="checkbox"/>Places patient flat  <input type="checkbox"/> fluid resiccitation  <input type="checkbox"/>Nurses prepare to give blood transfusion  <input type="checkbox"/>Recorder is charting sequence of events  <input type="checkbox"/> D+C is done  <input type="checkbox"/>Bakri ballon is placed, but bleeding continues  <input type="checkbox"/> MD calls for laparotomy  <input type="checkbox"/>antibiotics given  <input type="checkbox"/>laparotomy is done (on the pelvis)  <input type="checkbox"/> MD is doing bimanual compression. Will be ineffective  <input type="checkbox"/> MD can do B-Lynch, O'Leary Stiches on the cloth uterus</p>	<p>If patient is not placed in the shock position, blood is not started or no medical interventions done or considered...</p>	<p>Patient loses consciousness.           Support person is hysterical           Patient's sister: "Is my wife/ daughter going to be okay? Is she going to die?"</p>

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		<input type="checkbox"/> announce hysterectomy <input type="checkbox"/> Have OR tech open tray		
	<b>(5 minutes later)</b> Vitals: BP 82/44 HR 130 with apnea O2 sat <u>75%</u> Fundus continues to be boggy; Bleeding is heavy <b>2000 to 2500 and non-clotting.</b> Class 4 hemorrhage	Hyst proceeding <input type="checkbox"/> Communications person should be bringing blood (uncrossmatched but type-specific ok) and confirming that FFP and PLTs are being unthawed	If no hysterectomy	Pt will proceed to DIC and cardiac arrest

**Depending on the objectives - It's a wrap when.....** IV med and IM meds are given, bimanual compression is done, MTP initiated, blood transfusion started, or two surgical interventions are initiated and hysterectomy is performed up to the uterine arteries.

**Patient will continue to deteriorate if:** Fundal massage is not done, primary caregiver does not call for help, medications are not given, second IV access is not obtained, Chaos may happen without use of the MHP, or if Code Blue not initiated at sign of apnea.



## Appendix D

### TEACHING OBJECTIVES

#### Cognitive:

1. identify PPH and alert the team
2. identify risk factors of PPH
3. run thru the PPH algorithm: call for help, estimate blood loss, rule out other causes, attempt medical management, demonstrate surgical maneuvers

#### Behavioral:

1. Call for help/backup (OB, RN, peds, Anesthesia)
2. professional behavior
3. communication between team members (Team Steps principles)
  - a. closed loop communication
  - b. briefing of new team members arriving at the scene
  - c. de-brief at the end of the case
  - d. situational awareness
  - e. allocating a recorder
  - f. allocating someone to be with pt
  - g. situational leader
  - h. mutual support
4. patient/family communication

#### De-briefing guide:

##### Cognitive:

1. what was your DDX when you diagnosed PPH? How was your estimation of EBL?
2. how did you run through the medical management?
3. what made you decide to call for OR?
4. how did you decide to attempt laparotomy?
5. what did you think about the timing and what when on?

##### Behavioral:

1. give examples of what went well:
  - situational awareness
  - closed loop communication
  - briefing of newcomers
  - check-backs
  - mutual support